

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. Project of research ethics consultant training and educational curriculum

Waki Toya

In a research ethics consultant training project (Principal Investigator: Kenji Matsui in the National Cancer Center Japan) based on the Grant by the Japan Agency for Medical Research and Development (AMED) since FY 2016, we have published a text, held many training sessions, and are in the process of launching an association-certified consultant qualification examination. To raise awareness of research ethics consultation and the role of consultants, we made the following presentation at the conference for Clinical Research Coordinator: Waki Toya, Research Ethics Consultant's Practice. In symposium 15, How can I become a CRC who can also be a research ethics consultant? - From the basics of research ethics consultation to the role of a research ethics consultant -, in the 24th Conference on CRC and Clinical Trials 2024 in Sapporo, on 15th Sep. 2024.

2. ELSI on internal medicine research for fetus 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. Our research group made a presentation from a legal perspective, focusing on internal medicine research for fetus in the womb: Waki Toya, Legal Issues in Internal Medicine Research for Fetus. Symposium on ELSI in Internal Medicine Research for Fetus, Japan Association for Bioethics 36th Annual Meeting in Osaka, on 17th Nov. 2024.

3. Future Prospects

Specific themes that we have worked on are as follows:

- Research on ELSI and legal policies in assisted reproductive technology
- 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

We will also investigate ELSI in the areas of infectious disease research. And a textbook on research ethics for medical students will be published next FY.