Kyushu University

Standard Operating Procedure for Storage of Specimens and Information in Medical and Biological Research Involving Human Subjects

Created: May 21, 2015 Ver. 1.0
Revised: November 29, 2017 Ver. 2.0
Revised: June 30, 2021 Ver. 3.0

Table of Contents

1. General Provisions

(1) Purpose and Scope of Application

The purpose of this manual is to ensure the proper implementation of research based on the "Guidelines for Medical and Biological Research Involving Human Subjects" (2021 Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labour and Welfare; and Ministry of Economy, Trade and Industry Notification No. 1) (hereafter, "the Guidelines") and the "Kyushu University Regulations for Medical and Biological Research Involving Human Subjects" (2021 Kyushu University Regulations No. 48) and, towards that end, prescribes the procedures for preserving samples and information obtained from human bodies as well as the procedures stipulated in the "Kyushu University Standard Operating Procedures for Medical and Biological Research Involving Human Subjects" (hereafter, "Medical and Biological Research Manual").
However, in the case of research for which other laws, regulations, etc., apply, these shall take precedence.

(2) Definition of Terms

The following are the definitions of the terms used in this manual.

1. Medical and biological research involving human subjects
   This refers to research performed at the Medical Institutions which uses humans as subjects and is conducted for the purpose of a. or b. below (hereafter, "Research").
   a. To obtain knowledge, via 1), 2), 3) or 4) below, which will contribute to citizens' health preservation and promotion, patient recovery from injury or illness, or quality of life improvement.
      1) Understand the etiology of injury or illness (including the frequency and distribution of various health-related phenomena and the factors affecting them)
      2) Understand pathology
      3) Verify improvement in, or effectiveness of, injury and illness prevention methods
      4) Verify improvement in, or effectiveness of, medical diagnostic and treatment methods
   b. To obtain knowledge, via human-derived samples or data, about human genome and gene structure or function, or about genetic mutation or expression.
2. Guidelines
   This refers to guidelines and related agreements that stipulate the essential matters involved in preserving research data in the institutions conducting research, based on the Kyushu University's "Guidelines for Research Data Preservation" (implemented August 18, 2015).
3. Sample/information
   This refers to human body-derived samples and information used for research, including those derived from the deceased.
      1) Human body-derived samples refer to anything taken from a human body, such as blood, fluid, tissue, cells and waste products, or the DNA taken from them, which is used for research purposes.
      2) Information used for research refers to any human health-related information or other information obtained from medical examination or treatment of research subjects, such as names of illnesses, content of drug administration, results of examinations or measurements, etc., which is used for research.
      3) Existing samples/information refers to samples/information for which either of the following criteria apply.
         a) Any sample/information which already exists prior to research plan creation
         b) Any sample/information obtained after research plan creation but, at the time it is obtained, not for the purpose of the research in question
      4) Genetic information
         This refers to information about personal genetic traits or makeup obtained in the course of research using samples/information or from heritable information associated with existing samples/information.
4. Research subject
   This refers to any person, including the deceased, for whom either of the following criteria apply.
      1) A person upon whom research is performed (including anyone who has sought to have the research performed)
      2) A person from whom existing samples, information, etc., have been obtained and which will be used for research
         When referring not only to research subjects but to others associated with them, such as legal

representatives, the expression “research subjects and related parties” is used.

5. Research institution
   This refers to any corporation or government institution which conducts research, or to any individual conducting research as a sole enterprise. However, this does not include those contracted to perform only some of the research-related tasks, such as sample/information storage and statistical processing.
6. Joint research institution
   This refers to any institution with which research is carried out jointly and in accordance with a research plan (this includes institutions which obtain new samples/information from research subjects to provide to other research institutions for the purposes of the research in question).
7. Research affiliate
   This refers to an institution, other than one which conducts research in accordance with the research plan, which solely obtains and provides to research institutions new samples/information from research subjects (not including cases where invasive procedures (but not minimally invasive procedures) are used to obtain samples) for the purposes of the research in question.
8. Multi-institutional joint research
   This refers to research which is conducted by multiple research institutions based on a single research plan.
9. Researchers and related parties
   This refers to the principal investigator and the other parties involved in conducting research (including the tasks carried out at institutions which collect and provide samples/information), but it does not include anyone who does not belong to a research institution and for whom any of the following apply.
   1) Someone whose sole involvement is obtaining new samples/information and providing these to research institutions
   2) Someone whose sole involvement is providing existing samples/information
   3) Someone who is contracted to perform only some of the research-related tasks
10. Principal investigator
    This refers to the individual who is involved in conducting the research as well as responsible for supervising all tasks connected with the research at Kyushu University. As a rule, the principal investigator must be a Kyushu University staff member.
    In cases of multi-institutional joint research, the term “research representative” can be used as an equivalent term for “principal investigator” when necessary.
11. Research representative
    This refers to the principal investigator who is the representative for the principal investigators of multiple research institutions in the case of multi-institutional joint research.
13. Research director
    The head of an institution conducting research.
14. Informed consent
    This refers to the consent of the research subjects or his/her legal representative or related party regarding implementation or continuation of the research (including handling of samples/information), and this consent is freely given to the researchers and related parties, or the parties providing existing samples/information, based on an understanding of the research objectives, significance and methods, as well as the burdens for research subjects, the expected outcomes (including risks and benefits), etc., as sufficiently explained by the researchers and related parties or the parties providing existing samples/information.
15. Personal information
    This refers to information about a living individual for which either of the following criteria apply.
    1) The information includes names, dates of birth or other statements or descriptions (i.e., any matters (excluding individual identification codes) described or recorded in a document, drawing or electromagnetic record (created via an electromagnetic method (i.e., an electronic or magnetic method or any other method not comprehensible using human perception)), or expressed through voice, movement or other means) by which a person can be identified (including statements or descriptions which can be easily checked or compared with other information to identify a person)
    2) The information includes individual identification codes
16. Personal information (including the deceased)
    This refers to personally identifiable information about a person, whether that person is living or deceased.
17. Individual identification code
    This refers to any characters, letters, numbers, symbols or other codes, as provided for under the Order for Enforcement of the Act on the Protection of Personal Information (Cabinet Order No. 507 of 2003) and other laws and regulations, by which the identity of a specific individual can be identified and into which a bodily

partial feature of the specific individual has been converted in order to be provided for use by computers.

18. Anonymization
    This refers to the total or partial deletion of personal information (including the deceased) statements or descriptions (including individual identification codes) which can be used for identifying the specific living or deceased individual (total or partial replacement of these statements or descriptions with statements or descriptions unrelated to the living or deceased individual is also meant by this term).
19. Correspondence table
    This refers to a table, or something similar, which can be used when it is necessary to identify research subjects from anonymized information by collating research subjects with the replacement statements or descriptions used at the time of anonymization.

2. Responsibilities of Researchers and Related Parties, Principal Investigators and Research Directors

(1) Responsibilities of Researchers and Related Parties

1) Researchers and related parties shall ensure the accuracy of the information used in research and the materials related to this information (including the records relating to the samples/information which are used in research; hereafter, "information and materials"). In addition, they will confirm that information and materials which they did not create (including records created by research subjects) are accurate.
2) Researchers and related parties shall be responsible for preserving and managing samples/information. In the event that a researcher or related party is transferred, retires, etc., while the preservation and management period specified by this manual is still in effect, the responsibility shall be entrusted to another party capable of performing appropriate preservation and management.

(2) Responsibilities of Principal Investigators (Including Research Representatives)

1) When preserving samples obtained from human bodies, as well as information and materials, the principal investigator shall describe the preservation methods in the research plan and instruct/manage researchers and related parties in ensuring the accuracy of information and materials and in performing the management necessary to ensure no samples obtained from human bodies, nor information or materials, are unintentionally or improperly leaked, mixed up, stolen, lost, etc.
2) The principal investigator shall prepare the research environment by creating rules and taking other steps with regard to sample/information preservation and management, and he/she shall endeavor to provide researchers and related parties with relevant training and guidance. In addition, the principal investigator shall regularly check the preservation and management status of samples/information, including those associated with researchers and related parties who have been transferred, have retired, etc.
3) When a researcher or related party is transferred or retires/resigns, the principal investigator shall handle, in line with relevant guidelines, samples/information that need to be preserved. When it is the principal investigator who is being transferred or who is retiring/resigning, the research director shall be the one to perform this handling.

(3) Responsibilities of the Research Director

1) The research director shall, in line with the Guidelines and all other relevant guidelines, perform supervision essential to ensuring samples and information obtained from human bodies in connection with research conducted at the research institution are preserved appropriately, and he/she shall also endeavor to train and guide researchers and related parties by providing, and managing attendance of, research ethics training which encompasses the appropriate preservation and management of research data.
2) Regarding research institution information and data, the research director shall endeavor to preserve it for as long as possible, with the minimum being the period stipulated in 3. of this manual, and shall perform supervision essential to ensuring its appropriate preservation.
3) When samples/information are to be disposed of, the research director shall perform essential supervision to ensure that all appropriate measures are taken so that identification of any particular individual is not possible.

3. Preservation Period

(1) As a rule, the preservation period for samples shall be five years from presentation of the paper, thesis, etc., for which they were obtained. However, the preservation period for unstable substances (e.g., proteins, nucleic acids) and biological samples (e.g., cells, microbes) shall be three years from presentation of the paper, thesis, etc., for which they were obtained. This requirement shall not apply in the case of extremely unstable substances, temporarily prepared biological samples, samples which are used up in the course of experimentation and other samples which are inherently difficult to store/preserve or which cost an inordinate amount of money to store/preserve.

(2) As a rule, the preservation period for information shall be ten years from presentation of the paper, thesis, etc., for which it was obtained. Electronic data shall be preserved in a reusable form by organizing it according to creator, creation date and time, attributes, etc., and by making appropriate backups. Information recorded on paper media, as well, should ideally be preserved for at least ten years; however, when a lack of storage space or other, unavoidable circumstances exist, said information may be disposed of after a reasonably justified preservation period.

(3) With regard to anonymized information, if the research institution in question has a correspondence table, preservation of the correspondence table shall be performed the same as (2).

(4) This manual establishes the minimum preservation period; however, in cases where longer preservation is possible and/or warranted, such as if the paper, thesis, etc., associated with the samples/information presents research results of significant global importance, the preservation period can be extended as much as needed, regardless of the preservation period stipulated in this manual.

(5) The preservation period for data which does not serve as grounds for the research results in the announced paper, thesis, etc., or which has no anticipated use, shall be decided, as needed, by the researchers and related parties, principal investigator and head of the research institution.

(6) Unjustified or intentional disposal of samples/information prior to the completion of the preservation periods stipulated in this manual shall be viewed as improper conduct.

4. Records Related to Sample/Information Provision

(1) Provision of samples/information

A principal investigator or party whose sole involvement is providing samples/information shall create records of sample/information provision and shall preserve them for a period of three years from the date of sample/information provision. At a research affiliate, parties whose sole involvement is providing samples/information must ensure that the head of the research affiliate can access information about the provision.

(2) Receipt of provided samples/information

When receiving samples/information provided by other research institutions for research, the researchers and related parties must confirm that the party providing the samples/information follows appropriate procedures and shall create a record of the sample/information provision.

The principal investigator must preserve the records created by researchers and related parties for a period of five years from the reported date of research conclusion.

5. Procedures for the Preservation of Samples and Information Obtained from the Human Body

(1) The principal investigator shall, in accordance with the Guidelines, describe the following in the research plan.

i. Procedures for receiving informed consent regarding the obtaining of samples/information
ii. Handling of personal information (including method of anonymization)
iii. Method of preservation and disposal of samples/information
iv. If samples/information will be exchanged with other research institutions (including companies), the names of the institutions, the sample/information items, the method of exchange, the method of anonymization, etc.

(2) The principal investigator shall, once per year, provide an update on the status of management stipulated in 2. (2)-1) by completing the separately prescribed “Research Implementation Status Report” and submitting it to the research director.

(3) When the principal investigator exchanges samples/information with other research institutions, the research plan and Research Implementation Status Report shall be used to keep record of these sample/information exchanges. These documents shall be preserved, either electronically or in paper

form, for the period stipulated in 3. in the laboratory of the relevant field. Also, at a research affiliate, parties whose sole involvement is providing samples/information must ensure that the head of the research affiliate can access information about the provision.

(4) If a researcher or related party will be transferred, retire or resign, he/she will confirm with the principal investigator the necessary details of materials relating to his/her research activities which need to be preserved; such details include the names of papers, the location of preserved samples/information and, if later confirmation will be required, how to contact said researcher or related party.

(5) If the principal investigator is transferred, retires or resigns and there is a successor principal investigator to take his/her place, this successor shall take the measures stipulated in the preceding item; however, if there is no immediate successor, the research director shall take the measures stipulated in the preceding item.

Supplementary Provisions

1. All revisions to this manual must be approved by the Kyushu University Medical Ethics Council.
2. This manual shall come into effect from June 1, 2015.
3. This manual shall come into effect from February 19, 2016.
4. This manual shall come into effect from November 29, 2017.
5. This manual shall come into effect from June 30, 2021.