

XI. Japan – Case 1-10 according to Japanese Law

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According to the Japanese Law almost all cases are not explicitly regulated, only Case 2 is banned by the so-called Human Cloning Regulation Act 2000 as a human (somatic cell)-animal (enucleated egg) fused embryo, which is regulated in Article 2 Paragraph 1 No.14 and the production of such a human-animal fused embryo is still prohibited by the Guideline for Handling of a Specified Embryo 2001.

In the original Case 3, for this type of animal-animal xenotransplantation a researcher must get an approval from the Ministry of Health, Labour and Welfare and institutional ethics commission according to the Guidelines of the Institution. The Law for the Humane Treatment and Management of Animals, which was amended in June 2005, includes the provision of Refinement, Replacement and Reduction. The so-called 3R principles of animal experiments and related activities are adopted. On the basis of the Law the Fundamental Guidelines of the Ministry of Education, Culture, Sports, Science and Technology for Proper Conduct of Animal Experiment and Related Activities in Academic Research Institutions provide some regulation of animal experiments (Notice, June 1, 2006). Under changed conditions, as for animal-human xenotransplantation these Fundamental Guidelines also work in Case 1 and permit it. The Guidelines for Derivation and Utilisation of Human Embryonic Stem Cells provides no obstacle to it.

In the new Case 3, for this type of animal-human xenotransplantation researchers are required to submit the protocol to the IRB and to get the approval under the investigation according to the following four forms of regulation:

the Law for the Humane Treatment and Management of Animals (amended in 2005);

the Basic Guidelines for Proper Conduct of Animal Experiment and Related Activities in Academic Research Institutions issued by the Ministry of Education, Culture, Sports, Science and Technology(2006);

the Guidelines of Infection in Xenotransplantation issued by Ministry of Health and Welfare(2001); and the Guidelines of each institution.

From the viewpoint of safety, since the risk of infection is regarded as highly disputable due to the use of primates, it would be difficult to get approval for this research in Japan. As for animal welfare, as the Law for the Humane Treatment and Management of Animals calls for so called 3Rs principles: Refinement, Replacement and Reduction, researchers must observe them. It is not possible, however, to use primates for this research.

On the other hand, informed consent of the recipient is obtained not from the baby but from its parents, so the baby could be treated as a means for the development of the research in the name of life-saving. In conclusion, there is little possibility for such research to be permitted in Japan.

In Cases 5, 6 and 7, those treatments are not prohibited by law, but an academic researcher must get the approval of the institutional review board.

As for Case 8, so-called Golden Hamster test, medical doctors are presented with no barrier to it. An infertility clinic offers this test in its Web as daily use as if it were only one method of male infertility test.

Case 9 is a mixing of embryos and is prohibited by the Human Cloning Regulation Act and the Guidelines for Handling of a Specified Embryo.

As for Case 10, the transfer of an animal embryo into a woman's uterus is itself not directly prohibited by the Law, though the Human Cloning Regulation Act prohibits the transfer of a specified embryo into a uterus of woman or animal in Article 3. However, it would violate human dignity, because the woman was in this case treated only as a surrogate mother of an animal. The Human Cloning Regulation Act has an aim that the human dignity should not be violated and therefore a creation of a mixture of an animal and human is prohibited. Transferring a human embryo into an animal uterus would also violate human dignity. There is a story in which a wolf has given her milk to a human baby and he has grown up as if he were a sibling of a wolf. However, this is merely a story.