J Korean Med Sci 2003; 18: 1-2
ISSN 1011-8934



■ EDITORIAL ■

# Stages of Institutional Review Board Activities

The modern medicine is characterized by continuous and progressive changes from the incorporation and application of newly acquired scientific knowledge. Most of time, the final process of changes requires medical research involving human subjects. The aim of scientific research in medicine is to advance general knowledge by gathering evidence or data for testing hypotheses. Then what actually occurs in scientific research in medicine is benefiting the mankind rather than individuals. There are certain limitations to fulfill this utilitarian goal because the research participants that become a means for a study are prone to exploitation, and are at potential risks.

In response to the atrocious deeds of Nazi's human experimentation during the World War II, the Nürnberg Code was promulgated in 1947 as the first international guidance on permissible medical experimentation. The core statement in the Nürnberg Code centers on the principle of informed consent as ethical requirements for human research: "The voluntary consent of the human subjects is absolutely essential". In terms of moral responsibility, the Code presumes the protection of human subjects primarily at an individual investigator rather than at an institutional level. In the 1960s and 1970s, however, a succession of unethical researches, notably as in Tuskegee Syphilis Study, was revealed. This alarmed that the welfare and rights of human subjects could not be guaranteed by relying solely on the discerning investigators. Since 1974, after public outcries over scandalous human experiments, the American Federal Government established the regulations which require the beneficiary institutions review of all biomedical and behavioral researches involving human participants. This consists of prior approval and continuing monitoring by Institutional Review Board (IRB). The Declaration of Helsinki, which was first adopted by the World Medical Association in 1964 and revised several times thereafter, also requires all biomedical research involving human subjects to be reviewed by ethics review committees. Both authors and publishers are responsible to publish papers the studies that meet the ethical requirements of the Declaration of Helsinki.

As a system to protect human subjects, the IRB review does not depend solely on the responsibility of individual investigators. While investigators should abide by the ethical and legal requirements of their research throughout its process of initial study design, implementation, analysis and publication, the IRB review system requires research institutions to take an official responsibility for ensuring human participant protection by prospective and continuing review of researches conducted at each institution. International guidelines on the IRB operation state clearly that the tenets of the IRB review are independence, transparency and competency. Each IRB should operate independently from investigators, sponsors, institutions, the professional community, or any other undue influences. Since investigators have many legitimate interests in the research, an independent review of the research must intervene to minimize any conflicts. To reflect the ideal of independence of IRB activity, the IRB should include at least one non-medical person and another unaffiliated to the institution. Independent review also reassures society that the researchers will not take advantage by the abuse of participants. As such, the IRB offers a central role that ensures the protection of human participants.

Recently, however, concerns about the system to protect the right of human participants are rising worldwide. For the last couple of decades, the tremendous development of biomedical research enterprises-with its increasing complexities and commercial nature-pose great challenges concerning the protection of human participants and the restoration of public trust. Therefore, international organizations and the developed countries took the initiative and seriously examined the current systems of human participants protection, including IRB system, and decided to continue collaborative efforts to solve the problems as it finds. The issue as to how to protect human participants while maintaining public trust and promoting scientific progress becomes both an international and a local task.

In this issue of the *Journal* of *Korean Medical Science*, a special article (*2003; 18: 3-10*) appears to describe the current status of IRB operations in Korea. This article poses us with a challenge by depicting the reality of shortcomings in IRB performance, and by providing the reader with general picture of the state of research ethics in Korea. However, the early stage of IRB activities and the lack of the experience in operating IRB are not necessarily an explanation why scandalous medical researches have not been exposed. In fact, few medical research scandals, unlike medical malpractice, have been public issues in Korea. It has been culturally unimaginable to design a medical research which may harm human participants. Since the appalling exposure of unethical Japanese military doctors' experimentation involving the ethnic Koreans during the wartime in China (*Lancet 2002; Suppl; S5-6*), potentially harmful medical experiments have been regarded as a crime. However, these general beliefs in medical research fields in Korea do not verify that there has not been any individual researcher's aberrant researches. In another aspect, the

benevolent attitude toward research and the environment inadvertently have rather been a barrier for the medical researches involving human participants in Korea.

Since Korea abandoned the law that had granted to domestic pharmaceutical firms a patent and marketing privilege for a drug made by new synthetic process in 1987, the situation of medical research involving human subject began to change. Korean pharmaceutical firms should begin to find new materials as candidate drugs for human use. The change of pharmaceutical industry in Korea urged Korean Government to make a guideline in clinical trials of new candidate drugs, and finally in 1995, the Korean Good Clinical Practice was enacted in which clinical trials should abide by the IRB regulations. While these series of events developed in relation with human research, many well recognized medical institutions in Korea perceived quickly the importance of ethical issues of human experimentation, began to form and actively run IRBs since the late 1980s. Many medical institutes have not formed their own IRB, and even if they have, they are at the stages of growing experiences. Overall, the IRB activities in this country are still in the early stages. In 2002, the Korean Academy of Medical Sciences accepted the Korean Association of Institutional Review Boards as a sister organization to promote its activities.

In the survey report of this issue on the operational problems of IRBs in Korea, it was found that the most serious one is the scope of the review. Not all human related researches are reviewed by IRBs. Also, there are many issues related with the independence and the transparency of the activities. Considering the recent volume of biomedical research in Korea, the academic research protocols reported as being reviewed by this survey seems not to be on a level with the scope of review intended by the Declaration of Helsinki. As the protection of research participants in biomedical research has become a global issue, the medical researchers are requested to abide by international standards of research practice more rigorously. Therefore, it is further required in practice that the research protocols should be approved at their births by the designated IRBs, and the editors of medical journals request authors to explicitly state that their study was reviewed by an ethics committee at the time when the paper is submitted.

The Editor