Letter in reply to: 'therapeutic misconception and the role of the Research Ethics Committee'

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We would like to thank the writer of the Letter to the Editor of *Regenerative Medicine* [1] for providing his/her opinions on our published Commentary article [2]. The purpose of our Commentary was to analyze the meeting minutes from the review committees regarding the world's first-in-human (FIH) trial using induced pluripotent stem cells (iPSCs) and to define points to consider when reviewing cutting-edge FIH trials in the regenerative medicine field. We respond here to three points presented in the letter related to our Commentary. At this time, we will not discuss any comments from the Future perspective and Conclusion sections of the letter that concern the governance of research ethics committees in Japan because this does not fall within the scope of our Commentary, which was focused on discussion points pertaining to the review of the FIH trial.

Therapeutic misconception

The sentence quoted by the letter writer that was purported to cause therapeutic misconceptions had nothing to do with the FIH trial of age-related macular degeneration (AMD) using iPSCs. The cited sentence was about an event regarding patient involvement in clinical trials hosted by a patient-led association that supports research into retinitis pigmentosa (RP) – the Japanese Retinitis Pigmentosa Society (JRPS) [3]. The purpose of this event was to deepen patients' understanding of the clinical trial's systems and regulations, and to exchange opinions on ethical considerations, as it is assumed that RP will be a target disease in the future. Our purpose in referring to the report of this event was to present an example of efforts taken by researchers to avoid unrealistic patient expectations in early-stage clinical trials. The sentence cited by the letter writer did not come from a document provided to research participants with AMD. Thus, the information contained in that sentence did not directly affect, nor was it the cause of, therapeutic misconceptions by AMD trial participants. The sentence, therefore, cannot be used to support the 'strong assumption' that the writer formed about such misconceptions.

Furthermore, the writer of the letter assumed that the informed consent form (ICF) that was actually used was different from the approved ICF. His/her request that both ICFs should be disclosed was based on his/her misunderstanding. We did not state that the researchers used anything other than the approved ICF. As in other countries, researchers in Japan are required to use ICFs that have been approved by review committees according to regulations.

Role of the committee & author recommendations

The letter writer's question about the committee's function is also based on his/her misunderstanding. We did not state that committee members should meet each individual participant.

Our recommendation was for the committees to confirm whether the research protocol would be designed to ensure 'reasonable accommodation', as defined in Article Two of the United Nations' Convention on the Rights of Persons with Disabilities (2006), when obtaining consent from the participants. These considerations are necessary when committees review clinical trials involving vulnerable populations, in this trial case, persons with visual impairment.

Again, as in other countries, the members of review committees in Japan are not expected to meet individual research participants in order to observe that reasonable accommodations have been provided when obtaining consent. In this context, the review committee's role is only to confirm that the research protocol specifically includes measures for special assistance and appropriate consideration for disabled research participants. We also endorse this practice and do not question this role for the committee.

Clarification of the statement made by the Japanese government

With regard to the government official's statement, we did not realize that this sentence would cause such confusion. We did not state that the government, or any other stakeholders, told the researchers that they are not allowed to fail. Our wording in the Commentary was meant to imply that any risks taken that might lead to failure would receive a great deal of public attention. This could be one of the reasons why review committees in the Commentary needed to pay great attention to 'any risks' associated with the trial during their review process [2].

Author contributions

K Takashima wrote the initial draft of the manuscript. Y Inoue, S Tashiro and K Muto contributed to the analysis of contents of the Letter to the Editor and assisted with the preparation of the manuscript. All authors contributed to the critical review of the manuscript, approved the final version of the manuscript, and agreed to be accountable for all aspects of the work, which ensures that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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