

Human Genome Center

Department of Public Policy

公共政策研究分野

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The Department of Public Policy contributes to accomplishment of the following major missions: research ethics consultation to help scientists to comply with ethical guidelines and build public trust; public policy science studies of translational research and its societal impact; and promotion of patient and public involvement/engagement in research and health care. Through qualitative and quantitative social science studies and policy analysis, we facilitate discussion of the challenges posed by the advances in medical science.

1. Public attitudes toward cloud computing and willingness to share personal health records (PHRs) and genome data for health care research in Japan.

Japan's government aims to promote the linkage of medical records, including medical genomic testing data and personal health records (PHRs), via cloud computing (the cloud). However, linking national medical records and using them for health care research can be controversial. Additionally, many ethical issues with using cloud networks with health care and genome data have been noted. However, no research has yet explored the Japanese public's opinions about their PHRs, including genome data, being shared for health care research or the use of the cloud for storing and analyzing such data. Therefore, we conducted a survey in March 2021 to clarify the public's attitudes toward sharing their PHRs, including genome data and using the cloud for health care research. We analyzed data to experimentally create digital health basic literacy scores (BLSs). Our results showed that the Japanese public had concerns about data sharing that overlapped with structural cloud computing issues. The effect of incentives on changes in participants' willingness to share data (WTSD) was limited. Instead, there could be a correlation between WTSD and BLSs. Finally, we argue that it is vital to

consider not only researchers but also research participants as value cocreators in health care research conducted through the cloud to overcome both parties' vulnerability.

2. Is legislation to prevent genetic discrimination necessary in Japan? An overview of the current policies and public attitudes

Genetic discrimination (GD) has not been discussed in East Asia as extensively as in Europe and North America. Influenced by UNESCO's universal declaration in 1997, the Japanese government took a stringent approach toward GD by releasing the Basic Principles on Human Genome Research in 2000. However, Japanese society has mostly been ignoring the prevention of GD for decades, and the principle of prohibiting GD was never adhered to in any of the Japanese laws. We conducted anonymous surveys among the general adult population in 2017 and 2022 to explore their experiences of GD and attitudes toward laws carrying penalties to prevent GD in Japan. In both years, approximately 3% of the respondents had experienced some unfavorable treatment regarding their genetic information. They showed higher recognition of the benefits of using genetic information and lower recognition of concerns about using genetic information and GD in 2022 than in 2017.

However, the awareness regarding the need for legislation with penalties on GD had increased over the five-year period. In 2022, the framework of a bill to promote genomic medicine and prevent GD without any relevant penalties was released by the Bipartisan Diet Members Caucus. Considering that the absence of regulations may be a barrier to obtaining genomic medicine, as the initial step toward making the prohibition of GD more effective, legislation that no form of GD will be tolerated may stimulate education and awareness regarding respect for the human genome and its diversity.

3. Hope for the best, but prepare for the worst: Social media posted by participants in stem cell clinical trials

This article examines the influence of social media posts on clinical trials involving stem cell-based interventions. Based on the literature review, we identified three potential risks associated with social media posts regarding clinical trials that involve stem cell-based interventions: (1) threats to scientific validity, (2) amplification of excessive expectations, and (3) breaches of confidentiality. Additionally, preliminary recommendations are provided to safeguard the value of stem cell clinical trials for future patients in the age of social media. Our approach aims to safeguard the well-being of forthcoming participants and ensure the scientific validity of stem cell research, as well as possibly aid in the further development of shared guidelines for posting stem cell clinical trial information on social media platforms..

4. Attitudes towards human fetal tissue research: Survey of researchers and the public in Japan

The rules for human fetal tissue (HFT) research in Japan are unclear. We conducted a web survey to examine the attitudes of Japanese researchers (n=535) and the public (n=3,000) toward HFT research. The results demonstrated that 5.8% of researchers and 18.8% of the public explicitly opposed HFT research, and 71.8% of the researchers thought that the rules for HFT research need to be clarified. Even among researchers who intended to consider conducting HFT research, 74.2% responded that the rules should be clarified. Although different from attitudes to make decisions regarding HFT donation, being non-religious and in their reproductive age among women in the public group were factors for accepting attitudes toward HFT research. To establish the rules, it is necessary to develop a system that can adequately protect vulnerable women who are asked to provide HFT.

5. Survey of Japanese researchers and the public regarding the culture of human embryos in vitro beyond 14 days

The International Society for Stem Cell Research (ISSCR) has eliminated its prohibition on research in-

volving the culturing of human embryos beyond 14 days within the updated 2021 guidelines. We conducted a survey of Japanese researchers working in stem cell- or embryo-related research (n = 535) and the public (n=3,000) about their attitudes toward the 14-day rule. Among the researchers, 46.2% agreed that embryos could be cultured beyond 14 days, a result that was slightly lower among the public (37.9%). Among those that disagreed with embryo culturing beyond 14 days, 9.5% of researchers and 5.1% of the public agreed with culturing embryos within 14 days. Among the public, higher comprehension levels correlated with both agreement and disagreement with the culture of embryos beyond 14 days compared with "cannot judge." Further research and public discourse are necessary in order to better understand the factors informing participant decisions regarding the 14-day rule.

6. Current situation of the hospitalization of persons without family in Japan and related medical challenges

This study aims to determine the approximate number of hospitalizations of persons without family and the medical challenges they encounter in hospitals across Japan. Self-administered questionnaires were mailed to 4,000 randomly selected hospitals nationwide to investigate the actual conditions and problems, decision-making processes, and use of the government-recommended Guidelines for the hospitalization of, and decision-making support for, persons without family. To identify the characteristics of each region and role of hospitals, chi-square tests were used to make separate group comparisons by hospital location and type. Responses were received from 1,271 hospitals (31.2% response rate), of which 952 hospitals provided information regarding the number of admissions of persons without family. The mean (SD) and median number of hospitalizations (approximate number per year) of patients without family was 16 (79) and 5, respectively. Approximately 70% of the target hospitals had experienced the hospitalization of a person without family, and 30% of the hospitals did not. The most common difficulties encountered during the hospitalization were collecting emergency contact information, decision-making related to medical care, and discharge support. In the absence of family members and surrogates, the medical team undertook the decision-making process, which was commonly performed according to manuals and guidelines and by consulting an ethics committee. Regarding the use of the government-recommended Guidelines, approximately 70% of the hospitals that were aware of these Guidelines responded that they had never taken any action based on these Guidelines, with significant differences by region and hospital type. To solve the problems related to the hospitalization of persons without family, the public should be made aware of these Guidelines,

and measures should be undertaken to make clinical ethics consultation a sustainable activity within hospitals.

7. Examination of the concept of FPIC (Free, Prior, and Informed Consent) with reference to the draft Ethical Guidelines for Research on the Ainu People

The Ainu Association of Hokkaido and academic anthropology and archaeology societies are developing “Ethical Guidelines for Research on the Ainu People,” which position free, prior, and informed consent (FPIC) as their basis. This is the first document that Japanese research ethics regulations introduce FPIC. Based on a literature review, this article examines the expectations and unsolved problems of introducing FPIC in Japanese research ethics. As FPIC was originally advocated to protect lands and resources from exploitation, the challenges of adapting FPIC to research ethics are assessed.

The Ainu are the only officially recognized Indigenous people in Japan. However, after a long history of assimilation, the Ainu do not have representative organizations or an identity certification system. Past excavations of Ainu human remains for the purpose

of academic research have been an important topic. The draft guidelines are expected not only to clarify how to handle such human remains but also to cover research about living Ainu people. Against the background of criticism of global genomic projects such as the Human Genome Diversity Project, community engagement is increasingly valued. Therefore, it is appropriate to focus on FPIC, which was advocated to ensure opportunities for Indigenous peoples to be consulted regarding the relevant research project. Canada and Taiwan have governmental structures to ensure such opportunities with guidelines or laws, but some adjustments to their research contexts can be seen. Japanese draft guidelines could also increase opportunities for Ainu people to engage in research projects by introducing FPIC. However, as the draft guidelines are overseen by a limited number of societies, their effectiveness and scope are somewhat limited. To enhance their efficiency, a wider variety of related academic societies should be involved in discussions. Moreover, as the Ainu people have no representative organizations, the problem of how to ensure meaningful consultation is vital. Further evaluation of practices and international comparisons will be required.

Publication list

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