Regulations on Osaka University Research Ethics Committee

Article 1:

Osaka University (“University”) shall have a Research Ethics Committee (“Committee”).

Article 2:

The Committee shall be responsible for reviewing the acceptability of the following research and other related matters:

1. Research on human cloning techniques
2. Research on human genome and gene analysis
3. Medical and health research involving human subjects (excluding research to be reviewed by the relevant division of the University or by external organizations)
4. Research on human tissues and primary-cultured human cells (excluding research to be reviewed by the relevant division of the University)

Article 3:

1. In addition to the responsibility stipulated in Article 2 above, the Committee shall be responsible for examining and reviewing the following matters relating to the derivation and utilization of human embryonic stem cells:
2. Important matters relating to the derivation and utilization of human embryonic stem cells
3. Important matters relating to the safety and ethical acceptability of utilizing human embryonic stem cells
4. Important matters relating to educational and training programs on utilizing human embryonic stem cells
5. Matters necessary for reviewing the utilization of human embryonic stem cells shall be set forth separately.

Article 4:

In addition to the responsibilities stipulated in Articles 2 and 3 above, the Committee shall be responsible for reviewing matters necessary to ensure the acceptability of research involving human subjects to be conducted at the University.

Article 5:

1. The Committee shall consist of:
2. A few individuals with enough expertise and experience to conduct comprehensive reviews on research-related matters from a scientific perspective
3. A few individuals with enough expertise and experience to conduct comprehensive reviews on research-related matters from the perspectives of humanities and social sciences including ethics and law, as well as the perspectives of diverse members of society including the general public
4. Individuals appointed by the President of the University
5. At least two (2) members of the Committee shall be selected from among individuals who are not staff of the University (said individuals shall not include those who were affiliated with Osaka University or who had an interest in Osaka University within five (5) years prior to the appointment of Committee members) and at least half of the members shall be those stated in Item (2) of the preceding Paragraph.
6. The Committee members representing the University shall be selected from among professors or associate professors of the University.
7. If a research project in which any of the Committee members is involved is to be reviewed by the Committee, said member shall not be allowed to participate in the review therefor.
8. The Committee members shall be appointed by the President.
9. The Committee members shall serve a term of two (2) years. In case a vacancy arises in the Committee, the term of service of the member who filled the vacancy shall be the remaining term of service of the predecessor.
10. The Committee members stated in the preceding Paragraph may be reappointed.

Article 6:

The Committee shall have a Chairperson, who shall be elected by mutual vote from among the Committee members.

Article 7:

1. The Committee shall have a Vice Chairperson, who shall be selected by the Chairperson from among the Committee members.
2. The Vice Chairperson shall assist the Chairperson, and in the event of the inability of the Chairperson to act, shall perform the duties of the Chairperson.

Article 8:

1. The Committee may convene a meeting only when the quorum of more than two thirds of the members present is met.
2. When a meeting is to be held to review any of the research projects stated in Article 2, at least one (1) member stated in Item (2) of Paragraph 1 of Article 5 shall be present at the meeting.

Article 9:

In principle, a unanimous vote shall be required for the adoption of decisions by the Committee, provided, however, that if a unanimous vote cannot be reached, decisions may be adopted by a two-thirds vote of the members present.

Article 10:

The Committee may allow non-member(s) to attend a meeting thereof and present opinions when deemed necessary.

Article 11:

1. The Committee may have member(s) designated by the Chairperson conduct a fast-track review on the research stated in Items (2), (3) and (4) of Article 2 if the review is conducted on any of the following matters:
2. Minor change of a research plan
3. A collaborative research plan that has been approved by the research ethics review committee of the principal research institution, in which researcher(s) of the University are to participate as co-investigator(s)
4. A research plan that involves no more than minimal risk (which means socially acceptable risk with the probability and magnitude of physical, psychological or social harm anticipated in the research being not greater than those ordinarily encountered in daily life or during health examinations) to donors and proxy consenters
5. The Chairperson shall report the results of a fast-track review to all the Committee members other than the member(s) who performed said review.
6. Any of the Committee members who received the report pursuant to the preceding Paragraph may file a request to the Chairperson for further review by the Committee for the relevant research plan, along with the reason for the request, and if the Chairperson admits the necessity of further review, the Chairperson shall convene a meeting without delay to review the research plan.

Article 12:

The organization of the Committee, review process, results of reviews and other matters relating to the Committee shall be made public unless doing so might threaten human rights, privacy, originality of research or intellectual property rights.

Article 13:

The Committee may establish a special subcommittee as necessary.

Article 14:

The administrative work relating to the Committee shall be carried out by the Research Promotion Division of the Department of Research Promotion.

Article 15:

Matters relating to the administration of the Committee not specified herein shall be set forth separately.

Supplementary Provision

These Regulations shall come into effect on October 18, 2000.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2001.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2004.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2005.

Supplementary Provision

These Regulations as amended shall come into effect on October 24, 2006.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2007.

Supplementary Provision

These Regulations as amended shall come into effect on October 1, 2007.

Supplementary Provision

These Regulations as amended shall come into effect on December 15, 2010.

Supplementary Provision

These Regulations as amended shall come into effect on July 19, 2011.

Supplementary Provision

1. These Regulations as amended shall come into effect on November 1, 2012.

2. Any individual who serves as a Committee member stated in the former Item (2) of Paragraph 1 of Article 4 as of the effective date of the amendment shall be deemed to have been appointed as a Committee member under the amended provision, provided, however, that his or her term of service shall be the remaining term of the original appointment, notwithstanding the provision of Paragraph 6 of Article 4.

Supplementary Provision

These Regulations as amended shall come into effect on April 1, 2015.