



# Uehiro Research Division for iPS Cell Ethics



## 05 Uehiro Research Division for iPS Cell Ethics

Stem cells are a hotly debated ethical topic. This group seeks to build policy that allows scientists to communicate with the public in order to clarify expectation of stem cell applications.



## Probing ethical, legal, and social issues in regenerative medicine

Department head  
—— Misao Fujita MS, MPH, Ph.D.  
Associate Professor



### Members

Yoshimi Yashiro (Associate Professor)	Tsutomu Sawai
Taichi Hatta	Mika Suzuki
Emi Kuwabara	Miki Tanigawa

Fig.1 The Berman Institute of Bioethics at the Johns Hopkins University.



### Misao Fujita

1995 M.S. (Psychology), College of Graduate Studies, Univ. of Idaho (U.S.A.)  
2003 M.P.H., the School of Public Health, Graduate School of Medicine, Kyoto Univ.  
2004 Researcher, Center for Biomedical Ethics and Law, Univ. of Tokyo  
2006 Ph.D., the School of Public Health, Graduate School of Medicine, Kyoto Univ.  
2008 Assistant Professor, Department of Biomedical Ethics, The Graduate School of Medicine, Univ. of Tokyo  
2009 Assistant Professor, Department of Biomedical Ethics, The Graduate School of Medicine, Univ. of Tokyo  
2013 Current position

### Publication Highlights

- (1) Risk of tumorigenesis and patient hope.  
Fujita M *et al. J. AJOB Neurosci.* (2015) 6(1): 69-70
- (2) Throwing the baby out with the bathwater: a critique of Sparrow's inclusive definition of the term 'in vitro eugenics.'  
Fujita M *et al. J Med Ethics.* (2014) 40(11): 735-6
- (3) Handling incidental findings in neuroimaging research in Japan: current state of research facilities and attitudes of investigators and the general population.  
Fujita M, *et al. Health Res Policy Syst.* (2014) 12: 58
- (4) decision-making process for the fate of frozen embryos by Japanese infertile women: a qualitative study.  
Takahashi S, *et al. BMC Med Ethics.* (2012) 13: 9
- (5) Requirements for general consent and their ethical underpinnings: considering the ideal form of general consent.  
Oikawa M, *et al. Seimeirinri.* (2014) 24(1):235-43 (in Japanese)

## Department Overview

### Problems raised in cell therapy implementation

The Regenerative Medicine Safety Law, enacted in 2014, has led to the regulation of for-profit cell therapies in Japan. Our collection and analysis of websites for Japanese clinics that provide for-profit cell therapy has revealed that many declare expertise in regenerative medicine and use of somatic stem cells to treat a wide variety of diseases in a way that violates medical advertising regulations. Whether the new law will remedy these problems requires investigation.

Another issue in cell therapies is "general consent," in which consent is obtained in advance from the provider of specimens regarding the possible use of the samples and corresponding information in future research. Because this system often entails the acquisition of consent without specific explanation of the purpose of such future studies, its ethical appropriateness has long been debated. We have proposed that general consent can be ethically obtained by limiting the purpose of the study, review by an institutional review board, and building a relationship of trust between specimen/information providers and research institutions/researchers.

### Research Ethics Consultation and Research Support

Since 2000, bioethics researchers in the United States have been conducting "research ethics consultation," where they consult re-

searchers in the biological sciences about solutions to ethical issues that arise in the research process. We have been visiting the United States to learn about the roles and division of functions between bioethics researchers and administrative support personnel to improve the structure in Japan (Fig.1).

In order to support research projects at CiRA, we have held four workshops (Fig.2). The objectives of these workshops are: to share 1) ethical, 2) legal, 3) social knowledge and know-how necessary to conduct clinical research, and 4) to contribute to the establishment and reinforcement of research ethics support activities. We also are preparing materials that explain study details when researchers obtain informed consent for their research.

Also, in collaboration with researchers at Kyoto University, we have created a pamphlet, which explains ethical issues and other aspects of stem cell research to promote dialogue between researchers and the general public.



Fig.2 1st workshop for research support staffs.



## Conceptualizing life in modern society ——— Yoshimi Yashiro Ph.D. Associate Professor



Uehiro-Carnegie-Oxford Conference 2014  
Open Symposium.

### Yoshimi Yashiro

- 2009 Ph. D., Medical Science Graduate Program,  
The Univ. of Tokyo/  
Assistant Professor, Center for Integrated  
Medical Research, School of Medicine,  
Keio Univ.
- 2011 Senior Lecturer, Institute of Advanced  
BioMedical Engineering and Science,  
Tokyo Women's Medical Univ.
- 2012 Associate Professor, Center for Integrated  
Medical Research, School of Medicine,  
Keio Univ.
- 2013 Current position



### Publication Highlights

- (1) In Order to Put Artificial Intelligence in "Authenticity."  
Yashiro Y. *Journal of the Japanese Society for Artificial  
Intelligence*. (2014) 29(5): 502-6 (in Japanese)
- (2) Relations with the general public and Stem Cell.  
Yashiro Y. *Research Hormone frontier  
in gynecology*. (2014) 21(2): 53-57 (in Japanese)
- (3) ELSI issues about intractable disease research using  
iPS cells.  
Yashiro Y. *Journal of the Japanese Society for Clinical  
Chemistry*. (2014) 7: 203-210 (in Japanese)

### An understanding of science is necessary to advance regenerative medicine

In order to sustain public support for regenerative medicine, researchers must anticipate the ethical, legal, and social issues (ELSI) that may arise in regenerative medicine and actively provide laymen with opportunities to learn about these issues. ELSI in regenerative medicine raises two problems. The first, as has been indicated in other areas of advanced medicine, is how to protect the rights and physical well-being of patients and subjects. The second is the issue of what constitutes life, which will help evaluate the appropriateness of injecting human pluripotent stem cells into animal embryos to create chimeric embryos and chimeric animals, which is done to research the creation and fertilization of germ cells and create three-dimensional organs. In regard to the second problem, we must construct a foundation of scientific knowledge for the general public.

### Social acceptance of stem cell research

To gain and sustain public support for the research done at CiRA, our laboratory has adopted a two-pronged approach. One prong involves surveying trends by analyzing discourse on regenerative medicine in newspapers and other media, and using questionnaires to recognize gaps in understanding between experts and laymen. The other prong involves evaluating social acceptance of stem cell research through subculture channels that have generally received little attention, such as science fiction, manga, and anime. Whereas science defines the word "chimera" as the formation of an individual organism as a "mosaic," our research indi-

cates that subculture channels imagine "chimera" as an "abominable mixture," which could partially explain the general public's reaction with repulsion towards this word.

In addition to the above ethical research, we are also disseminating information through a wide variety of media in order to create new values and concepts of life in a post-iPS cell society. Also, as a part of the Risk Communication Model Construction Project launched in 2014 by the Japanese Ministry of Education, Culture, Sports, Science, and Technology, we are preparing lectures aimed at the general public to explain the implications of iPS cells. 2014 saw an incidence of fraud in the field of stem cell research, which grabbed the public's attention and more importantly enforced a sense of mistrust. In response to this scandal, we are holding discussions that incorporate findings in stem cell research and stem cell ethics to investigate how public trust can be restored.



Books for the public.

■ Members	Misao Fujita (Professor)	Emi Kuwabara	Miki Tanigawa
	Taichi Hatta	Tsutomu Sawai	
		Mika Suzuki	