

Advanced Clinical Research Center

Division of Bioethics and Medical Law

生命倫理・医事法研究分野

| Associate Professor Waki Toya, Ph.D.

| 准教授 博士(医学) 遠矢 和 希

Our division took over from the former Division of Bioethics and opened in September 2024. We study ethical, legal, and social issues (ELSI) in cutting-edge medical science research and clinical settings. As experts in research ethics within here IMSUT, we also provide research ethics consultation services to those involved in clinical research who are faced with ethical issues.

1. ELSI on clinical research for fetuses in the womb

Waki Toya

Advances in fetal diagnostic technology have led to the development of treatments for fetuses in the womb to prevent congenital diseases and miscarriages. These are conditions that would traditionally have been treated after birth. Such technologies must be developed carefully as clinical research. However, to date, there has been insufficient discussion, both globally and in Japan, about how to protect subjects in such interventional research on pregnant women and fetuses. Who are the subjects in fetal treatment research? Who bears the risks of the research, and who directly benefits from the research intervention? At the very least, in many cases there is no direct health benefit to the pregnant woman herself. Through discussing and analyzing the ELSIs, we have concluded to take Fetal-Maternal Complex Model, which brings solutions to ELSI One-Patient Model and Two-Patient Model could not solve. Our research group will publish some papers next FY on our Fetal-Maternal Complex Model.

2. ELSI in the areas of infectious disease research

Waki Toya

In collaboration with the Department of Public Policy, we worked on the University of Tokyo Pandemic Preparedness, Infection and Advanced Research Center (UTOPIA) research topic "Overcoming ethical, legal, and social challenges for rapid vaccine development." In this FY, we especially tackled the Legal issues surrounding controlled human infection model (CHIM) trials for vaccine development in Japan. To conduct CHIM trials in Japan, there are some ELSI to consider and we have not been properly ready on legal arrangement. We made the following poster presentation at the conference: W Toya, M Kitao, Y Inoue, K Muto. Legal issues surrounding controlled human infection model (CHIM) trials for vaccine development. The 3rd UTOPIA Symposium VACCINE DEVELOPMENT, Oct. 21-22, 2025 in Tokyo.

3. Future Prospects

Specific themes that we will work on are as follows:

- ELSI and research ethics regarding life through cutting-edge artificial technology (e.g., ectogenesis).
- Research on ELSI and law regarding biobanks and follow-up research
- Research on medical and clinical research from a gender perspective

- Research on ELSI on medical or biological research/ tings
experiment involving human subjects in space set-

Publications

遠矢和希. ヘルシンキ宣言の改訂 (医事法トピックス). 年報 医事法学. 40: 246-250, 2025