Preface

The Difficulties of Anonymization

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We are all delighted to see the third issue of the English-language Toho Journal of Medicine, which is, from this year, separate from the Japanese-language journal. This auspicious event is the result of substantial efforts by the editorial board, production manager, and all the other staff. An important section in our journal is Clinical Observation Studies, which require declarations regarding the use of appropriate ethical procedures, especially the protection of the privacy of human subjects. Such ethical concerns are now well understood by our researchers and becoming firmly established at our center. I would like to take this opportunity to discuss ethical issues regarding the conduct of clinical observation studies, particularly the use of human biological material.

The importance of ethical norms in biomedical science has long been understood. A number of organizations in Japan have proposed ethical recommendations or guidelines, and those of us involved in journal editing cannot overlook the problem of research misconduct. Japanese guidelines recognize three main forms of misconduct: data fabrication, falsification, and plagiarism. To supervise the integrity of research, journal editors must depend on the willingness of reviewers to carefully review submissions, as editors have no surefire way to expose misconduct before publication. Most researchers understand that ethical guidelines do not provide easy answers. Nevertheless, it is essential to continue our involvement with biomedical ethics. In addition, protection of the rights of research participants is essential in any model of clinical research. The 2013 Declaration of Helsinki strongly emphasized the need to protect all vulnerable groups and individuals and the importance of informed consent procedures.

It could be one of the typical process of comprehensive consent that Opt-out process usually applied in case of autopsy examination.

Our center has conducted more than 9200 autopsies since 1927, and tissues have been preserved in paraffin blocks since 1936 (Fig. 1). The oldest recorded autopsy was that of a teenage girl with hyperthyroidism who developed fatal pneumocystis pneumonia. Consider her parents, who accepted the request for an autopsy as part of university education and research. Informed consent was likely explained before the examination, which at that time comprised only gross examination and light microscopic observation. More than 50 years ago, there would have been no discussion of techniques such as gene analysis. However, today we are able to conduct such analyses of formalin-fixed and paraffin-embedded tissues and microbial pathogens. Thus, we have a dilemma regarding how to protect the privacy of individuals who donated human biological

Fig. 1 Photographs of the record book and oldest tissue blocks at Toho University. The blocks of formalin-fixed and paraffin-embedded tissues are wrapped with oil paper.

materials for biomedical research, because genome-wide analysis, especially when exhaustive, allows us to identify individuals, even those who thought they were providing anonymous donations of biological materials.

Russ Altman and colleagues framed the dilemma facing genomic researchers and privacy advocates. They estimated that examining as few as 75 statistically independent single-nucleotide polymorphisms (SNPs) would yield a small group that contained the individual contributing the DNA. Put simply, the more SNPs examined, the more easily a person can be identified and, therefore, the less privacy protection that can be expected. A diagrammatic representation of their proposal, known as Altman's Curve, is available online (www.sciencemag.org/cgi/content/full/305/5681/183/DC1).

I believe that our journal will soon be registered in PubMed. I would like to offer my gratitude to the editor-in-chief and editorial board for a job well done. It is a great honor to be asked to present this short essay for the third issue of the Toho Journal of Medicine.