BRIEF INTRODUCTION of Joint institutional review board (JIRB) in Taiwan

To ensure the independent operation of institutional review boards (IRBs) and to provide an efficient and high-quality IRB review service for clinical trials in Taiwan, a joint IRB (JIRB) was established in 1997. With the endorsement of the government, the original founder members of JIRB come from the major medical centers in Taiwan. Since then, the approval letters of the JIRB have been honored by more than 40 local hospital IRBs in Taiwan. The JIRB received 79 proposals for review in 2010, 51 protocols in 2011, and 29 protocols in 2012. Of the 159 proposals reviewed by the JIRB between 2010 and 2012, 91 (57%) were for phase 2 clinical trials and 17 (11%) were for phase 3 trials. Most (76%) proposals passed after the first meeting with minor amendments. The quality and efficacy of the review are maintained in the JIRB.

The JIRB administrative quality has been recognized by international quality assurance organizations. The JIRB was assessed by the Energy & Environment Accredited Quality Assessment organization and has met the quality assurance requirement of ISO 9001: 2000 since 2002. The JIRB mechanism can assure the quality of the study protocol, enhance human subject protection in Taiwan, and also increase the attraction of Taiwan to multi-center trials, even United States' IND and pre-New Drug Application (NDA) trials.

In December, 2011, the law of human subjects research act was issued, which cover almost all kinds of the human studies in Taiwan. Since then, the JIRB receives more and more research projects initiated by the principle investigators for the academic and/or for the market purposes. Considering the rapid growth of clinical trials as well as human researches and the researchers in Taiwan, the JIRB also provides serial more advanced teaching and training courses for all the potential investigators as well as to the publics. Given the large and increasing amounts of clinical drug trials and the encouragement of hospital IRBs by the government, a central IRB was organized by a group of the medical centers in July, 2013, which review only the drug company-sponsored multicenter clinical trials in these hospitals. Today, the JIRB reviews whole scope and diverse research projects from the drug companies, biotechnology companies, medical organizations, universities, and individual researchers, etc. In such case, the JIRB is the only independent IRB that is able to review all kinds of clinical trials and human studies in Taiwan.

INTRODUCTION of Joint institutional review board (JIRB) in Taiwan

■ Background

To ensure the protection of human subjects in biomedical research studies, study protocols must be reviewed and approved by an IRB before patient recruitment. The appropriate and independent operation of IRB is a critical issue for effective protection of human subjects in research. The World Health Organization (WHO) is involved in many ways in supporting improved ethical standards and review processes for research with human subjects. Several WHO departments have undertaken training programs for researchers and/ or IRB members and have supported other capacity-building activities at the local, regional, and international levels. WHO has developed guidance documents in this field, alone in cooperation with other groups, particularly with the Council for International Organizations Medical Sciences (CIOMS). However, the implementation of these IRB operation guidelines is not yet well recognized in many countries. A trial model for an IRB will be very helpful to foster improved understanding and implementation of ethical review of biomedical research studies in Taiwan.

The international Conference on Harmonization (ICH) has ushered in the concept of global research and development and marketing for multinational pharmaceutical companies. As suggested by the ICH E5 candidates other than Caucasians may be enrolled in the early phase clinical trials. Given the ethnic linkage with China, qualified investigators, and adequate coverage of national health insurance, Taiwan was recently selected as a site in several pre-NDA multi-center clinical trials.

However, in approving the protocols of these multi-center clinical trials, many difficulties were encountered. Every local IRB has its own format of application forms, review processes, meeting schedules, and worst of all, different opinions on modifying the protocol/ informed consent. The repeated approval process for multi-center trials by different local IRBs might give the redundant review that does not improve the quality of trials. It was soon appreciated that one or a few jointed IRB review mechanisms may be required for the efficient, high-quality IRB review for multi-center trials, which could not only assure the universal protection of patients but also facilitate the timely processing of Pre-NDA clinical trials in Taiwan.

■ The Concept of The JIRB

The JIRB was officially inaugurated on March 4, 1997 but the concept of a JIRB has been evolving since 1996. Although Taiwan’s Department of Health provided grant

funds to establish the JIRB, the goal is for the JIRB to be a financially self-sustained nonprofit committee to maintain its autonomy and to avoid conflict of interest. The status of the JIRB is the same as local IRBs from the perspective of Department of Health. Since the JIRB is not associated with any particular medical institute, its approval of protocol should be adapted and/or recognized by local IRBs before the trial may be started in the related hospitals. Hospital IRBs reserved the right to review the proposals that have already been approved by the JIRB.

The JIRB was originally designed to accept mainly statistically sound pre-NDA trials. While these trials represent only 20% of all the registration trials, they are the trials that need the JIRB most. However, there are increasing investigator-initiated studies and collaborative multi-center studies due to the academic indication as well as the requirement of public and/or private funding agency in these years. Without the full supports of commercial companies, the protocol of these studies should be more carefully prepared and reviewed to assure the quality of study and patient/subject protection. By focusing on reviewing these multicenter trials, the objectives of the JIRB can be achieved with limited resources. Sponsors and the investigators can choose to use the JIRB or a local IRB to review their protocols. The JIRB guarantees monthly conferences, rapid review (the turnaround time for reviewers is three days), a high-quality review process, a rapid administrative process, and two-way face-to-face communication and consultation with the investigators via secretariats (JIRB members with a background in clinical pharmacology and biostatistics) to facilitate the review process. Protocols approved by the JIRB would be reviewed in a priority process by Department of health to further speed the process.

■ The Operation of The JIRB

In the beginning, the local IRBs at Taiwan's top five medical centers nominated members of the JIRB in accordance with the spirit of ICH's and Taiwan's Good Clinical Practice guidance. The JIRB now has two different boards with board members from more than 15 medical centers and universities in Taiwan. Each board meets monthly with the members including both medical and nonmedical professionals (lawyers, social workers, clergymen and statisticians). There are more than 80 scientific experts, who are also recommended by local IRBs, serving as the scientific reviewers for the JIRB.

Proposals submitted to JIRB are reviewed by both scientific and nonscientific peer experts. The principal investigator and the sponsor will have a face-to-face consultation if indicated, which is very helpful for the principal investigator and the sponsor and enable them to respond to the expert's points. The expert's opinions

and their responses will be discussed at the JIRB's monthly conference. The principal investigator and sponsor usually received the decision letter within a week of the meeting.

■ The status of The Joint IRB

In December, 2011, the law of Human Subjects Research Act was issued, which cover almost all kinds of the human studies in Taiwan. Since then, the JIRB receives more and more research projects initiated by the principle investigators for the academic and/or for the market purposes. Considering the rapid growth of clinical trials as well as human researches and the researchers in Taiwan, the JIRB also provides serial more advanced teaching and training courses for all the potential investigators as well as to the publics. Given the large and increasing amounts of clinical drug trials and the encouragement of hospital IRBs by the government, a central IRB was organized by a group of the medical centers in July, 2013, which review only the drug company-sponsored multicenter clinical trials in these hospitals. Today, the JIRB reviews whole scope and diverse clinical trials and research projects from the drug companies, biotechnology companies, medical organizations, universities, and individual researchers, etc. In such case, the JIRB is the only independent IRB that is able to review all kinds of clinical trials and human studies in Taiwan.

(Updated March, 2019)