

COMMENTARY

Mandate of Establishing an Ethical Review Committee

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ABSTRACT:

The National Bioethics Committee (NBC) was approved by the Government of Pakistan in 2004. Its basic mandate is to "promote and facilitate ethical health services delivery and health related research. The secretariat of NBC is the Pakistan Medical Research Council (PMRC) under Ministry of Health Government of Pakistan. A Code of Ethics has been issued by Pakistan Medical and Dental Council (PMDC) and according to this code all research protocols must be reviewed by an Ethical Review Committee (ERC) at their local institute.

A 15- member committee which comprises of faculty from basic sciences, representatives from social science departments, clinicians, a person with knowledge of ethics of medical research and a lay person is an ideal team. This is essential to cater to the well being of patients and safety of research. In this way the importance of ethics will be realized by all health providers. The ERC should inculcate the sense of ethics in health providers and must be realized as an important component of any institution.

Key words: ERC, guidelines, CIOMS, terms of reference, human tissue.

INTRODUCTION:

Declaration of Helsinki and council for international organization of medical sciences (CIOMS) guidelines should be consulted and referred to in formulating and designing the code of ethics outline^{1,2}. World Medical Association had issued the original Declaration of Helsinki in 1964 and an amended version in 1975³. Recently, CIOMS presented its revised international ethical guidelines for biomedical research in a symposium at the 12th World Congress of the international association of bioethics, Mexico City 2014. This council is a non government organization established jointly by WHO and UNESCO in 1949^{4,5}. The guidelines given in this relate mainly to ethical justification and scientific validity of research. It deals with ethical review, informed consent, vulnerability (of individuals, groups, communities, populations and women), equity regarding burdens and benefits, choice of control in clinical trial, confidentiality, and compensation for injury due to the research protocol.

They also deal with strengthening of national or local capacity for ethical review and look after the obligations of sponsors to provide health- care services. Their scope reflects the changes, the advances and the controversies that have characterized biomedical research ethics in the last two decades. CIOMS guidelines are designed to be of use to countries in defining national policies on the ethics of biomedical research involving human subjects,

applying ethical standards in local circumstances and establishing or improving ethical review mechanism. A meticulous aim of these guidelines is to reflect upon the needs and conditions of low-resource countries, and to look after the implications for multinational or transnational research in which different countries may be working together in the same project^{6,7}. If the Australian's National Health and Medical Research Council's (NHMRC) basic requirements is consulted we can appreciate that its main theme is to include all medical and scientific researches done whether on humans or animals which must be approved by a properly constituted ethic committee. The specific requirements of using humans including left over tissue must be laid down by this committee^{3, 4}.

Use of discarded human tissue in research has extensively been used by researchers but it is mandatory to maintain a controllable and transparent system. This should be in addition to consent by the local ethics commissions.⁵ In order to maintain this system, a German law, the charitable state-controlled foundation Human Tissue Cell Research (HTCR) was founded in 2000 at the University of Regensburg, Germany⁶.

To take responsibility of the ethical and legal aspects of using human tissue for research was the main goal of this foundation. In order to fulfill this, the foundation has established an ethics and scientific council which is responsible to approve such studies that involve human tissue. The foundation HTCR was established in Germany but the ethical and legal aspects of donating and using discarded human tissue for research is quite similar in other countries. The way the HTCR foundation handles the procedure, it may be helpful in finding solutions to the existing law.⁵ Very importantly it may serve as a platform to practice standard procedures for using human materials in accordance to ones legal system, religion and culture. It must be remembered by investigators involved in research which is conducted on human subjects that their primary duty is to respect individual patients. It must be kept in mind that subjects must participate willingly. The participants must have sufficient

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Received: 24-06-2014
Revised 17-07-2014
Accepted: 12-08-2014

knowledge about the research and proper informed consent must be sought.

The need of establishing an Ethical Review Committee (ERC) at any institute in Pakistan should be based upon the research activity of faculty members and students and must be established in health care centers in line with HEC/PMDC guidelines and policy. Majority of the researchers do research on humans including their left over tissue in order to fulfill the requirements of the degree and attain appropriate experience but they are unaware of the ethics involved in usage of subjects or their tissues without appropriate consent. There is also a need of developing ethical values among the medical students so that they should know the value of human life and its application in their professional career^{6,7,8}. The objectives of establishing this committee at any institute should not only be to look at research proposals but to go beyond that and try to fulfill other aspects as the name indicates it is a committee that reviews ethics. The duties of such a committee must be wider, some of which must include⁹,

- To enhance ethical values in research
- To approve only those research proposals which are ethical and safeguard the rights and well being of research participants including humans and left over tissues that will be used for research purposes.
- To educate the faculty and staff in ethical research
- To foster and encourage research
- To develop ethical values among medical and other health related students in their under graduate teaching.

A 15- member committee is its requirement, the members must include:

- a. Faculty from basic and clinical sciences
- b. Representatives from social science department
- c. A person with knowledge of ethics of medical research
- d. A lay person
- e. A religious scholar

These members should be nominated on the basis of interest in biomedical ethics. The members must first be trained via attending workshop on the functioning of an ERC which must be conducted by experts of biomedical ethics. An outline of duties and responsibilities of ERC members should be explained.

The terms of reference should be formulated by also taking into considerations the recommendations by the report of Royal College of Physicians of London (1996) which is entitled "Guidelines on the Practice of Ethics Committee in Medical Research involving Human Subject"^{10, 11}.

These terms of reference have been derived for application

to both biomedical and social science research^{12, 13, 14}. The ERC should not only limit its role by looking after the research proposals but must take a step forward to encourage all faculty members to especially present the ethical concerns in the meeting or other forums as provided by local institutions. In this way the faculty will look at the researches which they conduct from an ethical point of view as well and will learn to use these virtues in their researches. Ethical Issues should also be touched upon during class room learning especially during small group discussions for example in Problem Based Learning sessions, in which the students have to identify issues and then look for answers which are later discussed in group form^{13, 15}.

The ERC establishment is beneficial for the researcher as well as the subjects. In order to cater to the well being of individuals it is important to create awareness about their rights. It has been realized that in the past and present several unethical studies have and are being conducted therefore efforts can be made to make one realize of the unethical practices by such maneuvers. Such unethical practices have been noted in several studies all over the world. Even today we face such practices and in order to minimize or abolish this, the role of ERC is very essential and significant. The most important role that such a committee can and must play should be to inculcate ethical thinking in the faculty and students rather than just imposing rules and regulations^{16, 17}.

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