Data-based discussion of ethical issues of iPS cell technology

Misao Fujita Ph.D., Associate Professor

Examples of research using animal-human chimeric embryos

Summary

The clinical application of iPS cell technology will be difficult without public understanding and agreement. Accordingly, ethical, legal, and social issues need to be addressed. As a concrete example, we addressed the issue of research using human-animal chimeric embryos.

Research Progress

Questionnaire survey of attitudes to human-animal chimeric embryo research

Research using human-animal chimeric embryos involves injecting human iPS cells into animal embryos with the aim of creating human organs (figure). This research holds promise in organ transplant treatment, but it also has serious ethical concerns. According to ourquestionnaire survey among citizens and researchers, both groups displayed strong resistance to the inclusion of human cells in animal brain, sperm, or eggs, but not in animal heart, liver, blood, or skin. The findings were referred to in discussions on the relaxation of regulations in Japan.

Members

- Jusaku Minari
- (Associate Professor)
- Yoshimi Yashiro
- (Associate Professor)
- Taichi Hatta
- Yuko Kuvama ·Chiqusa Nakagawa •Tsutomu Sawai •Mika Suzuki

- - •Miki Tanigawa

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Embryo consisting of both humar

iPS cells produced

from human cells

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A pig with a pancreas made up of human cells





transplant To study whether the trans-

Publication addressing ethical issues in iPS cell research

We published a Japanese-language book entitled "Where scientific knowledge meets knowledge of humanty-Considering the ethical issues in iPS cell research." Covering the potentially wide impact of iPS cell research, the book aims to transcend barriers between sciences and humanities and inform the public about relevant issues.

Injection

Human iPS cells injected into a modified swine embryo that cannot produce pancreas.

Purpose

To study the growth process and functions of human iPS cells

Production

The embryo is transplanted into the uterus of a pig to produce a pig with a human pancreas.

Purposes

- · To study the process of pancreat-
- To study the development and recovery of pancreatic diseases
- · To develop pharmaceutical agents and treatments
- _ _ _ _ _ _ _ _ _ _ _ _

Transplant

The human pancreas produced in the pig's body is transplanted.

Purposes

- · To supply the pancreas for
- planted pancreas functions appropriately



Profile

- 1992 Graduated from Faculty of Human Sciences, Univ. of Tsukuba
- 2006 Ph.D., Graduate School of Medicine, Kyoto Univ.
- 2008 Research Assistant Professor, Graduate School of Medicine, The Univ. of Tokyo
- 2009 Assistant Professor, Graduate School of Medicine. The Univ. of Tokvo
- 2013 Current Position

Publication Highlights

(1) The Japanese generally accept human-animal chimeric embryo research but are concerned about human cells contributing to brain and gametes Sawai T et al., Stem Cells Translational Medicine (2017),

6 (8): 1749-1750 (2) Public attitudes in Japan towards human-animal

> chimeric embryo research using human iPS cells Sawai T et al, Regenerative Medicine (2017),

- 12 (3): 233-248 (3) 科学知と人文知の接点iPS細胞研究の倫理的課題を
 - 考える-(Where scientific knowledge meets knowledge of humanity-Considering the ethical issues in iPS cell research (Japanese only)) Supervised by Yamanaka S, Edited by Uehiro Research Division for iPS Cell Research (2017), Koubundou Publishers Inc.





iPS Cell Ethics

Working with society to create a new vision of life in the age of regenerative medicine



Profile

- 2003 Graduated from Faculty of Pharmacy, Meijo Univ.
- 2009 Ph.D., Graduate School of Medicine, The Univ. of Tokyo / Assistant Professor, School of Medicine, Keio Univ.
- 2011 Senior Lecturer, Institute of Advanced Biomedical Engineering and Science, Tokyo Women's Medical Univ.
- 2012 Associate Professor, School of Medicine, Keio Univ.
- 2013 Associate Professor, CiRA, Kyoto Univ.
- 2018 Professor, Health Innovation School Installation Preparation. Kanagawa Univ. of Human Services

Publication Highlights

- (1)再生医療報道を考える 手術日の即日報道は必要か? ヒトiPS細胞臨床試験と報道 (Clinical trial and news reports about human iPS cells (Japanese only)) Kaori Muto, Yoshimi Yashiro Journalism (2017), 326: 86-91
- (2) A comparative analysis of attitudes on communication toward stem cell research and regenerative medicine between the public and the scientific community Shineha R et al. Stem Cells Translational Medicine (2018), (2): 251-257
- Science communication in (3)regenerative medicine: Implications for the role of academic society and science policy Shineha R et al. Regenerative Therapy (2017), 7: 89-97

Yoshimi Yashiro Ph.D., Associate Professor

Summary

Regenerative medicine attracts a very high level of public interest and the media. We are conducting media analysis and questionnaire surveys to identify differences in the thinking of the general public and researchers. In parallel, we are creating opportunities for non-specialists to deepen their understanding of regenerative medicine.

Research Progress

For regenerative medicine to progress, an understanding of science is needed

Regenerative medicine is the focus of great public hope, but its application is still in its infancy. Our laboratory surveys the current state of reporting by analyzing regenerative medicine-related coverage in newspapers and other media⁽¹⁾, conducting questionnaire surveys to investigate differences in perceptions between non-specialists and researchers⁽²⁾⁽³⁾, and using subcultural contexts such as science fiction, manga comics, and anime to research the relationship between society and regenerative medicine.

Members

Chigusa Nakagawa

Miki Tanigawa

Differences in the response between the public and researchers to 'What do you want to know?" (for the public) and "What do you want to convey?" (for researchers) (Abstracted and modified from (2)) The Public (n=2137) Researchers (n=947) 76% Risk 53% Anticipated 72% new medical care 60% Cost of care 43% 53% Measures for safetv 47% 47% Responses to medical 25% accidents

To establish "responsible research and innovation"

As part of the Program for Developing Risk Communication Models launched by the Japanese Ministry of Education, Culture, Sports, Science and Technology, we are organizing public lectures to raise the level of public awareness about regenerative medicine.

Meanwhile, in FY 2016, we began research into the costs of regenerative medicine as a contribution to ensuring that its benefits can be enjoyed by a broad section of the population. In this research, we explore the optimal price structure of regenerative medicine products and the role that researchers can play in ensuring its soonest possible application. We also study other financial aspects, beginning from the initial stage of the technology's development.

Jusaku Minari Ph.D., Associate Professor

Summary

We study communication between researchers and the public, the rules and guidelines that govern research, and reactions to the social effects of scientific results, with an emphasis on iPS cell research.

Research Progress

Society and life science research

A key to iPS cell research is public trust. To understand how trust is made and preserved, we are engaged in the "ISLE (Innovation for Science, Life and Ethics) project" adopted by the Japan Science and Technology Agency (JST).

Initiatives under the ISLE project

Under the ISLE project, we are following two lines of research.

First, we are studying potential regulatory frameworks for the promotion of cutting-edge life science research. Here, with reference mainly to government-formulated guidelines, we are investigating guideline formulations, associated issues, and responses to the guidelines. In this examination, we focus mainly on the handling of blood and other samples provided by research participants and the genome data obtained from these samples. In stem cell research, we are working to build a picture of the regulatory environment surrounding clinical applications and biobank operations, especially in Japan and the U.K., which are leading countries in this field.

The other line of research concerns how to communicate with the public. Here, we are engaged in deepening discussions with specialists from a wide range of fields in Japan and overseas on the optimal structure of questionnaire surveys and workshops to extract perceptions and attitudes of the general public. In particular, we are using art and design to engage people with no great interest in life science research.



•Chigusa Nakagawa •Miki Tanigawa



Researchers discussing government-formulated guidelines



Profile

2005	Graduated from Faculty of Environmental
	Engineering, The Univ. of Kitakyushu
2010	Ph.D., Graduate School of Environmental
	Engineering, The Univ. of Kitakyushu /
	Postdoctoral Fellow, Institute for
	Research in Humanities, Kyoto Univ.
2013	Assistant Professor,
	Graduate School of Medicine, Osaka Univ.
2015	Deputy Director, Dept. of Research
	Infrastructure, Japan Agency for
	Medical Research and Development

Medical Research and Development (AMED) 2016 Assistant Professor, Graduate School

of Medicine, Osaka Univ. 2017 Current Position

Publication Highlights

 Including all voices in international data-sharing governance Kaye J et al. Human Genomics (2018), 12: 13

(2) Island lessons: inheritance, solidarity, creativity (Considerations of islands, science and technologies and art) (in Japanese) Minari J

Islands (2018), 253: 56-59
(3) Ethics policy and public engagement in biomedical research on genomic information (in Japanese) Minari J and Yoshizawa G Journal of Medicine, Life and Ethics, Society (2017), 14: 52-60