Rules on Medical and Biological Research Involving Human Subjects at Graduate School of Pharmaceutical Sciences, Chiba University

We certify that this English translation of the rules is a translation of the original Japanese rules. If there is any conflict in the interpretation of both languages, the Japanese version shall be original and prevail.

Date: 2022 / 5 / 31

Signature:

Kunikazu Moribe,
Dean of the Graduate School of Pharmaceutical Sciences, Chiba University

(Purpose)

Article 1.

These rules shall apply to medical and biological research in human subjects (hereinafter referred to as "research, etc.") conducted in the Graduate School of Pharmaceutical Sciences of Chiba University. The purpose of these rules is in accord with the Declaration of Helsinki (adopted by the World Medical Association in 1964), the Ethical Guidelines for Medical and Biological Research Involving Human Subjects (issued by the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare, and the Ministry of Economy, Trade and Industry on March 23, 2021), and the Regulations Concerning the Proper Promotion of Medical Research in Human Subjects of Chiba University (hereinafter collectively referred to as the "Declaration"), and to ensure ethical considerations such as respect for life and the dignity of the individual.

(Scope of Application)

Article 2.

These rules shall be applied to the research and other activities as deemed necessary by Article 1.3 of the Ethical Guidelines for Medical and Biological Research Involving Human Subjects and by the chairperson of the committee as stipulated in Article 8.

(Responsibilities of the Principal Investigator)

Article 3.

The principal investigator (including the general principal investigator in the case of multi-institutional collaborative research. Hereinafter collectively referred to as the "principal investigator, etc.") must ask the Institutional Review Board (IRB, including institutional review board established at research institutes other than Chiba University. The same shall apply hereinafter) for its opinion on the appropriateness of conducting the research.

(2) After hearing the opinions of IRB, the principal investigator, etc. shall submit the results of the hearing, the documents submitted to IRB, and other documents required by the Dean of this institute (hereinafter referred to as "Dean") to Dean, and obtain permission to conduct the research concerned at the Institute.

(3) When principal investigator, etc. has completed or discontinued research, he/she must report to IRB and Dean without delay using the separately specified report on the completion (discontinuation) of research, etc.

(Permission, etc. by the Director of the Research Institute)

Article 4.

When Dean is requested by a principal investigator, etc. for permission to conduct research, Dean shall decide on permission or non-permission to conduct the research and other necessary measures concerning the research, while respecting the opinions of IRB. In this case, Dean shall not permit the implementation of the research if IRB states that the implementation of the research is inappropriate.

(2) When the principal investigator, etc. requests permission under the preceding paragraph, Dean may ask IRB as specified in Article 5 for its opinion.

(Establishment of the Committee)

Article 5.

The Institutional Review Board of the Graduate School of Pharmaceutical Sciences, Chiba University (hereinafter referred to as the Committee) shall be established in the Institute.

(Composition)

Article 6.

The Committee shall be composed of the following persons

(i) Four professors of the Graduate School

(ii) Two experts in ethics and law other than the staff of the Institute

(iii) Two persons who are able to speak opinions on the matter from a general standpoint, including the viewpoint of the research subject, other than those of the Institute's employees.

(iv) Other persons deemed necessary by the Committee: a few.

(2) The Committee members set forth in the preceding paragraph shall consist of both men and women.

(3) The members of items (ii) through (iv) of paragraph (1) shall be appointed by Dean.

(Term of office)

Article 7.

The term of the Committee members shall be two years, and reappointment shall not be precluded. However, the term of a substitute member shall be the remaining term of the predecessor.

(Chair and Vice-Chair)

Article 8.

The Committee shall have a Chairperson and a Vice-Chairperson. The Chairperson shall be appointed by Dean, and the Vice-Chairperson shall be appointed by the Chairperson.

(2) The chairperson shall convene and preside over the Committee meetings.

(3) The Vice-Chairman shall assist the Chairperson and, in the absence or disability of the Chairperson, or in the event that the Chairperson is a researcher, etc., the Vice-Chairman shall take charge of the Chairperson.

(Agenda and Review)

Article 9.

The Committee shall not hold a meeting unless all of the following requirements are met.

(i) Attendance of five or more Committee members

(ii) Attendance of the Committee members at least one person from each of the listed in items (i) through (iii) of Article 6, paragraph (1).

(iii) One or more both male and female members, respectively.

(2) Every effort shall be made to ensure that the opinions of the Committee are unanimous in their decisions.

(3) The Committee may request the attendance of the principal investigator and have him or her explain the contents of the plan.

(4) Expedited review may be conducted by two or more Committee members appointed by the chairperson or vice-chairperson for any of the following research.

(i) Multi-institutional joint research in which the entire research has already been reviewed by IRB and an opinion that it is appropriate to conduct the research has been obtained.

(ii) Review of minor changes, such as changes in the duration of the research or in the persons in charge of the research.

(iii) Review of non-invasive research that does not involve intervention

(5) The results of the expedited review set forth in the preceding paragraph shall be reported to all the Committee members.

(Publication of Summary of Proceedings)

Article10.

The proceedings of the Committee shall be open to the public. However, the part of the research that may cause hindrance to the human rights of subjects, sample donors, or their families, or to the protection of creativity or intellectual property rights related to the research by making it public shall not be made public.

(Retention period)

Article 11.

The period of retention of documents related to the review of research shall be five years, except where as specified by law.

(2) Documents that have been in storage for a longer period may be retained for a longer period if the Committee deems it necessary.

(3) The period of retention shall be calculated from the first day of the fiscal year following the fiscal year in which the research was completed.

(General affairs)

Article 12.

General affairs of the Committee shall be handled by the Research Promotion Division of the Inohana District Office.

(Supplementary Provisions)

Article 13.

The definitions of terms in these rules and the conduct of research and other activities shall be as set forth in these rules. The other provisions shall be in accordance with the Declaration and other documents and as otherwise provided for.

Supplementary Provisions

1. These Rules and Regulations shall come into effect on July 1, 2021.
2. Notwithstanding the provisions of Article 7, the term of office of the Committee members first elected pursuant to Article 6 shall expire on July 1, 2021. Reappointment is not precluded.
3. The Rules of the Ethics Review Committee of the Graduate School of Pharmaceutical Sciences of Chiba University (enacted on July 1, 2019) is hereby repealed.

Reference from Ethical Guidelines for Medical and Biological Research Involving Human Subjects (issued by the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare, and the Ministry of Economy, Trade and Industry on March 23, 2021)

[Article 1.3] Application

This guideline applies to life science and medical research involving human subjects conducted by research institutions in Japan or conducted in Japan. However, in the case of research that falls within the scope of other guidelines, matters not stipulated in those guidelines shall be conducted in accordance with the provisions of this guideline. In addition, research that falls under any of the following categories shall not be subject to this guideline (except for the 21st item in the case of research using only anonymized processed information or non-identified processed information that has already been prepared <limited to those used for the purpose of being used for academic research by universities and other institutions or organizations for the purpose of academic research as stipulated in the Act on the Protection of Personal Information, or by persons belonging to such institutions or organizations>).

2)

(a) Research conducted in accordance with the provisions of (specific) laws and regulations

(b) Research that falls within the scope of application of standards specified by (specific) laws and regulations

(c) Research that uses only the following among the samples and information

(1) Samples and information that already have established academic value, are widely used for research purposes, and are available to the general public.

(2) Information that has already been anonymized (Only those that cannot be used to identify specific individuals and for which no corresponding table has been created.)

(3) Anonymized or non-identified processed information that has already been created.