Regulations on Medical and Health Research Involving Human Subjects Conducted at Osaka University

(Purpose)

Article 1:

At Osaka University (“University”), medical and health research involving human subjects (“Medical Research”) shall be conducted under these Regulations as well as the Ethical Guidelines for Medical and Health Research Involving Human Subjects (Public Notice of the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labour and Welfare No. 3 of 2014) (“Guidelines”).

(Definitions)

Article 2:

The terms used herein shall have the meanings defined in the Guidelines, and the following terms shall have the meanings set forth below.

1. The term “Division” shall mean any of the University’s graduate schools, undergraduate schools/faculty, university hospitals, research institutes, joint-use facilities, national joint-use facilities and other organizations equivalent thereto that conduct Medical Research.
2. The term “Division Director” shall mean the Dean or Director of the Division set forth in the preceding Item.

(Delegation of Authority to Division Directors)
Article 3:

The President of the University shall delegate the following authority and duties, which are to be assumed by the chief executives of research implementing entities under the Guidelines, to Division Directors pursuant to the provision of Part 6.2 (6) of the Guidelines. Said authority and duties shall be delegated to the Director of Osaka University Hospital for the Faculty of Medicine and Graduate School of Medicine, and to the Director of Osaka University Dental Hospital for the School of Dentistry and Graduate School of Dentistry.

1. Obligations of the chief executive of the research implementing entity stipulated in Part 6 of the Guidelines, excluding Part 6.2 (6) thereof
2. Procedures related to research plans stipulated in Part 7 of the Guidelines
3. Procedures, etc. for obtaining informed consent stipulated in Part 12.1 of the Guidelines
4. Procedures for providing samples and information to researchers in foreign countries stipulated in Part 12.9 of the Guidelines
5. Protection of personal information stipulated in Part 14.1 of the Guidelines
6. Arrangement of systems and supervision, etc. for security control measures stipulated in Part 15.2 of the Guidelines
7. Disclosure, etc. of retained personal information stipulated in Part 16 of the Guidelines
8. Response to serious adverse events stipulated in Part 18 of the Guidelines
9. Storage of samples and information, etc. for research stipulated in Part 20 of the Guidelines
10. Monitoring and audit stipulated in Part 21 of the Guidelines

(Obligations of the President)

Article 4:

The President shall supervise the Medical Research conducted at the University and perform the following duties:

1. To consult the Osaka University Research Ethics Committee concerning amendment and/or abolishment of any of the provisions of these Regulations and/or other important matters relating thereto, and take necessary measures accordingly.
2. To inspect approximately once a year how the duties delegated to Division Directors pursuant to Article 3 have been performed.
3. To give instructions related to matters that require attention or improvement to Division Directors and Principal Investigators as necessary.

(Obligations of Division Directors)

Article 5:

1. Division Directors shall exercise overall control over Medical Research conducted at the respective Divisions, arrange systems and regulations necessary for implementation thereof, give approval for implementation thereof, and submit reports to Ministers when necessary, pursuant to the Guidelines.
2. When submitting a report to the Minister of Education, Culture, Sports, Science and Technology and/or the Minister of Health, Labour and Welfare pursuant to the Guidelines, or when deemed necessary, the Division Directors shall notify the President of the content of the report.

(Establishment of Ethics Review Committee)

Article 6:

1. An Ethics Review Committee shall be established in each Division pursuant to Chapter 4 of the Guidelines.
2. Matters concerning the Ethics Review Committee shall be determined by each Division.

(Review by Ethics Review Committee)
Article 7:

1. When an approval is sought for a Written Plan of Medical Research to be conducted jointly with other Division(s) or research institute(s), the Division Director may ask an Ethics Review Committee to conduct a collective review on the propriety thereof pursuant to Part 7.2 of the Guidelines.
2. Notwithstanding the provision of Paragraph 1 of Article 6, if an Ethics Review Committee cannot be established within a Division, the Division Director may ask the Osaka University Research Ethics Committee or any other Ethics Review Committee stipulated in other guidelines to conduct a review specified in Part 7.2 (1) of the Guidelines.

(Disclosure of Personal Information)

Article 8:

Division Directors shall handle personal information submitted in connection with Medical Research and retained by the respective Divisions following the procedures set by them and according to the Regulations for Procedures for the Publication, Correction, or Suspension of the Use of Personal Information held by Osaka University, when a request is made for disclosure, correction or suspension of use thereof.

(Miscellaneous Provision)

Article 9:

Matters relating to the application of these Regulations not specified herein shall be set forth separately.

Supplementary Provision

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

Supplementary Provision

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