

## Letter to the Editor: The challenges of medical ethics educators at a research university

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As medical ethics educators at a research facility, we are in charge of ethics reviews and research misconduct prevention education and come in contact with many researchers. In this letter to the Editor, we would like to briefly discuss conflicts of interest and ethics education concerning research activities in present Japan. First, we are critical of the assumption that a researcher's conflicts of interest can be well managed through the current self-reporting system. Self-declaration of the researcher's conflict of interest to one's institution, academic society, and journal is expected to prevent one from both interpreting and presenting study results in a biased manner according to self-interest. However, we feel that undesirable influences of researchers' conflicts of interest are likely never going to be eliminated at the basic level. This is because self-advancement, self-actualization, self-preservation, and family life of researchers all depend on the amount of research funds they have obtained and the number of papers they publish. Regardless of self-declaration, substantial conflicts between fundamental self-interests and public and professional interests never dissolve.

Second, ethics education for researchers is not likely to be effective enough to prevent research misconduct. In Japan, the Ethical Guidelines for Medical and Health Research Involving Human Subjects (December, 2014) state that the chief executive of the research implementing entity as well as investigators shall receive education and training on the ethics of research and on knowledge and skills necessary to carry out the research prior to its implementation and that they shall also receive education and training during the research period on a regular basis as necessary. At Japanese research institutions, one cannot receive an ethics review of a research proposal without undergoing research ethics education. A "certificate" of having received the education is necessary. Nowadays, many researchers do not participate in the education to learn about ethics, but rather to obtain proof that they attended the classes. There is a feeling that they are undergoing education merely to expedite the process of ethics review. In other words, they are akin to students who show up to class merely for attendance purposes.

Current research misconduct prevention policies in Japan could be summarized as "plowing the field and forgetting the seeds." Many researchers adopt the "shortest distance principle," making it their motto to achieve maximal results with the least amount of time

and effort. There is no room to consider ethics with such a mindset. We ourselves have no bright ideas for planting the seeds of ethics in people's minds, and welcome any suggestions from the readers.

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## Informed Consent: Substantive v. Formalistic Approach and the Law

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### Abstract

The rule of informed consent is universally regarded as a cornerstone in governing patient-physician relationships. The key element of "informed" stresses that only the consent given after consideration of sufficient information constitutes valid consent. However, various studies in many countries have shown inadequate information can often take place resulting in lack of understanding of medical procedures. What role does the legal system play in promoting substantive informing and respecting the will of the patients? And how does it realize the true idea of informed consent?

Taking Taiwan as an example, this paper reveals the dynamic and interactive relationships between law and practices on this issue. First, the law may incorporate the idea of informed consent into specific mandates to prompt its implementation. Second, however, the need of evidence in court may sustain or even reinforce undesirable formalistic practices that largely focus on written consent forms rather than substantive explanation. Third, to respond to these formalistic practices, courts could reconstruct the shape of the legal requirement and guide institutions and physicians to the new direction. The assertion of this paper is that formalistic practices are inconsistent with the legal nature of informed consent, regardless of whether they appear to have complied with the law or not. If courts can acknowledge the problem of formalism and are willing to actively investigate or request institutions for alternative evidence to determine whether a meaningful dialogue existed or not, the practices may be directed further towards fulfilling the spirit of informing.

### Introduction

The rule of informed consent is universally regarded as a cornerstone in governing patient-physician relationships. The key element of "informed" stresses that only the consent given after consideration of sufficient information constitutes valid consent. It follows that the purpose of requiring physicians to provide this information is so as to allow patients to gain sufficient enough understanding to

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