

Advanced Clinical Research Center

Division of Bioethics

生命倫理研究分野

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Medical research has high expectations from society, however, it imposes burdens and risks on subjects. Also, research using advanced medical technology may raise new ethical, legal and social issues (ELSI). For these reasons, certain rules are required for medical research. In our laboratory, we consider what kind of rules are necessary for protecting subjects and responding to the new ELSI.

1. Survey on Public Awareness of Medical Research Terminology and the Accuracy of Physicians' Predictions regarding that Awareness in Japan

Ayako Kamisato, Hong Hyunsoo

One of the ethical principles of medical research involving human subjects is obtaining proper informed consent (IC). However, if the participants' actual awareness of medical research terminology is lower than the researchers' prediction of that awareness, it may cause difficulty obtaining proper IC. Therefore, this study aims to clarify the presence of "perception gaps" and then discuss IC-related issues and measures based on the insights obtained. We conducted two online surveys: a "public survey" to understand the Japanese public's awareness of 11 medical research terms and a "physicians' survey" to investigate physicians' predictions regarding public awareness. In the "public survey," for each term, respondents were instructed to select their situation from "understand," "have heard," or "have never heard." In the "physicians' survey," respondents were asked to estimate the proportions of the general public who would "have understood," "have heard," or "have never heard" by using an 11-step scale. We analyzed separately in two age groups to understand the age-related difference. We received 1002 valid re-

sponses for the "public survey" and 275 for the "physicians' survey." Of the public respondents, more than 80% had never heard of terms such as *interventional study*, *prospective clinical study*, *cohort study*, *Phase I clinical trial*, or *double-blind study*. Concurrently, physicians overestimated general public awareness of the terms *placebo*, *cohort study*, *double-blind study*, and *randomized clinical trial* (in the group of people under 60). The results revealed the perception gap between the general public and physicians which raises serious concerns about obtaining proper IC from clinical research participants.

2. Research on the Japan's clinical research review system

Ayako Kamisato

As of the end of 2023, clinical research is being conducted under four laws, orders based on them, and eight guidelines. All of these laws and guidelines have in common that they require researchers to create a research protocol and get it reviewed by a review body established at the research institution (hereinafter referred to as a local committee). However, on the other hand, there are many differences on the review system between laws and guidelines, such as whether additional review is required by a review body set up by the government or whether there is a

local committee certification system. Therefore, we examined the examination system of all laws and guidelines and considered the issues that emerged from this and the future system design.

3. Ethical support for “The Center of Well-being Regional Society Innovation project.”

Ayako Kamisato, Kazuyo Arisawa, Yoshiko Takahashi

“The Center of Well-being Regional Society Innovation project,” promoted by Hirosaki University (Hirosaki COI-NEXT), is one of the projects of the JST Program on Open Innovation Platform for Industry-Academia Co-Creation. The goal of this project is to build and utilize a big data platform on medical and health. To achieve this goal, one of the wide-ranging efforts of Hirosaki COI-NEXT is the implementation of a large-scale health survey called the “Iwaki Health Checkup Project” (hereinafter referred to as “Iwaki Health Checkup”), targeting residents of the Iwaki district of Hirosaki City. In this checkup, Hirosaki University collaborates with companies and research institutes to collect 2,000 to 3,000 items of health and medical data per person. The aim is to quickly find preventive and therapeutic methods for dementia and lifestyle-related diseases by analyzing such big data from multiple angles. Our laboratory is

in charge of ethical support for the Iwaki health checkup. As part of our support, in 2023, we established an ethics review committee dedicated to this project. We began reviewing it to promote the use of health checkup data for research and development.

4. The REC Education program (RECs) for Research Ethics Committees (REC) members and researchers

Ayako Kamisato, Kazuyo Arisawa, Hong Hyunsoo, Yoshiko Takahashi

We have constructed the REC Education program for Research Ethics Committees (REC) members with support from the Japan Agency for Medical Research and Development (AMED) since FY 2016. So far, we have produced fifteen video programs and released them on our website. Two thousand two hundred fifty-two members and 778 institutions have registered with our program as of 31 May 2022. Also, we have constructed the REC Education program for researchers and produced five video programs with support from the AMED since FY 2019. Currently, we have 2,939 members registered with this program as of 31 May 2022.

In 2023, we revised the video programs following revisions of the “Ethical Guidelines for Medical and Biological Research Involving Human Subjects.”

出版物

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- ・ 神里彩子「第5章 臨床研究の審査体制－現状と今後の在り方」甲斐克則編『臨床研究と医事法 (医事法講座 第13巻)』(信山社、2023年)
- ・ 神里彩子・武藤香織編『医学・生命科学の研究倫理ハンドブック第2版』(東京大学出版会、2023年)
- ・ Hideki Yui, Ayako Kamisato, Kaori Muto, Yoshimi Yashiro, Saori Watanabe, Yukitaka Kiya, Kumiko Fujisawa, Yusuke Inoue, Zentaro Yamagata. Attitudes towards human fetal tissue research: Survey of researchers and the public in Japan. *Regenerative Therapy*, Volume 24, 2023, Pages 78-84, <https://doi.org/10.1016/j.reth.2023.05.007>.
- ・ Kamisato, A., Hong, H. & Okubo, S. Public Awareness

of Medical Research Terminology in Japan, and the Accuracy of Physicians' Predictions regarding that Awareness. *ABR* (2023). <https://doi.org/10.1007/s41649-023-00247-4>

- ・ Iimura, Yohei & Nakazawa, Mitsuko & Tsuru, Yukari & Togashi, Hitomi & Honda, Tomoe & Baba, Keisuke & Ishibashi, Masaaki & Sasuga, Chieko & Furukawa, Naoki & Sato, Tomoko & Matsubara, Yasuo & Kamisato, Ayako & Yoshii, Eiko & Kuroda, Seiichiro & Boku, Narikazu. Evaluation of clinical effects of a multidisciplinary-collaborated cancer support team for gastrointestinal cancer chemotherapy: prospective observational study protocol of M-CAST study. *Research Square*; 2023. DOI: 10.21203/rs.3.rs-2529768/v1.10.21203/rs.3.rs-2529768/v1.
- ・ 神里彩子「生殖技術に関する倫理的・法的・社会的課題 (ELSI) の全体」医事法研究第8号 (甲斐克則責任編集、信山社、2023年12月)