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Chiaki Sato

Visiting Associate Professor, Meiji Institute for Global Affairs, Meiji University

Short Curriculum Vitae - Chiaki Sato
Associate Professor, Faculty of Law, Aoyama Gakuin University
Project Associate Professor, Graduate School of Public Policy, The University of Tokyo
Special competence in the area of legal policy in medical field; research of trust legislation as a related domain. Received a Master of Laws (LL.M.) degree at the University of Washington School of Law in 2008, and Doctor of Philosophy Law at the University of Tokyo in 2010. Service as Project Researcher at the University of Tokyo Graduate School for Law and Politics from April to August 2009, and as Assistant Professor at the University of Tokyo since September 2009 and as Associate Professor at the Aoyama Gakuin University Faculty of Law since April 2015. Also served as Visiting Scholar at the Center for Health Policy, Economic Studies Program, The Brookings Institution, from August 2012 to 2016. Author of *"U.S. Product Liability Law"* (published by Koubundou Publishers Inc. in 2011), and major papers appearing in publications such as PLOS Medicine.

Toward the Use of Personal Information in the Medical Field

In Japan, the full effectuation of the Amended Act on the Protection of Personal Information (hereinafter referred to as the "Amended Act") is raising the possibility of a rapid increase in utilization of personal information and the like in the medical field. In the medical field, both the protection and the utility of personal information are extremely important in the clinical medicine and research scenes and detailed discussions have consequently continued on this subject. The Amended Act, whose

passage was based on the results of past discussions, could exert an immense influence on actual practice.

The Amended Act was passed on September 3, 2015 and promulgated on September 9 of the same year. A cabinet decision made on December 20, 2016 set the date for full effectuation of the Amended Act as May 30, 2017. Once the Amended Act is fully effected, a new concept of "special care-required personal information," which has been completely absent from past legislation, will begin to be applied. What kind of changes will emerge in the medical field due to the appearance of this new concept?

The unique nature of personal information in the medical field

In the medical field, the issue is not simply a matter of making provisions for the protection of personal information. This is because use of personal information is indispensable for preserving and improving the balance of access, cost, and quality in medical services. The question is the advisable approach to use of sensitive personal information, and more specifically, the nature of procedures for its provision to third parties.

Under the Amended Act, several categories could be applied for personal information in the medical field as well. At the very least, a distinction can be drawn between information that corresponds to special care-required personal information and information that does not.

According to the Amended Act, personal information is essentially information about living individuals and is a personal identification code or information that enables identification of the particular individual through any and all matters. Although I will not go into the details of personal identification codes, they are essentially base sequences that comprise the dioxyribonucleic acid (DNA) extracted from cells. They include items that meet the standards established by the rules of the Personal Information Protection Commission as being sufficient for identification of a particular individual.

Special care-required personal information is a concept that will have an extremely

significant impact in the context of the Amended Act. Special care-required personal information is defined as “personal information comprising a principal's race, creed, social status, medical history, criminal record, fact of having suffered damage by a crime, or other descriptions etc. prescribed by cabinet order as those of which the handling requires special care so as not to cause unfair discrimination, prejudice or other disadvantages to the principal.” It is excluded from the scope of third-party provision (Article 23, Paragraph 2 of the Amended Act) through opting-out. In other words, the provision of special care-required personal information that includes items such as medical history is restricted. As a general rule, such information cannot be provided to a third party without the consent of the principal. Exceptions are made for third-party provision without consent from the principal in the following cases: 1) cases based on laws and regulations; 2) cases in which there is a need to protect a human life, body or fortune, and when it is difficult to obtain a principal's consent; 3) cases in which there is a special need to enhance public hygiene or promote fostering healthy children, and when it is difficult to obtain a principal's consent; and 4) cases in which there is a need to cooperate in regard to a central government organization or a local government, or a person entrusted by them performing affairs prescribed by laws and regulations, and when there is a possibility that obtaining a principal's consent would interfere with the performance of the said affairs.

To go into a little more detail, it must be admitted that the Amended Act leaves some margin for provision to a person other than the principal even in the case of special care-required personal information including medical history. Specifically, it allows for provision to third parties in the cases of entrustment, business succession, and joint utilization stipulated in the items of Article 23, Paragraph 5 (see also Article 7, Item 2 of the Order for Enforcement of the Act on the Protection of Personal Information (Cabinet Order 507 of 2003)). However, in the case of entrustment, the Amended Act only permits parties to entrust the handling of personal data, in whole or in part, solely within the scope required for achieving the purpose of use (for which consent has already been obtained). Similarly, the exception for joint utilization is limited to cases in which the personal data utilized jointly with a specific party are provided to that party, and advance notification is made to the principal of this as well as of the items of personal data involved in the joint utilization, the scope of the joint users, the purpose(s) of the

joint utilization, and the name of the individual or organization responsible for managing the personal data, or if there are arrangements in place making this information readily accessible to the principal. At medical service sites, it may not always be easy to make all of this information clear in advance.

Until now, there was no category of special care-required personal information in the class of personal information. In the medical field, all types of personal information have been handled as subjects of third-party provision through opting out. The Amended Act, however, is clearly a departure from the former stance, and even a search of the Diet Record reveals no mention to the effect that the medical field is to receive special treatment. At best, there is only a statement to the effect that the Personal Information Protection Commission must solidly coordinate its activities with the Ministry of Health, Labour and Welfare (MHLW) to prevent confusion at epidemiological research and clinical sites.

The real intention of the new guidance

In the handling of third-party provision of special care-required personal information, it goes without saying that it is important to set forth the proviso "when it is difficult to obtain a principal's consent" in more specific terms. The more appropriate approach, however, may lie in considering what can be done so that the principle will be deemed to have given his or her consent to third-party provision.

Page 14 of the Guidance for Appropriate Handling of Personal Information by Medical- and Nursing-Related Business Entities (notification on April 14, 2017 and application beginning on May 30 of the same year), issued jointly by Personal Information Protection Commission and the MHLW, contains some highly interesting statements. In short, while the new guidance has mutually different descriptions for medical institutions and medical/nursing-related business entities, it can be seen that it ascertains the concept of consent in broader terms than was the case previously.

"Medical institutions etc. shall clearly post, in advance and within their facilities (internal posting), the scope of use of personal information thought to

be ordinarily necessary in that medical institution for the purpose of providing appropriate medical services to patients. If the patient does not express any particular, clear opposition or reservation about this use, it may be assumed that he or she has given his or her consent to the use of personal information, within the scope posted."

"If medical- and nursing-related business entities properly obtain special care-required personal information from the principal directly, in writing, orally, or by other such means, it may be deemed, from the fact of provision of said information by the principal, that these entities have obtained the principal's consent to the acquisition of said information."

Because the Amended Act does not contain any provisions defining consent, it definitely leaves some margin allowing handling as acquisition of the principal's consent even without expression orally or in writing, or, to go even further, without any clear indication of intention by the principal. For example, the General Rules section in the Guideline for the Act on the Protection of Personal Information describes acquisition of consent as recognition by the business entity handling personal information of an indication of the principal's intention to give his or her agreement. It adds that this acquisition must be based on both rational and appropriate methods thought to be necessary for the person to make a decision on consent, in accordance with the nature of the business and the state of personal information handling.

As for both rational and appropriate methods for acquiring the principal's consent (i.e., indication of intention to give agreement) with full consideration of the unique nature of personal information in the medical field, the spirit of the Amended Act, which newly incorporates the concept of special care-required personal information, will probably be gradually reflected with the passage of time. In other words, as sensitive information is clearly excluded from the scope of third-party provision through opting out (in Article 23, Paragraph 2 of the Amended Act), it will presumably become important to devise some type of additional measures of a more opt-in character, to join those of conventional opting out. Unfortunately, the authorities are unlikely to adopt a

legal interpretation that would permit acquisition of the person's consent through exactly the same procedure as applied for third-party provision through opting out, which has conventionally been practiced in actual work.

Approaches to ensuring effectively the same level of protection as in Europe

The medical field is, of course, only one field, but the degree of protection in it could nevertheless become a major problem in the event of attempts to have personal information transferred between Japan and Europe. The Amended Act initially advocated fully adequate protection on par with that in Europe for personal information in order to permit the conclusion of agreements to make personal information transferrable with Europe. Besides the achievement of both appropriate and adequate protection, searches should presumably be made for legal interpretations and practices to prevent detraction from utility.

Endless efforts for further use of personal information

The full effectuation of the Amended Act does not mean that the legislative system for medical information is now complete. It, too, is just another step forward in gradual progress. Even after we have finished taking measures for conformance with the full effectuation, there is no need to stop discussing use of personal information in the medical field. On the contrary, I believe it will become even more necessary. While enforcement to halt illegal use of personal information might begin before discussion on its expanded use, in anticipation of the expansion of use, the topic of discussion could become how to enforce the regulations without daunting personnel at medical sites. I earnestly hope that, in Japan as well, continued discussion aimed at further use of personal information, ultimately to the benefit of actual and latent patients, will in the end lead to improvement of medical safety, quality, and efficiency.