Regulations on Human Genome Research at Osaka University

(Purpose)
Article 1:

The purpose of these Regulations is to stipulate matters necessary for human genome research conducted at Osaka University (“University”), thereby ensuring appropriate implementation of said research at the University.

(Definitions)
Article 2:

The term “Research Sample” as used herein shall mean a specimen taken from the human body, whether alive or dead, including, but not limited to, blood, tissue, cell, body fluid and excrement, and DNA extracted therefrom, and medical information pertaining to the donor, which is used for research purposes. However, Research Sample shall not include tissue, cell, body fluid, excrement, DNA extracted therefrom and other specimens whose scientific value is well established and recognized through past research and evaluation, and which are widely used for research purposes and readily available.

(Basic Rules of Research)

Article 3:

1. Human genome research shall be conducted only when significant results are likely to be achieved in biology, genetics and medical science.
2. In conducting human genome research and applying the results thereof, Researchers shall fully take into consideration ethical, legal and social concerns over the research.

(Approval of Research)
Article 4:

1. To conduct human genome research, Researchers of the University shall fill in the Research Review Application Form giving the following information and submit the form to the Dean or Director of the relevant Division (“Director”) in advance:
2. Specific details of the research plan
3. Expected research results
4. Matters to explain to the donor of a Research Sample
5. Disadvantage that may be experienced by the donor of a Research Sample
6. Necessity and method of keeping a Research Sample in storage
7. Method of disposing of a Research Sample
8. Method of protecting personal information and keeping personal information anonymous
9. Other matters deemed necessary by the President of the University
10. Upon receipt of the application stated in Paragraphs 1 and 5 of this Article, the Director shall apply to the President for a review of the research plan.
11. Upon receipt of the application stated in the preceding Paragraph, the President shall give approval to the applying researcher via the Director if the research plan is accepted as a result of the review by the Osaka University Research Ethics Committee (“Committee”).
12. If the human genome research plan for which an application for review is submitted pursuant to Paragraph 2 of this Article is to be conducted jointly with an external institution, the President may request the research ethics review committee of said institution (“External Committee”) to review the plan in place of the Committee. In this case, the review conducted by the External Committee shall be deemed to serve the purpose of the review by the Committee stated in the preceding Paragraph.
13. If any Researcher whose research plan was given approval pursuant to Paragraph 3 of this Article (“Researcher”) wishes to change the approved research plan, he or she shall fill in the Review Application Form for Change in Research Plan and submit the form to the Director in advance.
14. Notwithstanding the provisions of the preceding Paragraphs of this Article, human genome/gene analysis research pertaining to clinical trials conducted by Osaka University Hospital shall be reviewed for approval pursuant to separate regulations set forth by Osaka University Hospital.
15. The Director of Osaka University Hospital shall, upon approval of a research plan pursuant to the preceding Paragraph, immediately notify the President thereof.

(Report of Research Progress)

Article 5:

1. Researchers shall report the progress of research regularly to the President via the Director.
2. If any serious concern arises about the protection of human rights of the donor of a Research Sample, his or her family members and/or other persons concerned, the Researcher shall immediately notify the President thereof via the Director.
3. If the Director becomes aware of any research being conducted improperly, the Director shall notify the President thereof.
4. Upon receipt of notification pursuant to Paragraphs 2 and 3 above, the President may order the relevant Researcher to improve the research method, change the research plan or discontinue the research via the Director, after consulting with the Committee or External Committee that reviewed the research plan in question.

(Investigation into State of Research)

Article 6:

The President shall have external specialists conduct a firsthand investigation into the state of research if necessary for the purpose of protecting the human rights of the donor of a Research Sample, his or her family members, and/or other persons concerned.

(Informed Consent)

Article 7:

In conducting human genome research, Researchers shall give sufficient explanation to the donor of a Research Sample in advance to obtain his or her consent.

(Storage and Disposal of Research Sample)

Article 8:

Research Samples shall be stored and disposed of with the approval of the donor thereof by the method specified in the application form stated in Paragraph 1 or Paragraph 5 of Article 4, as appropriate.

(Provision of Research Sample to Profit-Making Organization)

Article 9:

If a Researcher intends to provide a Research Sample or genetic information obtained therefrom to any profit-making organization, he or she shall notify the President of the intention via the Director.

(Protection of Personal Information)

Article 10:

The President shall draw up detailed guidelines for the management of personal information to keep any personal information strictly confidential.

(Privacy Officer)

Article 11:

The President shall appoint a Privacy Officer to ensure the appropriate management of personal information.

(Privacy Sub-Officer)

Article 12:

1. The Director in each Division shall appoint a Privacy Sub-Officer to ensure the appropriate management of personal information.
2. Each Privacy Sub-Officer shall report the state of personal information management in the relevant Division to the Privacy Officer at the end of each academic year.

(Disclosure of Research Results)

Article 13:

1. In principle, the results of human genome research shall be disclosed unless doing so might threaten personal information, originality of research or intellectual property rights.
2. Researchers shall endeavor to sufficiently explain to society the significance of human genome research and the benefits that the research can bring to society and the future.

(Applicable Rules)

Article 14:

In conducting human genome research, Researchers shall comply with the Fundamental Principles of Research on the Human Genome (adopted by the Bioethics Committee of the Council for Science and Technology on June 14, 2000) and the Ethical Guidelines for Human Genome/Gene Analysis Research (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare, and the Ministry of Economy, Trade and Industry No. 1 of 2013), in addition to these Regulations.

(Other Matters)
Article 15:

Matters relating to human genome research conducted at the University 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 December 1, 2007.

Supplementary Provision

These Regulations as amended shall come into effect on November 16, 2011.

Supplementary Provision

These Regulations as amended shall come into effect on May 30, 2017.