Cite as: 10 TECH. L. REV., June 2013, at 61.

Medical Research and Personal-data Protection —Take Japanese Epidemiology Research as the Basis

Chen-Mei Fan Chiang

Abstract

Medical progress is based on research that ultimately must include studies involving human subjects. For medical research using identifiable human material or data, it is the duty of physicians who participate in medical research to protect life, health, right to self-determination, privacy, and confidentiality of personal information of research subjects.

This article provides an overview of ethical principles for epidemiology research which enacted by Japan in 2008. The ethical principles set forth three important subjects, the first how to get the informed consent from potential research subject, the second is the construct, function and duty of research ethical Committee, and the third protect personal information of research subjects. In Accordance with this ethical principles, the individual research subject should be provided appropriate access to participation in research, can constitute an adequate regulatory

---

[*] Associate Professor, the College of Law Tunghai University; Ph. D. of Law, Tokai University Japan.

framework for protection in epidemiology research.

On the other hand, Taiwan have, in the past enacted Human Research Act, Human Biobank Management Act, Medical Care Act, in order to regulate medical research and protect research subjects. Yet the scope of the existing regulations are restricted and there is considerable confusion about how the rules would be applied, they are insufficient to personal-data protection. Therefore to study ethical principles for epidemiology about Japan, we believe that can get some available reference to engage in constructive debate on the issue about personal information protection of research subjects.

Keywords: Medical Research, Ethical Principles for Epidemiology Research, Ethical Committee, Informed Consent, Human Material or Data Ethical Principle Personal-Data Protection