



Original Article

Opinions on research involving human embryo models by researchers and the general public

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ABSTRACT

Rules and ethical considerations regarding research on embryo models have been debated across numerous countries. In this paper, we provide insights from our attitude survey conducted among Japanese researchers, including members of the Japanese Society for Regenerative Medicine, and among the general public residing in Japan, the US, the UK, Canada, and Australia. Our survey revealed that many researchers expressed the need for clear guidelines for embryo model research. Furthermore, a minority but significant portion of the general public in each country expressed opposition to research on embryo models but did not oppose research involving real embryos.

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1. Introduction

Research on creating embryo models from human pluripotent stem cells has progressed, and a news article in *Nature* [1] indicated that human embryo models at an equivalent stage (13–14 days after fertilization) have been reported in 2023 [2,3]. Embryo models mimic early human embryonic development, enabling experimental simulation of early embryonic development; this helps in understanding early pregnancy loss, placental failure, and the origins of congenital defects in various organs [4]. However, ethical considerations surrounding embryo models are extensively

discussed in scientific literature [5,6]. Debate over the regulations governing research on embryo models is ongoing in various countries, with the crux often revolving around whether these models should be treated equivalent to real embryos [6]. The guidelines outlined by the International Society for Stem Cell Research (ISSCR) in 2021 prohibit the use of human embryo models for reproduction, while requiring that laboratory-based integrative embryo model research be reviewed in the same category as human embryos [7].

While regulations concerning research on embryo models are ambiguous, it appears feasible for researchers in Japan to pursue such investigations in accordance with the Guidelines on the Utilization of Human ES Cells (in the case of embryonic stem cells (ESCs)) or the Ethical Guidelines for Medical and Biological Research Involving Human Subjects (in the case of induced pluripotent stem cells (iPSCs)) [8]. Nonetheless, the lack of clarity regarding these regulations may lead to confusion among researchers. Therefore, the first objective of this study was to investigate researchers' perspectives on the regulatory framework for research on embryo models (Study 1).

Embryo models are promising alternatives to actual embryos for research purposes. However, certain individuals may resist the

Abbreviations: ESCs, embryonic stem cells; iPSCs, induced pluripotent stem cells; ISSCR, International Society for Stem Cell Research; AMED, Japan Agency for Medical Research and Development; JSRM, Japanese Society for Regenerative Medicine; HFT, human fetal tissue.

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adoption of embryo models. It is imperative to consider the perspectives of such individuals when devising regulations governing the use of embryo models. Therefore, the secondary objective was to assess the prevalence of such perspectives among the general public residing in Japan, the United States (US), United Kingdom (UK), Canada, and Australia (Study 2).

2. Methods

2.1. Study 1 method: survey for researchers

2.1.1. Research participants and data collection

We conducted a web-based attitude survey with the researchers. A link to the survey screen was sent to all members of the Japanese Society for Regenerative Medicine (JSRM) via email and mail. Furthermore, the same link was emailed to researchers conducting stem cell-related research supported by the Project for Regenerative/Cellular Medicine and Gene Therapies in the Japan Agency for Medical Research and Development (AMED), a government fund. The survey was conducted from March 2 to March 31, 2022. The research procedure was the same as that used in our previous papers [9,10].

2.1.2. Survey items

First, we asked about their plans to conduct research on human embryo models: “Would you consider conducting research on embryo models in the future, or if you are currently conducting such research, would you consider continuing to do so?” The answer choices were “Would consider conducting,” “Don’t know,” and “No plan to conduct.”

For those who answered, “No plan to conduct,” we subsequently asked about their acceptability of research on embryo models, “Do you think Japanese rules should be changed to prohibit such research?” The answer choices were “No change, should remain allowed,” “Change, should be prohibited,” and “Cannot judge.” We considered those who answered “Change, should be prohibited” as those who explicitly opposed the research.

We then asked their opinion on Japanese rules: “Do you think that the rules for research on embryo models should be clarified in Japan?” The answer choices were “Clarification of the rules is necessary,” “Clarification of the rules is not necessary,” and “Cannot judge.” We did not provide explanation of the embryo model to the researchers.

Furthermore, demographic questions regarding sex and age were asked. See Note S1 for a partial English translation of the questionnaire, including background explanations.

2.1.3. Data analysis

First, we present the respondents' characteristics. Second, a simple tabulation of researchers' plans to conduct research on human embryo models and their acceptance of such research is presented. Third, the researchers' opinions on the clarification of the rules of such research were presented in a cross-tabulation with their acceptability.

2.2. Study 2 method: survey for the general public

2.2.1. Research participants and data collection

We conducted web-based attitude surveys that targeted public groups residing in Japan, the US, the UK, Australia, and Canada. The participants were selected based on the criterion of being between 20 and 69 years of age. Our aim was to gather responses from 3000 individuals in Japan and approximately 1000 individuals from other countries. Participants were recruited from individuals who voluntarily registered with research panel companies. Data

collection in Japan was conducted by the Nippon Research Center, whereas the GMO Research handled data collection in other countries. These are private Japanese companies that specialize in market research, public opinion analysis, and related fields, and operate on a contractual basis. The GMO Research provides international research services through partnerships with affiliated research firms in various countries. Data collection took place from January 5 to 13, 2022 in Japan and from January 5 to 12, 2023 in other countries. The questionnaire was prepared in Japanese for the survey conducted in Japan and in English for surveys conducted in other countries. The research procedure in Japan was the same as that used in our previous papers [9,10]. Note S1 shows a partial English translation of the questionnaire.

Countries surveyed, excluding Japan, are those where stem cell and embryo research are thriving, where the GMO Research has affiliated research firms, and where English is spoken daily. Due to budget constraints and our belief in the importance of avoiding nuance gaps resulting from multilingual translation, we were unable to survey countries where languages other than English are predominant.

2.2.2. Survey items

The survey collected opinions regarding several stem cell- and embryo-related research activities. The questions used in this paper were primarily related to research activities involving human embryo models created from iPSCs, human embryo cultures beyond 14 days, and human embryo cultures within 14 days. The fixed responses were “Should be allowed,” “Should be prohibited,” and “Cannot judge.” For embryo research, we first asked about studies involving embryo cultures beyond 14 days. For respondents who answered, “Should be prohibited,” a follow-up question was asked about research involving the culture of human embryos within 14 days. In the analysis, “Should be allowed” was treated as “agree” and “Should be prohibited” was treated as “disagree” for ease of reading. “Cannot judge” remained “cannot judge.”

We opted to utilize iPSCs instead of ESCs in our inquiry regarding embryo models. This decision stems from the fact that ESCs are derived from real embryos, which we believe might confuse respondents. Furthermore, we explained the concept of embryo models: “An ‘embryo model’ is not a fertilized ovum (embryo), but rather is a model that functions as a fertilized ovum (embryo). The use of embryo models allows us to understand the growth process of fertilized ova (embryos) without having to use actual fertilized ova (embryos).” We have provided additional background information on these research activities in the text and accompanying illustrations. Moreover, we supplemented our questionnaire with an original video aimed at explaining the questions (accessible at https://figshare.com/articles/media/Explanation_by_video/19977308). Please refer to Note S2 for an analysis of how the video contributed to enhancing public comprehension.

We previously published a separate paper examining the attitudes of the general public in Japan using the same survey instrument employed in this study [9] given the ongoing global debate surrounding human embryo culture beyond 14 days, notably highlighted by the International Society for Stem Cell Research (ISSCR) 2021 guidelines, which exclude such cultures beyond 14 days from the prohibited category [7]. However, data pertaining to public attitudes toward human embryo culture beyond 14 days in the US, the UK, Canada, and Australia remain unpublished.

2.2.3. Data analysis

To analyze the data, we initially delineated the attitudes toward each research activity within each country. Subsequently, we delineated the proportion of respondents who either opposed or

did not oppose embryo research among those who indicated ‘disagree’ regarding research on embryo models. These proportions were compared across countries. We classified individuals who disagreed with research involving embryo culture within 14 days as opposed to the embryo research itself. To facilitate intercountry comparisons, chi-square tests were conducted, with p-values subjected to the Bonferroni correction. The significance level was set at 0.05 (5%) for each analysis. Data were analyzed using the IBM Statistical Package for Social Sciences (version 27).

2.3. Ethical statements

The surveys (Study 1, 2, and Note S2) were conducted with the approval of the Institutional Review Board of the University of Yamanashi (approval number: CS0005). Informed consent was obtained from all participants by requesting them to click on a checkbox on an online platform since the surveys were web-based.

3. Results

3.1. Study 1 results: survey for researchers

3.1.1. Respondent characteristics

Table 1 illustrates the characteristics of the respondents. A total of 535 respondents were analyzed. See our previous papers for detailed information [9,10].

3.1.2. Researchers’ plan to conduct research on human embryo models

Table 2 illustrates the researchers’ plans to conduct research on embryo models and their acceptability. In total, 93 (17.4%) of

Table 1
Researcher characteristics (n = 535).

	n (%)
Age	
20–29	21 (3.9%)
30–39	104 (19.4%)
40–49	172 (32.1%)
50–59	161 (30.1%)
60–69	66 (12.3%)
70–	11 (2.1%)
Sex	
Male	413 (77.2%)
Female	122 (22.8%)

Table 2
Researchers’ plan to conduct research on human embryo models and their acceptability.

Plan to conduct the research (n = 535)			Degree of acceptance of the research (n = 338)			
	n	%		n	% of 338	% of 535
Would consider conducting	93	17.4%	No change, should remain allowed	186	55.0%	34.8%
Don’t know	104	19.4%	Cannot judge	125	37.0%	23.4%
No plan to conduct	338	63.2%	Change, should be prohibited	27	8.0%	5.0%

Table 3
Researcher’s acceptability of research on human embryo models and their perspective regarding clarification of the Japanese rules.

	All: n (%)	Explicitly opposed the research: n (%)	Intended to consider conducting the research: n (%)	Other: n (%)
Clarification of the rules is necessary	412 (77.0%)	22 (81.5%)	60 (64.5%)	330 (79.5%)
Clarification of the rules is not necessary	47 (8.8%)	3 (11.1%)	22 (23.7%)	22 (5.3%)
Cannot judge	76 (14.2%)	2 (7.4%)	11 (11.8%)	63 (15.2%)

researchers responded, “Would consider conducting,” and 338 (63.2%) responded, “No plans to conduct.”

Subsequently, we asked about the acceptability of the research to those who responded, “No plan to conduct,” and 27 (8.0% of 338, 5.0% of 535) of researchers responded, “Change, should be prohibited.” We considered these respondents to explicitly oppose the research.

3.1.3. Researchers’ perspective regarding the clarification of Japanese rules

Table 3 depicts the researchers’ perspectives regarding the need for clarification of Japanese rules concerning research on human embryo models. The table provides a breakdown of the respondents into groups that explicitly oppose the research, those considering conducting it, and others. It revealed that 77.0% of all respondents and 64.5% of those intended to consider conducting the research believed that the rules required clarification.

3.2. Study 2 results: survey for the general public

3.2.1. Characteristics of the respondents in each country

No major bias in relation to sex or age was observed among the respondents in any country (Table 4).

3.2.2. Attitudes toward embryo model, embryo culture beyond 14 days, and embryo culture within 14 days in each country

Table 5 presents attitudes toward research involving human embryo models, research involving the culture of human embryos beyond 14 days, and research involving the culture of human embryos within 14 days.

Regarding the inquiry into research on human embryo models, Japan and the UK exhibited the lowest and highest proportions, respectively, of respondents selecting “disagree” (8.0% and 12.1%, respectively).

Concerning research involving human embryo cultures beyond 14 days, the US and UK displayed the lowest and highest percentages, respectively, of respondents choosing “disagree” (18.1% and 30.6%, respectively).

On the matter of research involving human embryo culture within 14 days, the lowest and highest percentages of respondents selecting “disagree” were observed in Japan and the UK, respectively (10.0% and 16.5% in all respondents, respectively).

Table 4
Characteristics of respondents in each country.

		Japan n = 3000	US n = 1090	UK n = 1120	Canada n = 1138	Australia n = 1126
Sex	Male	50.6%	51.5%	50.4%	50.0%	49.6%
	Female	49.4%	48.5%	49.6%	50.0%	50.4%
Age	20–29 years	15.8%	23.3%	19.8%	19.5%	21.3%
	30–39 years	18.2%	20.2%	21.8%	20.8%	24.2%
	40–49 years	23.8%	20.0%	20.0%	20.2%	19.8%
	50–59 years	21.8%	19.1%	21.3%	19.8%	18.7%
	60–69 years	20.3%	17.4%	17.1%	19.7%	16.0%

Table 5
Attitudes toward the embryo model, embryo culture beyond 14 days, and embryo culture within 14 days in each country.

		Japan	US	UK	Canada	Australia
Embryo model	Agree	49.8%	76.2%	66.7%	66.3%	66.0%
	Disagree	8.0%	9.9%	12.1%	8.5%	10.9%
	Cannot judge	42.1%	13.9%	21.2%	25.1%	23.1%
Embryo culture beyond 14 days	Agree	37.9%	68.4%	48.3%	49.3%	51.2%
	Disagree	19.2%	18.1%	30.6%	25.5%	26.1%
	Cannot judge	42.9%	13.5%	21.1%	25.2%	22.6%
Embryo culture within 14 days (in all respondents)	Agree	5.1%	6.4%	10.8%	8.1%	9.3%
	Disagree	10.0%	10.4%	16.5%	13.3%	14.2%
	Cannot judge	4.1%	1.3%	3.3%	4.1%	2.6%
Embryo culture within 14 days (in those who were asked this question ^a)	Agree	26.4%	35.5%	35.3%	31.7%	35.7%
	Disagree	52.1%	57.4%	53.9%	52.1%	54.4%
	Cannot judge	21.5%	7.1%	10.8%	16.2%	9.9%

^a Only those who disagreed with embryo culture beyond 14 days were asked the question about embryo culture within 14 days.

3.2.3. Attitudes toward research on human embryo among those who disagreed to research on human embryo models

Over half of the respondents opposed to research involving human embryo among those who disagreed to research involving human embryo models in Japan (59.8%), US (63.0%), UK (55.9%), and Canada (58.7%) (Table 6). Australia was the only exception (43.1%). Significant differences were observed between Japan and Australia and between the US and Australia.

4. Discussion

While the structure of the questionnaires differed, rendering direct comparisons challenging, a smaller percentage of Japanese researchers expressed opposition to research on embryo models compared to the general public across all surveyed countries. Notably, attention should be drawn to the researchers' perspectives on the need to clarify the rules. Identically structured questions were posed to the same subjects in this survey regarding Human Fetal Tissue (HFT) research, which faces regulatory ambiguity in Japan [10]. The results revealed that 71.8% of all respondents believed that the rules governing HFT research required clarification, and 74.2% of those interested in conducting HFT research

expressed the same sentiment. Conversely, while 77.0% of the respondents felt that the rules for research on embryo models needed clarification, only 64.5% of those interested in conducting such research agreed. This discrepancy suggests that researchers may be concerned that clarifying the regulations for embryo models could entail navigation procedures as intricate as those involved in certain types of human embryo research. In the case of HFT, it could be interpreted that a moratorium on HFT research was imposed in the 2000s [11], prompting many researchers to advocate for explicit acceptance of HFT research within regulatory frameworks, even if it meant dealing with complex procedures. While more stringent procedures are mandated for certain aspects of human embryo research, such as ESCs generation and genome editing, basic research utilizing “surplus embryos” falling outside these scopes can proceed under procedures akin to those required for human subjects research. It is imperative to reassess the inconsistent Japanese regulations governing embryonic research. Simultaneously, a thorough debate encompassing diverse viewpoints is warranted to determine whether regulations for research on embryo models should compel adherence to the same stringent procedures as those currently in place for certain embryo research endeavors or advocate for a more moderate approach.

Approximately 10% of the general public in each country expressed disagreement with research on embryo models. While it is possible that some respondents may have misconstrued the purpose of embryo models by assuming that they were intended for reproduction, it is noteworthy that there was opposition to the creation of human-animal chimeric embryos, even when it was clarified that no chimeric creatures would be generated [12,13]. This suggests resistance to the concept of embryo models itself. Moreover, over half of the respondents who disagreed with research on human embryo models did not oppose research involving human embryos, except in Australia. However, the actual number of respondents was relatively small, comprising approximately 5% of each country (4.8% in Japan, 6.2% in the US, 6.8% in the UK, 4.9% in Canada, and 4.7% in Australia). Nevertheless, these

Table 6
Attitudes toward research involving human embryos among those who disagreed to research involving human embryo models in each country.

	Embryo: disagree	Embryo: not disagree
Japan (n = 241)	97 (40.2%)	144 (59.8%)
US (n = 108)	40 (37.0%)	68 (63.0%)
UK (n = 136)	60 (44.1%)	76 (55.9%)
Canada (n = 97)	41 (42.3%)	56 (57.7%)
Australia (n = 123)	70 (56.9%)	53 (43.1%)
Combinations showing significant differences (p < 0.05)	Japan–Australia	US–Australia

A Chi-square test was performed, and p-values were adjusted using the Bonferroni correction.

results imply that some individuals perceive human embryo models as ethically more sensitive than human embryos.

Our public survey only presented a concise description of the embryo model. Consequently, varying explanations could have led respondents to have different attitudes toward research on embryo models. For instance, if we had elaborated that an embryo model created from iPSCs might be considered equivalent to a cloned embryo of a presently living or previously deceased human (as noted by Sawai et al. [5]), this could have influenced the reduction in the number of individuals who accepted the concept of an embryo model.

This study has several limitations. First, we targeted researchers within a specific field, which may limit the generalizability of our findings. Additionally, the inclusion of individuals registered with a survey company may have introduced bias into the results in a survey of the general public. Furthermore, the larger sample size in Japan compared to other countries could have skewed the outcomes of international comparisons. Moreover, our analysis did not account for factors such as religion, educational background, or socioeconomic status, which could have influenced the respondents' attitudes. In addition, the ISSCR guidelines distinguished between integrated and non-integrated embryo models. The questionnaire for researchers implied integrated embryo models by stating, "According to the ISSCR guidelines, while this research activity is subject to a specialized scientific and ethics oversight process." However, we did not explicitly emphasize this distinction for both researchers and general public. This decision was made due to our concern that this distinction could confuse respondents, particularly from the general public. Nonetheless, recognizing the significance of this distinction is crucial for comprehensively analyzing people's attitudes. Therefore, the results of the present study are preliminary and further research incorporating larger sample sizes and considering these factors is warranted.

5. Conclusions

Many Japanese researchers have expressed the need to clarify the rules governing research on human embryo models. However, the proportion of respondents who held this view decreased when focusing on researchers who intended to pursue such research. Engaging in discussions encompassing diverse perspectives ranging from the most stringent to more moderate levels is crucial to determine the procedural framework to be incorporated into regulations.

Approximately 10% of respondents from the public in each country (Japan, the US, the UK, Canada, and Australia) who participated in our survey disagreed with research on embryo models. Additionally, a small proportion of respondents opposed research on human embryo models in all surveyed countries but did not express opposition to research involving real embryos. A comprehensive understanding of public opinion is imperative to formulate regulations governing the use of human embryo models.

Author contributions

H.Y., Y.Y., K.M., S.W., Y.K. and Z. Y. designed this study. H.Y., Y. Y., and Y.I. analyzed the dataset. Z.Y. supervised the study. All authors contributed to the data interpretation, revised the manuscript for important intellectual content, and approved the final version.

Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work the authors used Chat GPT in order to improve readability and language. After using this tool, the authors reviewed and edited the content as needed and takes full responsibility for the content of the publication.

Declaration of competing interest

The authors declare no competing interests.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.reth.2024.05.001>.

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