National Institutes of Health
Health Research Institute
National Bioethics Committee for Research (NBC-R), Pakistan
Government of Pakistan

National Bioethics Committee for Research (NBC-R) Operational Manual

Document No:	**ML No.NBC-R-001**
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Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad

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1. Introduction:

The tremendous advances in the field of modern medicine have brought immense benefits for human kind, while on the other hand has increased the potential for harm many folds. To minimize harm and protect the interest of individuals, guidelines and mechanisms are needed to be put in place within the Health Systems of countries that are relevant as well as contextual. To protect the interests of people of Pakistan the Ministry of Health constituted a **National Bioethics Committee (NBC-R)** according to international guidelines in consultation with a group of professionals who met under the chairmanship of the Director General Health.

The committee is truly multidisciplinary and multi-sectoral in composition with relevant expertise from across many disciplines of medicine, along with well-respected 'non-medical' people representing the interests and concerns of the community. There is also a mix of age and gender to ensure equitable representation on the committee. The Committee has been established in accordance with applicable laws and regulations of the country and in accordance with values and principles of the community it serves.

The committee was approved by the Ministry of Health, Government of Pakistan and notified in the Gazette of Pakistan on January 28, 2004.

The NBC-R has major role of an advisory body dealing with all aspects of bioethics in the health sector in the country. The Committee would promote and facilitate ethical health services delivery, health research and health education. It is an umbrella body linked with the ethical review bodies in organizations and institutions.

It is an independent functioning Committee has two sub-committees.

Research Ethics Committee (REC) to address ethics in research.

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NBC-R Membership

1.1 Selection:

Membership of NBC-R will be multidisciplinary, multi-sectoral and pluristic in nature. Members will be from both genders and of a wide age range. Those with background / formal training in Bioethics would be preferred, however individuals who are involved in ethics related activities in institutions should be considered also. . It is expected that members would be from teaching institutions, in clinical practice and research, nurses, dentists, pharmacists, social and basic scientists, and family physicians.

It will have 20 members and 11 ex-officio (see distribution below)

1.2 Composition:

Ex-officio (11)

For continuity it is expected that one/same individual either the ex-officio member or his/her representative should attend the meetings. (A different individual attending different meetings is not desirable).

1. Patron
2. Chairperson
3. NIH HRI (Secretary & Secretariat)
4. PMC
5. CPSP
6. Surgeon General (Army)
7. WHO Representative
8. Provincial Director General Health Services
9. Registrar Nursing Council
10. President Supreme Court Bar Association
11. President Association of Family Physician

2. Criteria for electing the "Elected Members":

Six months prior to completion of terms of members, the NBC-R Secretariat shall publicize on the NBC-R website a call for nominations for new members to fill the positions that will fall vacant. NBC-R will also send letters to various academic institutions asking for nominations. NBC-R members, regular and ex-officio, will also be requested to nominate up to 3 individuals. The NBC-R secretariat will then compile and circulate a coalesced list of all those nominated to ex officio and regular members for their votes. The deadline for submission of votes will be no more than 10 days after the nominees list has been emailed.

Depending on the number of new members to be elected, each NBC-R member will rank his/her choice from the nominee list with 1 being the top choice. Members will submit their ranked votes to the NBC-R Secretariat online within the specified deadline. NBC-R Secretariat will count number of points received by each nominee as follows - nominees ranked as 1 will receive 5 points, ranked as 2 will get 4 points, ranked 3 will get 3, and so on. These points will be added and the highest ranking nominees will be declared elected.

The Secretariat will announce the election results within 2 weeks following the voting deadline. It will be responsible for maintaining strict confidentiality during the entire election process. The process of replacement of members that have been absent from three consecutive meeting, or those that chose to resign will be the same as for the members that have completed their tenure. This process will be initiated once a year, preferably in January following report by NBC-R secretariat about the number of vacant seats

a. One nominee each from PBCs from all four province and AJ&K (5)
b. Others (15)

3. Meetings

- A minimum of three meetings per year
- NBC-R meeting shall be held alternately in four provinces and AJ&K .The meeting will be chaired by the chairperson or in his/her absence by the chair of REC alternately.
- The NIH will be the NBC-R's secretariat and will be the organizer of all meetings of NBC-R.
- Information of the meeting will be circulated at least 8 weeks prior to the date of proposed meeting.
- Call for agenda items will be made to all NBC-R members at least 4 weeks prior to the next meeting.
- Minutes of the previous meeting will be circulated electronically not later than 3 weeks after the meeting.

4. Research Ethics Committee (REC)

4.1 The Research Ethics Committee (REC) shall be review research on human subjects. The terms have been derived mainly from principles and generalized for application to both biomedical and social sciences research. A deliberate attempt has been made to avoid detail, as experience will determine the need for revision and elaboration.

4.2 **Content:** All research (medical or social science) projects involving human subjects, whether as individuals or communities, including surveys, drug/device trial, the use of foetal material, embryos and tissues from alive or the recently dead done with:

- International Funding specifically given for research done anywhere in Pakistan e.g. Research Advocacy Fund (RAF), DFID, USAID etc.
- Funded or supported by the Government of Pakistan.
- Any other research either done all over Pakistan or is a multi province.
- Drug trials for registration.

Shall be reviewed and approved by the NBC-R-REC before a study is started.

4.3 Any change in the study protocol (inclusion/exclusion criteria, change of PI or co PI number of subjects etc.) during at any stage of a study (before starting or during the study) must be informed and approved by NBC-R-REC to continue the study.

4.4 The duration of approval for a study shall be valid to a maximum period of one (1) year after which a re-approval is required. This will be standard for any study submitted irrespective of its duration whether one (1), five (5) or more years. Any change in conditions that could affect the rights/autonomy/welfare of subjects or serious adverse event during a study must be informed for approval to continue the study.

4.5 The Committee shall provide written guidelines on ethical considerations for research involving humans and review them every three years or earlier if required.

5. Method of Working:

5.1 The Committee will need substantial administrative and secretarial assistance from the NBC-R (and NIH).

5.2 The Committee shall report annually or more frequently, as necessary, to the NBC-R.

5.3 Authors of research proposals may be invited to attend meetings of the REC if found necessary by the REC members while reviewing their study.

5.4 Meetings will be conducted every three months (on the last Saturdays of March, June, September and December) or earlier especially if it can be combined with the NBC-R meeting. Some or all business may/will be conducted by email if for logistic reasons face to face meetings are not possible.

5.5 A minimum of 5 and a maximum of 11 individuals will constitute the NBC-R-REC.

5.6 At least 3 members must be present to complete the quorum for meeting if the total number of members is 5 or at least one-third attendance.

5.7 Additional member may also be co-opted. These ideally should have some experience in reviewing research for ethical issues or have special expertise that might be required in specific protocols.

5.8 A potential list of members that may be co-opted needs to be maintained ideally from all regions of Pakistan and AJ&K.

5.9 Decisions will be made by consensus. If consensus is not reached, then the decision will be by voting and in minutes it will be mentioned that consensus was not reached.

5.10 In exceptional circumstance urgent/expedited review may be done by at least two or more members and the chairman for approval or disapproval. Such approvals shall be reported to the next meeting of REC. The response letter to the applicant should mention that the decision is through expedited review. (This would be in special circumstance and not for convince).

5.11 Studies that do not require direct human subject participants e.g. chart review, already collected data for routine public health reasons etc, case reports may be exempted for review. But these studies and NBC-R-REC exemption form would have to be submitted to the REC to issue an exemption certificate. Such exemptions shall be reported to the next meeting of REC.

5.12 The Committee may withdraw approval if dissatisfied with the conduct of the study.

5.13 Confidentiality of the Committee's proceedings should be preserved.

5.14 Members of the Committee should declare their conflict of interest, for example when testing the product of a company of which the member is an advisor.

5.15 Members should report incidence of misconduct or noncompliance of TOR by any member, promptly to the chair/ secretary.

5.16 The voluntary efforts (as member are not remunerated) and contribution to research of NBC-R-REC members is highly appreciated.

6. Submission:

6.1 An application for ethical review should be accompanied by:
(a) Covering letter.
(b) Completed application form or exemption form available online at http://NBC-pakistan.org.pk/
(c) C.V of the Primary Investigator.
(d) Research Protocol.
(e) Budget to assess justification of funds.

6.2 Research must only be performed by persons with scientific, clinical, or other relevant qualifications appropriate to the project and expected to have basic knowledge of the ethical standards applicable to the project. The same should be reflected in curriculum vitae attached.

6.3 Student's application must be submitted under the responsibility of a qualified supervisor involved in the oversight of the student's work, countersigning the submitted application for ethical review.

7. Decision Making:

7.1 In making decisions on applications for the ethical review of biomedical research, the committee will do the following:
7.2 Submission of study is acknowledged via email / letter and a number assigned.
7.3 The study proposal will be circulated to all members however if number of member are adeque or large numbers of protocols are recovered at one given time - two members will be assigned as primary reviewers.
7.4 REC review will be sent to PI within six weeks. after submission. In exceptional circumstances expedited review will be done within 2 weeks. NBC-R-REC charges a fee which differs for multinational vs. national projects and for expedited vs regular review. (Fee structure is available at http://NBC-pakistan.org.pk/assets/guidelines_ethical.pdf).
7.5 Once the review by REC is sent to PI, it is expected that the PI must respond within 2-months, if no response from PI is received at the end of 2-months, a letter will be sent to PI stating *'that if in the next 1-month the PI does not respond the study will be considered to be abandoned by PI'* and will be marked as 'Null and Void' in the Submission Record.
7.6 A member should withdraw from the meeting for the decision procedure concerning an application if a conflict of interest arises; the conflict of interest should be indicated to the chairperson prior to the review of the application and recorded in the minutes.
7.7 Decisions should only be made at meetings where a quorum (See Point 3.4) is present if the meeting is being done face to face.

7.8 Method for arriving at a decision would be by consensus when possible. When a consensus appears unlikely, it is recommended that the REC to vote. However decision intimated to the applicant should mention that consensus was not achieved.
7.9 Non-binding advice may be appended to the decision.
7.10 In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be communicated to the applicant;
7.11 A negative decision on an application should be supported by clearly stated reasons.

8. Membership of REC:

8.1 Membership shall include both genders representing researchers, professionals from various disciplines and layperson.
8.2 The appointment of chair-by NBC-R.
8.3 The minimum number of members will be 05, including the chair.
8.4 The duration of appointment shall be for three years and may be renewed for one more term. Any additional term renewal in special circumstances for any member will be in consultation with NBC-R members. At any given time only half members should retire so maintain continuity.

9. Cessation of Membership:

9.1 NBC-R-REC may consider members for cessation of membership in any of the following circumstances:

(a) Members who are absent without prior intimation in three consecutive meetings.
(b) Members unable or un will to review 3 proposals consecutively. Members found not complying with the NBC-R-REC's TOR's.

10. Documentation and Archiving

All documentation and communication of an NBC-R should be dated, filed, and archived according to written procedures. A statement is required defining the access and retrieval procedure (including authorized persons) for the various documents, files, and archives. It is recommended that documents be archived for a minimum period of 3 years following the completion of a study. Documents that should be filed and archived include, but are not limited to

a. TORs, written standard operating procedures of the REC, and regular (annual) reports;
b. The curriculum vitae of all REC members;
c. A record of all income and expenses of the REC, including allowances and reimbursements made to the secretariat and REC members;
d. The agenda of the REC meetings;
e. The minutes of the REC meetings;
f. One copy of all materials submitted by an applicant;

g. The correspondence by REC members with applicants or concerned parties regarding application, decision, and follow-up;
h. A copy of the decision and any advice or requirements sent to an applicant;
i. All written documentation received during the follow-up;
j. The notification of the completion, premature suspension, or premature termination of a study;
k. The final summary or final report of the study

11. "COVID-19 Emergency Response": Ethical Review of Health Research in Pakistan *NBC-R-REC, TORs version 1.2*

"Rapid Turnaround Review (RTR)"

Background:
The purpose of this document i-e ***NBC-R-REC, TORs version 1.2;*** is to ensure that there are practical and effective actions put in place to ensure that a robust but rapid research ethics review is undertaken. Given the public health emergency, this guidance is being implemented on urgent basis for the sole purpose of facilitating the researchers in finding the best possible treatments and prevention to save the human lives.
These TORs are only applicable to the applications that have a COVID-19 research element and meet the scope of NBC-R Pakistan's REC review and must be read as an addition to the TORs in version 1.2.

All other research applications will continue to be reviewed under the previously placed REC TORs and NBC-R SOPs. While COVID-19 is a public health emergency, the ethical principles and values that are fostered by NBC-R for ethical review processes must continue to be upheld.
While the REC acknowledges that during pandemic situation, certain routinely applicable procedures considered essential in normal times may not be possible to be carried out to the fullest while conducting clinical and epidemiological studies. However, this does not mean that ethical parameters for human subject research can be ignored during crisis times, and safety of human participant will be kept paramount. The speed of review by the REC, and any possible discussion that goes on between the REC and the researchers will be compressed to be accomplished in the shortest possible time, but the stringency of review by the REC will not be compromised.

Enforcement and scope of the TORs:
These TORs approved by circulation by NBC-R Members will remain active from the date of its approval until the current Pandemic remains our "national emergency". Only new applications having a COVID-19 research element and meet the scope of NBC-R REC will be covered by these TORs.
The REC emphasizes that all human subject research involving the Corona Pandemic is subject to the already defined guidelines and processes as defined by the NBC-R. No study will be exempt from review. All studies, whether they are clinical trials, epidemiological studies, observational studies, social sciences studies, clinical audits or any other kind of studies will have to be presented to the REC for ethical review.
It is also emphasized that additional ethical review by institutional ethics committees will be applicable as in normal review processes, and the NBC-R review does not imply that institutional processes may be bypassed or ignored. The NBC-R has already issued directives to the institutions to institute similar Rapid Turnaround Review processes in order to facilitate research.

Emergency Review process for Rapid Turnaround Review

1. To be easily identified, "COVID-19" should be in the study title and researchers are encouraged to use this in their title for submission.
2. The Secretariat will keep a separate record of applications and substantial amendments reviewed with specific Identification number i-e COVID-(e.g number of project)

3. Application requirements and secretariat validation of new applications will be the same as previous.
4. In addition to the usual documents, (Protocol, CVs etc.) following should be submitted in addition.
    a. Letter of collaboration (MOUs) with institutions including study sites.
    b. Monitoring and safety management plan especially for the clinical trials, if applicable.
    c. Both data sharing and Material Transfer Agreements (MTA) for data and human biological material especially if they are being exported out of the country (a draft may be submitted initially).
    d. Procedures for updating the community regarding the research outcome.
    e. Plans to provide the results to the Provincial and Federal Government of Pakistan for utilizing them for public policy and required interventions.

5. The application will only enter this Rapid Turnaround Review timeline after all related documents as described in the requirements are filed with the REC. It will be the sole responsibility of the PI or corresponding person to provide the Secretariat will the complete documents and RTR time of review will commence from there onwards. Incomplete applications will not be entertained.
6. All applications and amendments must receive a decision within 3 working days (72 hours) from the date of completely filled application form along with the required documents submission.
7. Any responses to provisional approvals or decisions other than approvals will be provided within 24 hours.
8. The review process will be online. Meetings of the REC members whenever required will be established electronically on mutually agreed time as and when floated by the Chairperson REC.
9. The Rapid Turnaround Review process involves members of the REC however any subject matter expert if required may be co-opted by the Chairperson of REC.
10. Identification of subject experts and having experience/ knowledge of ethics (both in-country and abroad) that would be willing to serve as ad hoc or co-opted members during the pandemic will be identified and contacted in advance and their list will be available in Secretariat.
11. The quorum for any REC review meeting is one-third of the members (including the Chair).
12. In order to expedite the process of communication, the REC Chairperson/ REC Representative may wish to establish telephonic contact or a tele conference with PI and his/her team as per requirement to seek clarifications.
13. After the PI addresses the concerns the REC will be approving within the prescribed time.
14. The decision will be based on consensus of the Committee.
15. The Secretariat will issue the electronic copies of the approval letter signed by the Chairperson REC.
16. The hard copies will be sent through courier only after the emergency is over.
17. If decision is not communicated within this timeframe the researcher should contact the Secretariat.

18. In the spirit of RTR, in case the researcher/team does not respond to any queries made by the REC in connection with the application within 2 weeks of the receipt of the REC queries, the application will be deemed to have been abandoned/ withdrawn. Upon resubmission it will be considered as a new project.
19. All communications will be documented and archived at Secretariat.
20. **The fee structure remains the same as prescribed by NBC-R however, in view of the present situation of limited access/ lock down and the few administrative constraints in the country the fee submission may not affect the processing and approvals.**

Serious Adverse Event (SAE) Report.

It is mandatory for the Principal Investigator to report any Serious Adverse Event to the NBC-R immediately (within 48 hours) of the report.

It is further mandated to submit the report of Data Saftey and Monitoring Board's decision to the NBC-R on immediate basis.

The reporting should mention mitigation measures, follow up strategy, the treatment and financial arrangements for cases.

Upon failure to do so the study loses the approval for onwards continuation and will be proceeded against as per TORs of NBC-R.

Acknowledgments:
In preparation of this document the guidance for procedures was solicited from the WHO's draft document "Rapid research ethics review during disasters/epidemic/outbreaks: suggested Standard Operating Procedures for National (Research) Ethics Committees (N(R)EC)"

12. Conflict of Interest:

Members of the Committee should declare their conflict of interest, for example when testing the product of a company of which the member is an advisor.

A member should withdraw from the meeting for the decision procedure concerning an application if a conflict of interest arises; the conflict of interest should be indicated to the chairperson prior to the review of the application and recorded in the minutes.

NBC-R NOTIFICATIONS

REGISTERED No. M.302

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KARACHI, WEDNESDAY, JANUARY 28, 2004

PART IV

Notifications issued by the minor administrations and miscellaneous notifications not included in any other part

MINISTRY OF EDUCATION

Islamabad, the 15th January, 2004

No. F.4-4/2002-NI-I.—In exercise of powers conferred under Sub-Section 1 of Section 10 of the National College of Arts' Ordinance, 1985, the competent authority has been pleased to nominate following persons on the Board of Governors of the College, with immediate effect, for a period of two years :—

Relevant clause of the Ordinance.	*Name of the persons nominated.*
Clause (ix) (03 outstanding Professionals-one each in the field of Architecture, Commercial Design and Fine Arts to be nominated by the Controlling Authority *i.e.* E.M.).	(1) Mrs. Yasmin Lari, Chairperson, Heritage Foundation, E-6, 4th Gizri Street, DHA, Phase-4, Karachi. **Architect.** (2) Mr. Shaukat Rizvi, House No. 104-A, Sindhi Muslim Housing Society, Karachi. **Designer.** (3) Mr. Jamal Shah, Huner Kada, House No. 17, St. No. 83, G-6/4, Embassy Road, Islamabad. **Artist.**
Clause (x) (01 outstanding Industrialist to be nominated by the Controlling Authority *i.e.* E.M.).	Miau Shahzada Alam Monnoo, Monnoo Group of Industries, Monnoo House, 3 Montgomery Road, Lahore.
Clause (xi) (02 distinguished Educationists to be nominated by the Chairperson, BOG).	(1) Mr. Mazhar-ul-Haq, Siddiqui, Vice Chancellor, Sindh University, Jamshoro. (2) Dr. Khalid Aftab, Vice-Chancellor, Govt. College University, Lahore.
Clause (xii) (01 outstanding Alumnus to be nominated by the Chairperson, BOG).	Mr. Wilayat Khan, 14-D, Phase-I, Hyatabad, Peshawar.
Clause (xiv) (02 Distinguished citizens to be nominated by the Controlling Authority *i.e.* E.M.).	(1) Mr. Abdullah Baloch, Director, Balochistan Arts Council, M.A. Jinnah Road, Quetta. (2) Mr. Raza Kazim, Advocate, 13-Gulberg-V, Off Zafar Ali Road, Lahore.

Relevant clause of the Ordinance.	*Name of the persons nominated.*
Clause (xv) 102 Eminent Women representatives to be nominated by the Controlling Authority i.e. E.M.).	(1) Mrs. Soumiya Anwar, Minister for Education, Government of the Punjab, Lahore/Director, SOS Village in Pakistan (2) Prof. Dr. Mira Phailbus, Principal, Kinnaird College for Women, Lahore.

S. IRSHAD ALI SHAH,
Deputy Education Adviser.

MINISTRY OF HEALTH

Islamabad, the 12th January, 2004

Subject : Constitution of National Bioethics Committee.

No. 8-1/2003-MER.—The competent authority (Secretary Health) is pleased to constitute the National Bioethics Committee with the following composition :—

Patrons:

Minister Health :
Ministry of Health, Government of Pakistan,
Islamabad.

Secretary Health :
Ministry of Health, Government of Pakistan,
Islamabad.

Chairman :
Director General Health,
Ministry of Health, Government of Pakistan,
Islamabad.

Universities/Medical Colleges :

1. President, College of Physicians & Surgeons of Pakistan (CPSP).

2. President, Pakistan Medical & Dental Council (PMDC).

3. Executive Director, Pakistan Medical Research Council (PMRC).

4. WHO representative in Pakistan.

5. President, Supreme Court Bar Association, (as a representative of Lawyers).

6. Dr. Sarwar Jehan Zuberi,
Dean for Research, Ziauddin Medical University, Karachi, Scientists Emeritus, PMRC.

7. Dr. Mohammad M. Amin,
Dean, Shifa College of Medicine, Pitras Bukhari Road Sector H-8/4, Islamabad.

Bio-Scientists :

8. Dr. Anwar Nasim,
Adviser Science, Consteeb Sectt.,
3-Constitution Avenue, G-5/2, Islamabad.

9. Dr. S. Qasim Mehdi,
Director-General, Biomedical & Genetic Engineering Division,
Dr. A. Q. Khan Research Laboratories,
GPO Box 2891,25 Mauve Area, G-9/1,
Islamabad, Pakistan.

Academics :

10. Prof. Dr. Zulfiqar Ahmed Bhutta,
Prof. of Pediatrics & Child Health Deptt. of Pediatrics, The Aga Khan University and Director Neonatal Services, Aga Khan University Hospital (AKUH) Stadium Road, P.O. Box 3500, Karachi 74800.

11. Dr. Maqbool H. Jafary,
Director, Novartis Medical Centre, for Asia-Pacific, 15, West Wharf Road, Karachi-74000.

General Practitioner:

12. Dr. Sharriatullah Siddiqui,
President College of Family Medicine
Karachi.

Nurse :

13. Mrs. Faiz Alamzeb, Principal,
Postgraduate College of Nursing, Peshawar.

Journalist :

14. Mr. Shaukat Ali Jawaid,
Chief Editor (Pulse International) Managing Editor, (Pakistan Journal of Medicine) Chief Executive, Professional Medical Publications, Karachi.

Social Scientists :

15. Prof. Dr. Anis Ahmed,
Vice-Chairman of the Institute of Policy Studies, Nasr Chambers, Block 19, F-7, Islamabad. Meritorious Professor of Islamic and Comparative, Religion, Editor-in-Chief of West and Islam, Quarterly Journal, Islamabad, Chairman of the Foundation of the Faithful, an NGO committed to development of education, human resource development, and social welfare.

Religious Scholar :

16. Dr. Asmatullah,
Assistant Professor, Islamic Research Institute, Islamic University, P.O. Box 1035 Islamabad.

Industry :

17. Mr. Haider Karrar,
Managing Director, Biogenics Pakistan (Pvt.) Ltd., Karachi.

...man Rights Commission :

18. Nomination being sought from Punjab.

Nominee of Health Deptt.:

19. Balochistan Health Department.

20. NWFP Health Deptt.

Nominee of Surgeon Pak. Army :

21. Maj. Gen. Masood Anwar,
Commandant AFIP.

DR. FARAH SABIH,
Assistant Director-General Health.

FEDERAL SERVICE TRIBUNAL

Islamabad, the 7th November, 2003

No. F.15(1)/98-FST.—In supersession of this Tribunal's notification of even number, dated 3rd November, 2003. In exercise of powers conferred under Section 3-A of the Service Tribunals Act, 1973, the Permanent Bench of the Federal Service Tribunal at Karachi is reconstituted, with effect from 13th November, 2003 and until further orders and shall consists of :—

1. Mr. Barkat Ali Baloch, and
2. Mr. Nazar Mohammad Shaikh, Members.

AMANULLAH ABBASI, *(Justice Retd).*,
Chairman.

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KARACHI, WEDNESDAY, MAY 5, 2010

PART IV

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MINISTRY OF HEALTH

Islamabad, the 16th April, 2010

No. F. 8-1/2010-MER.—Ministry of Health has constituted a National Bioethics Committee (NBC) consisting of following members :—

1.	Dr. Asim Ahmed, Associate Professor/Chief Nephrologists The Kidney Centre, 197/9, Rafiqui Shaheed Road, Karachi-75530.	Nominee of Universities/Medical Colleges.
2.	Dr. Muhammad M. Amin ,Dean, Shifa College of Medicine Pitras Bukhari Road, Sector H-8/4, Islamabad.	-do-
3.	Dr. Anwar Nasim, Advisor Science, COMSTECH Secretariat, 3-Constitution Avenue, G-5/2, Islamabad.	Nominee of Bio-Scientists
4.	Dr. Farhat Moazam, Professor & Chairperson Centre of Biomedical Ethics & Culture, Sindh Institute of Urology and Transplantation (SIUT).	-do-
5.	Prof. Dr. Zulfiqar Ahmed Bhutta, Division Head Women and Child Health Faculty Office Building, Aga Khan University Hospital Stadium Road, P.O. Box 3500, Karachi.	Nominee of Academicia
6.	Dr. Maqbool H. Jafary, Consultant Physician and Cardiologist, Karachi Institute of Heart Diseases, Karachi.	-do-
7.	Dr. Saeedul Majeed, President, College of Family Medicine, 55-C, Gulmohar Lane, University Town, Peshawar.	Nominee of General Practitioners
8.	Dr. Anwar Aziz, Principal State School of Nursing Mirpur, Government of Azad Jammu and Kashmir, Mirpur, AJK.	Nominee of Nursing Institution.
9.	Mr. Shaukat Ali Jawaid, Chief Editor (Pulse International), Managing Editor, (Pakistan Journal of Medicine), Chief Executive Professional Medical Publication, Karachi.	Nominee of Journalists
10.	Prof. Dr. Anis Ahmed, Vice Chancellor, Riphah International University, Karachi.	Nominee of Social Scientists
11.	Dr. Asmatullah, Assistant Professor, Islamic Research Institute Islamic University, P.O. Box 1035, Islamabad.	Nominee of Religious Scholars
12.	Dr. Farid Khan, 68/1, Khayaban-e-Mahafiz, Phase-6, DHA, Karachi.	Nominee of Industry
13.	Prof. S. Haroon Ahmed, Director, Psycho Social Centre 11-13 Hilal-e-Ahmer House, Clifton, Karachi.	Nominee of Human Rights Commission
14.	Dr. Baqi Durrani, Professor of Medicine, Bolan Medical College, Quetta.	Nominee of Health Department
15.	Dr. Muhammad Zaheen, Deputy Director Management MRE Provincial Health Services Academy Duranpur, Budhni Road, Peshawar.	-do-
16.	Brig. Abdul Khaliq Naveed, Head Department of Biochemistry & Molecular Biology, Advisor in Basic Medical Sciences and Dean Faculty of Medicine, National University of Science & Technology, Rawalpindi.	Nominee of Surgeon General Pakistan Army.

2. Pakistan Medical Research Council declared as the Secretariat for the "National Bioethics Committee of Pakistan".

Islamabad, the 19th April, 2010

No. F. 3-10/2008-MER.—On recommendation of Pakistan Medical & Dental Council *vide* their Letter No. PF.1-C-2010(AIMC-Abbottabad)1169027, dated 18th March, 2010. Prof. Dr. Abdul Aziz Awan, Professor and head department of Ophthalmology, Abbottabad, International Medical College, Abbottabad, has been elected as member of Pakistan Medical & Dental Council, under Section 3(1) (f) of PM&DC Ordinance, 1962, for a period of five years, with effect from 18th March, 2010 or until his successor has been duly elected, whichever is longer.

No. F. 3-11/2008-MER.—On the recommendation of Pakistan Medical & Dental Council *vide* their Letter No. PF.1-C-2009(SMBBMU)/157211, dated 6th March, 2010. Prof. Dr. Sikandar Ali Shaikh, Vice Chancellor, Shaheed Mohtarma Benazir Bhutto Medical University, Larkana, has been elected as member of Pakistan Medical & Dental Council, under Section 3(1) (b) of PM&DC Ordinance, 1962 ,as representative of Shaheed Mohtarma Banazir Bhutto Medical University, Larkana, for a period of five years, with effect from 6th March, 2010 or until his successor has been duly elected, whichever is longer.

DR. QAZI MUJTABA KAMAL,
Deputy Director-General, Health.

Islamabad, the 16th April, 2010

No. F. 16-31/2008-MER.—On the recommendation of Federal Minister for Health, various ordinances of Health Professionals and Proposed Amendments, the proposed legislative Task Force is as under :—

1	Prof. Dr. Rashid Jooma.	Director-General Health.	Co-Chairperson
2	Dr. Tariq Hassan, Attorney & Advocate Supreme Court of Pakistan, International Legal Services, Islamabad.	International Legal Advisor.	Co-Chairperson
3	Dr. Shabnum Sarfraz	Coordinator, Lead trainer & Consultant Nur Foundation Centre for Research & Consulting Fatima Memorial System, Lahore.	Member
4	Dr. Qazi Mujtaba Kamal.	DDG (MER/PH)	Member/ Secretary.
5	Dr. Sabeen Afzal	ADG (MER-PH)	Member
6	Co-opted Member if required.		

No. F. 21-2/2010-MER.—In pursuance of section 2(f) sub-section (i) of Pakistan Nursing Council Act, 1973 and in consultation with Pakistan Nursing Council (PNC), the Federal Government has approved the following programs commenced/run under the authority of PNC to be included in "the schedule" under B. Postgraduate Nursing :

- Bachelor of Science in Nursing (BSN 4 years)
- Post Registered Nurse Bachelor of Science (Post RNBSN 2 years).
- Master of Science in Nursing (MSN)
- Master in Public Health (MPH) / Master of Science in Public Health (MSPH) (recognized by HEC) with background of Nursing.
- Doctorate in Nursing (PhD Nursing).

Islamabad, the 21st April, 2010

CORRIGENDUM

Reference this Ministry's notification of even number, dated 16th April, 2010, on the above subject.

No. F.8-1/2010-MER.—The following amendments may be inserted before the name and Serial No. of Dr. Asim Ahmed, Associate Professor / Chief Nephrologist, the Kidney Centre, Karachi, as it has been inadvertently missed in typing. Thus Dr. Asim will come at Serial No. 6 :

Patrons :

Minister Health :
Ministry of Health, Government of Pakistan,
Islamabad.

Secretary Health :
Ministry of Health, Government of Pakistan,
Islamabad.

Chairman :

Director General, Health,
Ministry of Health, Government of Pakistan,
Islamabad.

Ex-Officio Members :

1. President, College of Physicians & Surgeons Pakistan (CPSP).
2. President, Pakistan Medical & Dental Council (PMDC).
3. Executive Director, Pakistan Medical Research Council (PMRC).
4. WHO representative in Pakistan.
5. President, Supreme Court Bar Association, (as a representative of lawyers).

DR. SABEEN AFZAL,
Assistant Director-General, Health.

Current Composition:

NBC-R Ex. Officio Members

Sr. #	Designation
1.	Director General Ministry of NHSR&C
2.	Executive Director HRI
3.	Provincial Director General Health Services
4.	Nominee, College of physician & surgeon (CPSP)Pakistan
5.	Nominee Surgeon General Pakistan
6.	Chairman Council of Islamic Ideology
7.	President, Supreme Court Bar Association of Pakistan
8.	President Pakistan Medical Commission (PM&DC)
9.	WR Pakistan.
10.	Chief Executive Officer, Drug Regulatory Authority Pakistan (DRAP)
11.	Population & Welfare, Govt. of Gilgit Baltistan
12.	President Pakistan Nursing Council (PNC)
13.	Chairman, Higher Education Commission (HEC)
14.	President of Pakistan Association of Family Physicians

NBC-R Elected Members

Sr. No	Name	Designation
1.	**Prof. Dr. Saima Pervaiz Iqbal**	Section Head of Community and Family Medicines, Shifa College of Medicine
2.	**Prof. Dr. Munir A. Saleemi**	Associate Dean, University of Lahore.
3.	**Prof. Dr. Jamshed Akhtar**	Head of the Dept. of Pediatric Surgery NICH Karachi.
4.	**Dr. Farkhanda Ghafoor**	Ex Research Director PHRC
5.	**Prof. Dr. Saqib Mehmood**	The University of Health Sciences, Lahore
6.	**Prof. Dr. Nazli Hossain**	Prof. of OBGYN & Dean Dow University of Health Sciences (DUHS), **Karachi**
7.	**Prof. Dr. Marie Andrades**	Jinnah Sindh Medical University (JSMU),Rafiqui H.J ،Iqbal Shaheed Rd, Cantonment **Karachi**
8.	**Prof. Dr. Amjad Mehboob**	Gajju Khan Medical College GKMCS, **Swabi, KPK**
9.	**Prof. Dr. Sualeha Siddiqui Shekhani**	Sindh Institute of Urology and Transplantation (SIUT), Sardar Yaqoob Ali Khan Road, Near Civil Hospital, Karachi **Karachi.**
10.	**Prof. Dr. Saira Afzal**	Chairperson and Head of Community Medicine KEMU, **Lahore**
11.	**Prof. Dr. Abdul Rahman**	Associate Prof. Community Medicine BMC, **Quetta.**
12.	**Dr. Ejaz Ahmad Khan**	Shifa Tameer-e-Millat University, **Islamabad.**
13.	**Prof. Dr. Ejaz Ahmad Khan**	Associate Professor Public Health, HSA, Park Road, **Islamabad.**
14.	**Mrs. Sobiya Mohiyuddin Ayaz**	Microbiologist, **Islamabad.**

HEALTH RESEARCH INSTITUTE

(Research and Development Coordination section - NBC)

(Standard Operating Procedure - SOP)

CONTROLLED DOCUMENT

Document Information

Category	Information
Document Title	SOPs of **receiving submissions for ethical review**
Version	00
Document ID No	**NIH-ISB-HRI-RDC-SOP-18**
Author(s)	Dr Faiza Bashir
Reviewer(s)	Dr. Muhammad Ayaz Mustufa
Approver(s)	Dr. Nighat Murad
Creation Date	15.05.2022
Issue Date	15.05.2022
Effective Date	15.05.2022
Control Status	Controlled
Distribution: Issuance / Withdrawal	1. HOD 2. QMR (soft copy)
Disclaimer	This document contains confidential information. Do not distribute this document without prior approval from competent authorities of HRI.

Document Revision History

Author(s)	Date	Version	Description

Issue Date: 15.05.2022	Effective Date 15.05.2022	Revision Date:

1. **Purpose:**

   To receive the submissions for ethical approval in a standardized manner

2. **Scope:**

   Review of research studies submitted for ethical approval

3. **Responsibilities:**

   UDC, Assistant, National Coordinator

4. **Procedure:**

   Regardless of the type of submission, each application is processed in hard and soft form.

   Receiving of Projects (for Ethical Review):

   - After online receiving of soft copy of the project by email a specific number is generated in the format NBC-001.
   - The hard copy is requested if not already received.
   - If only hard copy is received first a soft copy is required for the process to start.
   - It is checked for the completeness of application package as guided on our website and includes the followings:

   Check list:

   i. One copy of ERC Application form with checklist *(copy attached)*
   ii. One copy of Research Protocol in standard format
   iii. A copy of Drug Brochure or any supplementary information enclosed (if applicable)
   iv. One copy of informed consent in English and Urdu or any other local language of the population study.
   v. One copy of Questionnaire in English and Urdu administered during the study (if applicable).
   vi. Please above requirement full fill

   Acknowledgement:

   After check list is found complete an acknowledgement with allotted the specific NBC number is communicated to the applicant along with intimation of payment amount and process for processing fee to by email.

   Payment of processing fee:

   - A payment of Rs 50,000/ is due for internationally funded submission and Rs 20,000/- is for nationally funded one.
   - Proof of payment is requested in the form of receipt on hard and soft copy format.
   - Meanwhile submission is processed for ethical review.

- Fee is waived off in certain circumstances upon request to only 50% and it is at the discretion of Secretary NBC i-e ED HRI or if he/ she delegates the powers to the Focal person.
- Fee waivers are to be applied on the letter head of institution and requests be made by the Head of institution with a valid justification for the request.

5. Reference:

SOPs of NBC submissions

6. Records:

1. List of files
2. List of registers

HEALTH RESEARCH INSTITUTE

(Research and Development Coordination section - NBC)

(Standard Operating Procedure - SOP)

CONTROLLED DOCUMENT

Document Information

Category	Information
Document Title	SOPs of **review of research studies**
Version	00
Document ID No	**NIH-ISB-HRI-RDC-SOP-19**
Author(s)	Dr Faiza Bashir
Reviewer(s)	Dr. Muhammad Ayaz Mustufa
Approver(s)	Dr. Nighat Murad
Creation Date	15.05.2022
Issue Date	15.05.2022
Effective Date	15.05.2022
Control Status	Controlled
Distribution: Issuance / Withdrawal	1. HOD 2. QMR (soft copy)
Disclaimer	This document contains confidential information. Do not distribute this document without prior approval from competent authorities of HRI.

Document Revision History

Author(s)	Date	Version	Description

Issue Date: 15.05.2022	Effective Date:15.05.2022	Revision Date:

1. **Purpose:**

   To receive the submissions for ethical approval in a standardized manner

2. **Scope:**

   Review of research studies submitted for ethical approval

3. **Responsibilities:**

   UDC, Assistant, National Coordinator

4. **Procedure:**

SOPs for new study (routine review):

- The received study after being identified with a unique ID and thorough screening for mandatory supporting documents is sent to the Chairperson of REC via email.
- The Chairperson sends the study to REC members and if need is felt to involve the subject matter expert also suggests and takes on board the Coopted member.
- For routine submissions an online meeting is scheduled within 4 weeks of submission.
- The study is discussed in the online meeting (mostly every Tuesday at 10:00 pm) via zoom link.
- If for some reason zoom meeting is not possible members agree to submit independent reviews.
- Reviews either from zoom discussion or individual submission by members are collated by the REC Chairperson.
- Collated comments are received at the Secretariat via email.
- Comments are communicated with the applicant via email.
- When the applicant submits the response to the comments these are forwarded to the Chairperson for review of the committee and its decision.
- After the review of justifications, the REC chairperson communicates the decision of either it is approved, needs further clarifications/ modifications or its cannot be allowed with proposed methodology.
- This decision is communicated to the PI via email which either contains approval letter or in other cases the response of REC.
- The whole process is aimed to be completed within 6 weeks of submission provided the applicant responds within a week of the response from REC.

SOPs for COVID related studies and Electromedical devices (EMD)- Rapid turnaround Review (RTR)

- The received study after being identified with a unique ID and thorough screening for mandatory supporting documents is sent to the Chairperson of REC via email.
- The Chairperson sends the study to REC members and if need is felt to involve the subject matter expert also suggests and takes on board the Coopted member.

- For routine submissions an online meeting is scheduled within 1st week of submission.
- The study is discussed in the online meeting (mostly every Tuesday at 10:00 pm) via zoom link.
- If for some reason some member is unable to join zoom meeting he/she is requested to submit independent reviews.
- Reviews either from zoom discussion or individual submission by members are collated by the REC Chairperson.
- Collated comments are received at the Secretariat via email.
- Comments are communicated with the applicant via email.
- When the applicant submits the response to the comments these are forwarded to the Chairperson for review of the committee and its decision.
- After the review of justifications, the REC chairperson communicates the decision of either it is approved, needs further clarifications/ modifications or its cannot be allowed with proposed methodology.
- This decision is communicated to the PI via email which either contains approval letter or in other cases the response of REC.
- The whole process is aimed to be completed within 02 weeks of submission provided the applicant responds within a week of the response from REC.

(At the start of pandemic the process was conceived and executed within 72 hours with daily zoom meetings but as the pandemic has settled now it takes 2 week. However the timelines are flexible and responsive to the situations.)

5. Reference:

SOPs of NBC submissions

6. Records:

1. List of files
2. List of registers

HEALTH RESEARCH INSTITUTE

(Research and Development Coordination section - NBC)

(Standard Operating Procedure - SOP)

CONTROLLED DOCUMENT

Document Information

Category	Information
Document Title	SOPs of **issuance of approval letters**
Version	00
Document ID No	**NIH-ISB-HRI-RDC-SOP-21**
Author(s)	Dr Faiza Bashir
Reviewer(s)	Dr. Muhammad Ayaz Mustufa
Approver(s)	Dr. Nighat Murad
Creation Date	15.05.2022
Issue Date	15.05.2022
Effective Date	15.05.2022
Control Status	Controlled
Distribution: Issuance / Withdrawal	1. HOD 2. QMR (soft copy)
Disclaimer	This document contains confidential information. Do not distribute this document without prior approval from competent authorities of HRI.

Document Revision History

Author(s)	Date	Version	Description

1. **Purpose:**

   To process of the submissions for extension requests in a standardized manner

2. **Scope:**

   Studies submitted for extension in time periods of approval.

3. **Responsibilities:**

   UDC, Assistant, National Coordinator

4. **Procedure:**

   - If the REC approves the submission for a defined time period i-e "One Year" for routine submissions and as for Covid or any other special circumstances for "6 Months", it is communicated to Secretariat.
   - A draft letter is prepared at NBC section and shared with chairperson for approval and signatures.
   - The Chairperson REC signs the approval letter and shares with NBC section via email.
   - The payment of processing fee is double checked and letter is issued to the ones who provide the proof of payment i-e receipt of payment via email and hardcopy whichever is received first.
   - The approval letter is first sent for dispatch number after dispatched the hard copy is shared with the applicant by post and soft copy by email.
   - One office copy is placed in the file of the project/ study for record.

5. **Reference:**

   SOPs of NBC submissions

6. **Records:**

   1. List of files
   2. List of registers

HEALTH RESEARCH INSTITUTE

(Research and Development Coordination section - NBC)

(Standard Operating Procedure - SOP)

CONTROLLED DOCUMENT

Document Information

Category	Information
Document Title	SOPs of **extension in time periods of the approved study**
Version	00
Document ID No	**NIH-ISB-HRI-RDC-SOP-22**
Author(s)	Dr Faiza Bashir
Reviewer(s)	Dr. Muhammad Ayaz Mustufa
Approver(s)	Dr. Nighat Murad
Creation Date	15.05.2022
Issue Date	15.05.2022
Effective Date	15.05.2022
Control Status	Controlled
Distribution: Issuance / Withdrawal	1. HOD 2. QMR (soft copy)
Disclaimer	This document contains confidential information. Do not distribute this document without prior approval from competent authorities of HRI.

Document Revision History

Author(s)	Date	Version	Description
Dr Faiza Bashir			

1. **Purpose:**

   To process of the submissions for extension requests in a standardized manner

2. **Scope:**

   Studies submitted for extension in time periods of approval.

3. **Responsibilities:**

   UDC, Assistant, National Coordinator

4. **Procedure:**

   - REC approves any study for a period of 1 year in general but for Covid related studies to have a vigilant monitoring on progress approval is valid for 6 months.
   - For continuing beyond this time period NBC requires an application along with the progress report.
   - The received extension requests after being identified with an ID for extension stated elsewhere and thorough screening for mandatory supporting documents particularly the progress report on a scientific format and a covering letter by PI stating the justification for extension is sent to the Chairperson of REC via email.
   - The Chairperson decides about the period of extension which is usually for one year and communicates with their approval status with the Secretariat.
   - Decisions are received at the Secretariat via email usually within 2 weeks.
   - This decision is communicated to the PI via email which contains approval letter of extension in time period for another term.
   - The whole process is aimed to be completed within 4 weeks of submission provided the applicant responds within a week of the response from REC.

5. **Reference:**

   SOPs of NBC submissions

6. **Records:**

   1. List of files
   2. List of registers

National Institutes of Health
Health Research Institute
National Bioethics Committee for Research (NBC-R)

****

Ref: No.4-87/NBC-REC/23/1327

Date: February 27, 2023

NOTIFICATION

The National Institutes of Health (NIH), is pleased to re-notify the National Bioethics Committee (NBC) as National Bioethics Committee for Research (NBC-R) with in Health Research Institute, NIH, as per directions of Board of Governors and as per the mandate given to (HRI) in the National Institutes of Health reorganization Act 2020.

Maj. Gen.
Prof. Aamer Ikram, HI (M)
Chief Executive Officer (CEO)
National Institutes of Health (NIH)
Islamabad.

Review Process of Clinical Validation Studies of Electro Medical Devices by Research Ethics Committee (REC) of NBC-R:

All Clinical Validation Studies (CVS) of electromedical devices that require human testing will be required to be reviewed by the NBC-R-REC. Only after approval of the NBC-R the study be submitted to DRAP for further processing and approval. The submission of the application must be on the prescribed REC form, together with all relevant supporting documents.

All CVS applications must submit evidence of scientific validation by a Technical Committee. Names and credentials of members of the Technical Committee must be furnished with the application. The scientific approval of the device undergoing CVS will be the sole responsibility of the Technical Committee, and the REC will have no responsibility to validate the scientific and technical reliability and safety of the device.

With regards to Class C & D applications, the applicant must also submit all the relevant non-clinical information in support of the application. The clinical investigator or manufacturer can submit the Clinical Validation Study (CVS), the patient informed consent form (ICF), and evidence of approval from all applicable IRBs.

Processing of application:

Timeline: The Clinical Validation S review, like all reviews by NBC-R-REC, may take 4 to 6 weeks after the full application with all required supporting documents is submitted to the secretariat. The NBC-R-REC may consider applying the Rapid Turnaround Reviews (RTR) system, with a response time of no more than a week in extenuating circumstances. The determination of applicability of RTR for a particular application will be made by the NBC-R-REC itself.

Application Fee: All applicable fees would be required to be submitted prior to the review.

Review Process: Following are 03 major steps of review process.

1. The CVS will be reviewed by the regular members of the NBC-R-REC. Additional reviewers may be specially co-opted for specific cases. The co-opted members will have relevant scientific and/or experiential background in the device being reviewed.
2. The REC will provide its review at the end of the stipulated period which will be communicated to the applicant by the secretariat. The outcome of a review can be one of the following:

    - Acceptance of proposal;
    - Amendments followed by approval of proposal;
    - Refusal of application;
    - Cancellation of an approved proposal.

3. Even after issuing an approval, the NBC-R-REC may ask the applicant to stop CVS, or withdraw its approval to a CVS entirely based on additional information regarding safety concerns coming to light after an initial approval.

4. The application of Clinical Validation Study (CVS) or revised application may be rejected if:

- The application or the required supporting documents are incomplete
- Safety concerns have not been adequately addressed
- The objective of the testing cannot be achieved

The REC secretariat will issue a "Letter of Refusal" stating the reasons for rejection. The applicant will have the right to apply again with a fresh application

Reporting of changes: The applicant will be required to report to REC if any changes in the device or any changes in the protocol of the CVS taking place after having been granted an approval, This must be communicated to the REC secretariat on an immediate basis. Failure to do so will result in a cancellation of the approval.

ANNEX I*: CLASSIFICATION SYSTEM FOR MEDICAL DEVICES-* *(available at: https://dra.gov.pk/Home/Download?ImageName=FFSCHEDULEACLASSIFICATIONOFMEDICALDEVICES.pdf)*

CLASS	LEVEL	DEVICE EXAMPLES
A	Low Hazard	Tongue depressors/ disposable masks
B	Low-moderate Hazard	Hypodermic Needles / suction equipment
C	Moderate-high Hazard	Lung ventilator / bone fixation plate
D	High Hazard	Heart valves / implantable defibrillator

Government of Pakistan

National Institutes of Health

Health Research Institute

National Bioethics Committee (NBC)

Pakistan

NBC-R REC RESEARCH ETHICS FORM

Adapted & used with thanks & permission of MSF Ethics Review Board

National Bioethics Committee (NBC) Pakistan

Note: All research projects must be submitted to NBC, located at Shahrah-e-Jamhuriat off Constitution. Avenue, Sector G-5/ 2 Islamabad

Checklist

This checklist is prepared in order to facilitate an investigator in preparing a complete application and to help Research Ethical Committee of National Bioethics Committee for expedited review. Your cooperation in completing it will be highly appreciated.

- ☐ One copy of ERC Application form with checklist
- ☐ One copy of Research Protocol in standard format
- ☐ A copy of Drug Brochure or any supplementary information enclosed (if applicable).
- ☐ One copy of informed consent in English and Urdu or any other local language of the population study.
- ☐ One copy of Questionnaire in English and Urdu administered during the study (if applicable).
- ☐ One copy of headwise budget, and source of funding.
- ☐ Make a copy of this entire application for your files.
- ☐ Send a soft and hard copy of all the documents.
- ☐ I have submitted the application form, research protocol and informed consent with Urdu translation by e-mail.

_____	_____
Signature: Principal Investigator	Date
_____	_____
Signature of supervisor (if applicable)	Date
_____	_____
Signature of Chairman of the Department	Date

Instructions / guidelines for researchers

1. Form to be filled out and submitted with the research protocol when requesting REC review.

2. Please use the NBC-R REC Research Ethics Framework – Guidance document to help answer the questions below. If appropriate, you may directly copy-paste text from the research protocol sections in the protocol.

3. Please answer all questions. It is the responsibility of researcher to fill the application form appropriately. Incompletely and inappropriately filled form will not be accepted/ considered for review and discussion in the meeting. This may result in delay in approval of the proposal.

4. The review process takes take 6 weeks in granting approval.

5. Application must be signed by Principal Investigator. In case of student's/ resident's application, it should also be signed by the supervisor.

Introductory Questionnaire

Research Proposal
Title:
Version number:
Date created:
Duration of proposed study (one year, two years, more than two years):
Name of Principal Investigator (PI):
PI Institute/Organization:
Address of PI Institute/Organization:
Country of PI Institute/Organization:
Collaborating Institutions: (Please provide information about all Institutions/Organizations collaborating in this research)
Has the protocol been submitted to or approved by other/institutional Ethics review Committee(s)? If not yet submitted, please indicate when and to which committee the protocol will be submitted. Please name the various ERCs.

1. Research Question and Methodology
(1.1) What is the research question? Why is it important?
(1.2) How is the methodology and proposed analysis appropriate given the research question(s)?
(1.3) What is the context in which the research will be conducted? How has this influenced the research design? The protocol must include details (if applicable) about existing and planned community engagement and collaborative partnerships and how they have influenced or shaped the proposed research.
(1.4) Are there any other parties involved in the research? What potential interests of these parties might be in conflict?
(1.5) Are all relevant resources and protections for the research secured?
(1.6) ***Have the research staff the relevant training and protections?***
2. Respecting and Protecting Research Participants and Communities
(2.1) What are the anticipated harms and benefits?

(2.2) What are your plans for obtaining consent?
(2.3) How do you plan to protect confidentiality?
(2.4) How do you plan to access, store and distribute any collected biological material? Guidelines for Collection, Usage, Storage and Export of Human Biological Materials are available at http://nbcpakistan.org.pk/guidelines.html
3. Implications and Implementation of the Research Findings
(3.1) What will happen when the research is either stopped or is complete?
(3.2) How will the findings be disseminated?

Guidelines for drafting an informed consent form

Although a sample of informed consent form is attached, additional guidelines are given here in order to help and facilitate the researchers in drafting a proper, acceptable consent form.

1. All studies involving human subjects should have a properly drafted consent form. No study should be done on human subjects without obtaining informed consent and sufficiently before the start of the study, at an appropriate time, and not at a time when s/he is under stress such as surgical procedure, and is unable to understand the study.
2. Consent may be written or verbal or telephonic. In case of unwritten consent, it should be signed by the person taking the consent and witnessed by a second person.
3. In case of children, an assent form from children and consent from guardian / parents is needed.
4. In case of mentally or physically incapacitated subject, consent should be obtained from immediate guardian or close relative
5. In case of community studies, community leaders, elders, local political leaders, religious leaders (in certain cases), and governmental officials should be taken into confidence, and a written consent should be obtained.
6. In case of doing a study in other locations such as other hospitals and clinics, permission from appropriate authority or physicians should also be obtained.
7. The consent form should be in English and Urdu with translation into other local language if needed. These should be identical in such a way that the translation of one into other is similar. The language should be easy which can be understood by study subjects (uneducated or primary passed). Use of technical terms should be avoided.
8. It should be written in “second or third person” and not in “first person”. For example, “You will be asked to give 10 cc blood” or “you will be asked few questions” etc.
9. A properly drafted consent form should contain the following important points.

    a) Information sheet. There should be one paragraph or page giving information about the nature of study, its purpose and need, possible benefits of the study, and procedures to be carried out on the study subjects.
    b) Possible risks and benefits to the study subjects
    c) Availability of alternate treatment in case of therapeutic trials
    d) Voluntary participation without any compulsion, moral or otherwise and without any financial incentive or coercion. However, financial assistance or reimbursement for time and traveling may/should be provided to study subjects; which should commensurate with the time spent, and should not be too high.
    e) Right to withdraw from the study at any time without affecting their rights and treatment.
    f) Confidentiality
    g) If any specimen is to be stored, its time of storage and permission to use it in further research.
    h) Name and contact number of the investigator in case the study subject wants further clarification or information about study.
    i) Authorization from study subjects with their signature, thumb impression, signature of witness etc.

Important Notes

1. Studies should not be done on patient's expenses.
2. If any new or additional tests are to be done as a requirement of study, their cost should be supported by the study.
3. If a new treatment is compared with an existing and established one OR two treatment modalities are being evaluated and compared, cost of treatment or difference in cost of treatment should be borne by the study. In addition any expected or unexpected complication arising as a result of new treatment should also be supported by the study.
4. Studies which are unlikely to produce any significant results because of faulty design are often considered not to be ethical as such studies cause wastage of time and resources. These should be avoided unless there is strong justification.

Government of Pakistan

National Institutes of Health

Health Research Institute

National Bioethics Committee for Research (NBC-R) Pakistan

REC Application Form for Exemption of Studies from Ethical Review

Adapted & Used with Thanks & Permission of Aga Khan University Ethics Review Committee

National Bioethics Committee for Research (NBC-R)
Pakistan

1. Study Title	

2. Principal Investigator	**Name**	**Department**
3. Co-PI's	**Names**	**Department**
4. Signature of PI		

Please mark the appropriate box as √

5. Types of study		Yes	No
a.	Retrospective review of patient's charts/routine collected data		
b.	Prospective data collection from patient's charts		
c.	Analysis of laboratory/ radiology data		
d.	Clinical audit		
e.	Evaluation of practice guidelines		
f.	Case reports		
g.	Others; please specify		

6. Period of data collection			
From			

7. Starting date of study			

8. Summary of data to be collected		Yes	No
a.	Demographics of the patients i.e. name addresses, phone numbers, e-mail address		
b.	Clinical notes		
c.	Photographs		
d.	Laboratory data/ radiology data		

e.	Management data		
f.	Other, please specify		

9. Utilization of data to be collected: Will it be used for		Yes	No
a.	Publication of papers in journals / newspapers		
b.	Oral / poster presentation in meetings / conferences		
c.	Students / residents' teaching		
d.	Planning subsequent larger studies		

10. Summary of Objectives & Methods of Study including selection and exclusion criteria of study subjects, sample size, analysis plan etc.

1. Aim and Objectives:

2. Study design: \

3. Study population:

4. Data Sources and Variables:

5. Analysis and Statistics:

11. Please answer the following questions and mark the appropriate box as √

		Yes	No
a.	Will any photographs be used/taken for publication?		
b.	If yes, has written permission been obtained from study subject or guardian?		
c.	Is there any ethical concern/issue?		
d.	If yes, what were the ethical issues?		
e.	Were those ethical concerns resolved?		

Government of Pakistan

National Institutes of Health

Health Research Institute

National Bioethics Committee for Research (NBC-R) Pakistan

NBC-R REC Application for Clinical Validation Study (CVS) of Electro Mechanical Device

National Bioethics Committee (NBC) Pakistan

Note: All research projects must be submitted to NBC located at Shahrah-e-Jamhuriat, off Constitution. Avenue, Sector G-5/ 2 Islamabad

Checklist

This checklist is prepared in order to facilitate an investigator in preparing a complete application and to help Research Ethical Committee of National Bioethics Committee for expedited review. Your cooperation in completing it will be highly appreciated.

- ☐ One copy of REC Application form with checklist
- ☐ One copy of Clinical Validation Study protocol
- ☐ One copy of informed consent in English and Urdu or any other local language of the population study
- ☐ Pakistan Engineering Council certification of safety
- ☐ Signed copy of quality check certificate by the manufacturer of the medical device
- ☐ List of members of the independent Technical Committee
- ☐ Evidence of all pre Clinical Validation Studies safety testing performed on the device (simulator studies, animal studies, others as applicable)
- ☐ Letter/s of collaboration from hospitals/institutions where CVS will be performed
- ☐ Institutional Ethical Review Board (IERB) approval letter/s from institution/s where Clinical Validation Study (CVS) will be performed
- ☐ I have submitted the application form, research protocol and informed consent with Urdu translation by e-mail.

_____ _____

Signature: Manufacturer (Name of company)

Date: ----------

_____ _____

Signature: Lead Clinical Investigator (Name of institution)

Date: ----------

National Bioethics Committee (NBC) Pakistan

Instructions / guidelines for Researchers

1. Form to be filled out and submitted with the research protocol when requesting REC review.
2. Please use the NBC-R REC Research Ethics Framework – Guidance document to help answer the questions below. If appropriate, you may directly copy-paste text from the research protocol sections in the protocol.

3. Please answer all questions. It is the responsibility of researcher to fill the application form appropriately. Incompletely and inappropriately filled form will not be accepted/ considered for review and discussion in the meeting. This may result in delay in approval of the proposal.

4. On normal circumstances, the review process will take 4 to 6 weeks in granting approval.

5. Rapid Turnaround Review may be applicable in certain cases, at the discretion of the NBC-R REC

6. Application must be signed by both, the representative of the manufacturer, and also the Lead Clinical Investigator performing the Clinical Validation Study (CVS).

Nature/name of device:
Title of CVS:
Version number:
Date created:
Duration of CVS:
Name of the manufacturer, and organization with address:
Name of the Lead Clinical Investigator of CVS and organization with address:
Country of investigators Institute/Organization:
Collaborating Institutions:

(Please provide information about all Institutions/Organizations collaborating in this CVS)
Has the CVS been submitted to or approved by other/institutional Ethics Review Committee(s)? If not yet submitted, please indicate when and to which committee the protocol will be submitted. Please name the various IERB/ ERCs.

1.0 Research Question and Methodology:

(1.1) Rationale for seeking approval for the electro mechanical device:

(1.2) Details of preclinical validation tests performed on the device so far:

(1.3) Methodology of performing Clinical Validation on human participants:

(1.4) Is the funding secure to perform the validation?

(1.5) Describe all potential Conflict of Interest situations in this CVS

2.0 Collaborating institutions roles and responsibilities

(2.1) Details of designated roles of collaborating institutions where CVS will be performed on human participants:

(2.2) Are the personnel trained to perform the validation?

(2.3) Does the validation site have all the necessary interventions for the safe conduct of the CVS?

3.0 Respecting and Protecting Research Participants
(3.1) What are the anticipated harms and benefits for volunteers on whom the CVS will be performed? **(3.2)What is the process for obtaining informed consent?** **(3.3)How will confidentiality be protected?**
(4.0)Implications and Implementation of the Research Findings
(3.1) What will happen when the clinical validation study is either stopped or is complete? **(3.2) How will the findings be disseminated?**

Guidelines for drafting an informed consent form for Clinical Validation Studies for testing electro mechanical devices

Although a sample of informed consent form is attached, additional guidelines are given here in order to help and facilitate the researchers in drafting a proper, acceptable consent form.

1. All studies involving human subjects should have a properly drafted consent form. No study should be done on human subjects without obtaining informed consent and sufficiently before the start of the study, at an appropriate time, and not at a time when s/he is under stress such as surgical procedure, and is unable to understand the study.
2. Consent for CVS always has to be written, by the volunteer himself/herself or a legally valid surrogate decision maker in case the volunteer cannot consent directly. The consent process must be witnessed by a second person.
3. CVS may not be performed on children unless, in the exceptional circumstances when the device is only for use in the pediatric age group. In case of children, an assent form from the child, when applicable, and consent from legal guardian / parents is needed. .
4. The consent form should be in English and Urdu with translation into other local language if needed. These should be identical in such a way that the translation of one into other is similar. The language should be easy which can be understood by study subjects (uneducated or primary passed). Use of technical terms should be avoided.
5. The consent document should be written in “second or third person” and not in “first person”. For example, “You will be asked to give 10 cc blood” or “you will be asked few questions” etc.
6. A properly drafted consent form should contain the following important points.

    a) Information sheet. There should be one paragraph or page giving information about the nature of the CVS, its purpose and need, possible benefits of the study, and procedures to be carried out on the study subjects.
    b) Possible risks and benefits to the study subjects
    c) Availability of alternate treatment modalities
    d) Voluntary participation without any compulsion, moral or otherwise and without any financial incentive or coercion. However, appropriate financial assistance or reimbursement for time lost should be provided to volunteers.
    e) Right to withdraw from the study at any time without affecting their rights and continuation of treatment.
    f) Confidentiality
    g) Name and contact number of the investigator in case the study subject or their surrogates want further clarification or information about the CVS.
    h) Authorization from study subjects or their legal surrogatesa with their signature, thumb impression, signature of witness etc.

Important Notes

1. Studies should not be done on patient’s expenses. The participant ought not to be worse off than he was outside of the study.

2. If any new or additional tests are to be done as a requirement of study, their cost should be supported by the study.
3. If a new device is being compared with an existing and established one OR two devices are being evaluated and compared, cost of treatment or difference in cost of treatment should be borne by the study.
4. Any expected or unexpected complication arising as a result of new device under evaluation should also be borne by the investigators.

Sample Informed Consent

This is a generic sample form to help you address most situations. Please adapt it to suit the requirements of your CVS protocol.

In case the CVS is recruiting participants who cannot consent themselves due to their medical conditions, please read "you" and "your" as "your patients" in the document below.

Project Information	
Name of device:	
Project Title:	Project Number:
ERC Ref No:	Sponsor:
Principal Investigator:	Organization:
Location:	Phone:
Other Investigators:	Organization:
Location	Phone:

Consent document must be clearly written and understandable to subjects. The language must be nontechnical (comparable to the language in a newspapers or general circulation magazine), and scientific, technical or medical terms must be plainly defined.

Informed Consent may not include language that appears to waive subjects' legal rights or appears to release the investigators or anyone else from liability for negligence.

1. PURPOSE OF THIS RESEARCH STUDY

- Include 3-5 sentences written in nontechnical language. "You are being asked to participate in the clinical validation study designed to test the (name of the device under investigation)"

2. PROCEDURES

- Describe procedures: "You will be ……."
- Identify any procedures that are experimental/investigational/non-therapeutic.
- Define expected duration of subject's participation.
- Indicate type and frequency of monitoring during and after the study.

3. POSSIBLE RISKS OR DISCOMFORT

Note that these include not only physical injury, but also possible psychological, social or economic harm, discomfort, or inconvenience.

- Describe known or possible risks of intervention with the device under study. If unknown, state so.

4. POSSIBLE BENEFITS

- Describe any benefits to the participant that may be reasonably expected. If the device under investigation is not of direct benefit to the participant, explain possible benefits to others.

5. FINANCIAL CONSIDERATIONS

- Explain any financial compensation involved or state: "There is no financial compensation for your participation in this research."
- Describe any additional costs to the subject that might result from participation in this study.
- Please indicate any financial benefits to the subjects including therapeutic or diagnostic costs being covered by the study.

6. AVAILABLE TREATMENT ALTERNATIVES

- Describe the availability of alternative devices available (conventional, non experimental) for meeting the requirements of the participant, and that he/she may choose not to participate in the CVS without risk of any penalty.

7. AVAILABLE MEDICAL TREATMENT FOR ADVERSE EXPERIENCES

- The informed consent must describe whether "This CVS involves (minimal risk) or (greater than minimal risk)."
- Informed consent document must provide information that if the participant is injured as a direct result of taking part in this research study, emergency medical care will be provided by [name] medical staff at the same facility, or if needed, he/she may be moved to a different facility for continuity of care. Indicate who will pay for this treatment.

8. CONFIDENTIALITY

- Describe how and to what extent confidentiality of records identifying the subject will be maintained.

  "Your identity in this CVS will be treated as confidential. The results of the CVS, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you."

9. TERMINATION OF CLINICAL VALIDATION STUDY

You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or to withdraw after agreeing to participate. In the event you decide to discontinue your participation in the study,

- These are the potential consequences that may result: (list)
- Please notify (name, telephone no., etc.) of your decision or follow this procedure (describe), so that your participation can be orderly terminated.

In addition, your participation in the study may be terminated by the investigator without your consent under the following circumstances. (Describe) It may be necessary for the sponsor of the study to terminate the study without prior notice to, or consent of, the participants in the event that (Describe circumstances, such as loss of funding.)

10. AVAILABLE SOURCES OF INFORMATION

- Any further questions you have about this study will be answered by :
  Name:
  Phone Number:
- Any questions you may have will be answered by:
  Name:
  Phone Number:
- In case of a research-related emergency, call:

Day Emergency Number:
Night Emergency Number:

11. AUTHORIZATION BY PARTICIPANT

I have read and understood the consent form, and I volunteer to participate in this Clinical Validation Study of ……. (name the device). I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study, or the malfunction of the device under testing. I further understand that nothing in this consent form is intended to replace any applicable laws.

12. AUTHORIZATION BY SURROGATE

I have read and understood the consent form, and on behalf of the patient ……..(name of the patient) I volunteer to include him/her in this Clinical Validation Study of ……. (name the device). I understand that on behalf of the participant I will receive a copy of this form. I understand that this consent does not take away any legal rights of the participant in the case of negligence or other legal fault of anyone who is involved in this study, or the malfunction of the device under testing. I further understand that nothing in this consent form is intended to replace any applicable laws.

Participant Name (Printed or Typed): OR Participant's surrogates Name and signature
Date:

Participant Signature:
Date:

Principal Investigator Signature:
Date:

Signature of Person Obtaining Consent:
Date: