Good Clinical Practice and Ethics in Biomedical Research

From November 25 to 27, DTU teamed up with the Agency of Science, Technology, and Training (Ministry of Health) to organize the training course on Good Clinical Practice (GCP) and Ethics in Biomedical Research. With its high-quality lessons from lecturers, scientists, and leaders of the MOH Agency of Science, Technology, and Training, of hospitals, and of universities specialized in biomedical training and research, the course brought the lecturers and research staff of DTU some essential knowledge on good clinical practice and on ethics in biomedical research, paving the way for the establishment of an Ethical Council for Biomedical Research at DTU.

Prof. Dr. Pham Thi Minh Duc, former Hanoi Medical University Vice Provost, explaining some ethical questions in biomedical research

"In 2009, DTU officially opened enrollment for its first course in Nursing," explained Assoc.Prof. Dr. Nguyen Ngoc Minh, DTU Vice Provost, in his opening speech at the course, *"and to date, we have opened enrollment for several more majors in the health sciences including a Bachelor in Pharmacy and General Practitioner. To improve its education, DTU has collaborated with several famous universities abroad, with universities of Medicine, Pharmacy, and Nursing nationwide, and also with 18 large and small hospitals where its students can train with prestigious doctors and get clinical practice with patients. With the organization of today's training course, DTU wishes to help its staff and lecturers to firmly grasp the knowledge and rules of professional ethics, to implement their research efficiently. In particular, the teachers will, right when they are teaching, impart the DTU students of Medicine, Pharmacy, and Nursing with the spirit of the Hippocratic Oath, the oath of medical ethics."*

DTU staff and lecturers take part in the training course

The training course on GCP and Ethics in Biomedical Research was divided into two courses. The first one was about Good Clinical Practice, aiming to instill students with knowledge on designing and implementing research on people (clinical research). The knowledge acquired during the course will help the learners reduce their shortcomings and the number of ethical issues in research they might encounter, and avoid violating people's rights and protect the interests of the patients and of the people participating in the research. In addition, the course also equips the learners with knowledge on: Ethical foundations in biomedical research; Source materials, essential documentation, product files; Overview of clinical experimental research; and so on. The teachers presented many real and vivid situations to help the learners rapidly approach the issues and profoundly understand the lessons through debate. At the closure of the course, all learners were to take a test with over fifty multiple-choice questions, and only those with more than 70% correct answers were awarded the GCP certificate. This certificate is a prerequisite to establish the Ethical Council in Biomedical Research. (All members of such a council must have the GCP certificate.)

The next course consisted of lectures related to the Ethical Council in Biomedical Research. The teachers of the course taught the learners crucial knowledge on the responsibilities, role, tasks, and legal bases of the establishment and of the operations, evaluations, and dossier management of an Ethical Council in Biomedical Research.

During the lessons, real situations were scrutinized, and students were to read a research proposal and give their opinions on feedback cards for the members of the Ethical Council. Although it was the first time they followed this course and its review format was completely new, the learners all mastered the knowledge and procedures to formulate accurate opinions and to clearly raise issues related to the interests of and dangers to the objectives participating in the research. This is an issue that is almost never

considered seriously at all in the approval procedures of scientific boards when routinely evaluating proposals. The learners were additionally equipped with a lot of knowledge regarding the design of written consent for research participants, the evaluation of dangers and of seriously adverse events, and how to formulate Standard Operating Procedures (SOPs).

The course was a success and the teachers were glad to have provided its contents fully and correctly and to have reached the objectives of the course. The participating learners were also very enthusiastic, as they could focus their research design more on the ethical aspects of scientific research from now on. This course is to pave the way for the establishment of a DTU Ethical Board in the near future. The representative leaders of the Agency of Science, Technology, and Training of the Ministry of Health consider DTU to be one of the first schools to really appreciate this issue, and these will be fundamental issues during integration and development.

(Media Center)