Bangladesh Journal of Bioethics, 2011; 2(2):24-25

INSTITUTIONAL ETHICAL REVIEW BOARD (IERB): CONCEPT & CONTEXT

Dr. Md. Humayun Kabir Talukder[1], Dr. Md. Zakir Hossain[2] , Dr. Nasrin Ahkter [3], Ismat Ara Perveen[4]

1. Associate Professor & Course Director, Centre for Medical Education, Dhaka
2. Registrar, Sapporo Dental College, Dhaka
3. Asstt. Prof, Dhaka Medical College, Dhaka
4. Instructor, Nursing College, Dhaka

Abstract: According to modern concept of institutional review board, all proposal of biomedical research involving human participants should be cleared/approved by an Institutional review board (IRB) is mandatory. Competence and independence are the two hallmarks of an IRB. The responsibilities of an IRB are protection of dignity, rights and well being of potential research participants. All research projects do not pass through IRB in Bangladesh. Many researches have been performed without ethical clearance. Young healthcare professionals are scare about IRB as they have little ides about IRB. Structure of IRB, Review procedures and IRB in Bangladesh are discussed in this paper to better understanding of ethical process of research paper to the health care professsionals.

Introduction: The modern concept of institutional review board originated in 1970s.[1] It is mandatory that all proposal on biomedical research involving human participants should be cleared/approved by an appropriately constituted institutional ethical review board (IERB)/ institutional ethic committee(IEC), also referred to as Institutional review board (IRB) ethics review board (ERB) and Research Ethics board(REB) in other countries.[2] Competence and independence are the two hallmarks of an (IERB)/ (IEC) .The responsibilities of an (IERB)/ (IEC) are protection of dignity, rights and well being of potential research participants; ensuring that universal ethical values and international scientific standards are expressed in terms of community values and customs and assistance in the development and in the education of a research community responsive to local health care requirements.[2] The boards are responsible for review of the proposed research proposal prior to initiation of the project. They also have the responsibility of regular monitoring of the approved research project to foresee the compliance of the ethics during the period of the project.[2] Actions of IERB are approval- approve without stipulation, approve with stipulations. They enforce rules regarding noncompliant investigations by rejecting a proposal or termination of an investigation[1]. In composition the (IERB)/ (IEC) should be multisectorial and multidisciplinary. Institutional ethical review board (IERB) is a body consisting of concerned odd number of persons (9-11). The (IERB)/ (IEC) may be comprised of a chairperson; One or two persons from basic medical science; one or two clinicians from various institutes ; one legal experts; one social scientist or representative of non governmental voluntary agency; one philosopher /ethicist/theologian **;** one lay person from the community [2,1]. The (IERB)/ (IEC) members should be encouraged to be updated of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted body**.**[2]

Review procedures by (IERB)/ (IEC): For a research proposal on human participants a scientific evaluation by a appropriate Scientific Review committee has been completed before ethical review is taken up. A

research proposal should be screened by the (IERB)/ (IEC) secretariat for their completeness and depending on the risk involved categorizes into three types , namely , exemption from review , expedited review and full review [2, 1]. A proposal which present less than minimal risk fall under the category of exemption from review and administratively reviewed does not require board review. The proposal having no more than minimal risk to research participants may be fall under the category of expedited review and usually reviewed by sub committee. All research presenting with more than minimal risk , or those proposal/ projects which do not qualify to fall under the category of exemption from review , expedited review and proposal/ projects that involve vulnerable population and special groups shall be subjected to review by all members of the (IERB)/ (IEC). Research intended for publication are generally subjected to be reviewed by institutional review board.[(2,1)] Completion of IRB process is time consuming and expensive . The Bell report for the national institute s of health described annual work load facing 491 IRBs including an estimated 284,000 reviews.[3]

Ethics review committees in Bangladesh: Bangladesh is a developing country in the South Asia region. Health research demand is increasing as there are huge health problems. In Bangladesh there is one central ethics review committee and nine institutional committees**.** The Bangladesh Medical Research Council ethics committee is considered as the central/ National ethics review committee[4]. The nine other ethics review committees are functioning in seven postgraduate medical institutes and two medical college. The institutes are Bangabandhu Sheikh Mujib medical university, National Institute of preventive and social medicine, National Institute of the Kidney Diseases and Urology (NIKDU), Institute of Child and Mother Health (ICMH), Bangladesh Institute of Child Health (BICH), Chittagong Medical College (CMC), Sir Salimullah Medical College (SSMC), Rajshahi Medical College (RMC) and Bangladesh Institute of Research for promotion of essential and reproductive health and technologies. ICDDR'B has its own ethics review committee. Bangladesh Medical Research Council (BMRC) was established in1972 as an autonomous body by order of the president under the Ministry of Health and Family Welfare. The central Ethics Review committee was established in 1979. At present committee consists of 11 members[5]. The clinicians, Lawyers, laypersons and religious leaders are included as members. The Committee is formed by the Executive Committee of the BMRC and has tenure of three years. The committee is registered in the Office for Human Resource Protection in the USA as an Official Institutional Review Board and it has federal wide assurance. About 100 research proposals are reviewed by Central Ethics Review Committee of BMRC.

References:

1. Parviji j, Tarity D, Conner K, Smith B, Institutional review board approval: Why it matters? Journal of bone and Joint Surgery .2007; 89:
2. Institutional Ethical Review Board Jawaharlal Nehru University http://www.jnu.ac.in/IERB/ICMR guideline
3. A central Institutional Review Board for a Multi – Institutional Trials. N Engl J Med 2002;346(18) www.nejm.org
4. Rashid HA, Regional perspectives in research ethics : a report from Bangladesh Eastern Mediterranean Health Journal, 2006 ;12 (1)
5. Bangladesh Medical Research council www.bmrcbd.org