

Pledge Concerning the Protection of Personal Information

To: President

Nippon Medical School Hospital

I fully understand and shall observe the Nippon Medical School Hospital Personal Information Protection Detailed Regulations.

I shall not disclose the personal information acquired at Nippon Medical School Hospital to any third party without a justifiable reason.

In addition, I shall take full responsibility in the event that I am found in violation of this pledge.

I hereby pledge to observe the above in good faith.

(Medical Institution name / Company name)

Print Name _____

Signature _____

Date _____

Nippon Medical School Hospital
Personal Information Protection Detailed Regulations

Date of enactment: **April 1, 2005**
Date of the latest revision: **December 1, 2012**

Established by Personal Information Protection Committee

Nippon Medical School Hospital Personal Information Protection Detailed Regulations

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Section 1 General Provisions

Article 1 Purpose

The purpose of these regulations is to protect the rights and interests of individuals while achieving proper and smooth administrative management by prescribing necessary matters regarding the appropriate protection of personal information handled at Nippon Medical School Hospital (hereinafter the "Hospital") under Article 31 of the Hospital's Personal Information Protection Regulations.

Article 2 Definitions

The meanings of the terms used herein shall be as set out in the following list.

(1) Personal Information

The term "personal information" shall mean information about a living individual that can identify the specific individual by name, date of birth, or other description contained in such information (including such information as will allow easy reference to other information and will thereby enable the identification of the specific individual).

Examples of personal information are provided below.

Medical records such as medical charts, medical prescriptions, operation records, midwifery records, nursing records, laboratory records, roentgenograms, letters of introduction, summaries, and dispensing records. Information on specimens, such as blood obtained from patients for purposes of testing. Records such as plans related to the provision of nursing care services or the details of provided services.

Information (curricula vitae and personal information forms at the time of hiring, staff medical examination records) relating to the staff (including department residents and department interns).

It is provided, however, that with respect to medical treatment, personal information protection is expected to also apply to information of deceased persons, and the Hospital handles such information similarly to personal information of living individuals.

(2) Personal Information Database

The term "personal information database" shall mean a set of information that is arranged and classified in such a way that specific personal information can be easily retrieved by organizing personal information contained therein according to certain rules (for instance, in the order of the Japanese syllabary, in order of date of birth) and that has a table of contents, an index, symbols, or other arrangement so that information can be easily retrieved, irrespective of whether it exists in a paper or electronic format.

(3) Personal Data

The term "personal data" shall mean personal information constituting a personal information database. Since test results are stored in such a way that they can be retrieved similarly to medical charts, they fall under the category of personal data. Medical charts and other medical records as well as nursing care records, regardless of the medium, fall under the category of personal data.

(4) Retained Personal Data

The term "retained personal data" shall mean such personal data over which a business operator handling personal information has the authority to disclose, to correct, add, or delete the content, to discontinue its utilization, to erase, and to discontinue its provision to a third party; provided, however, that (1) data harmful to public or other interests if its presence or absence is known and (2) data that will be erased within a period of no longer than six months (excluding updating of data) are excluded.

(5) Individual Concerned

The term "individual concerned" shall mean a specific individual who can be identified by personal information.

(6) Staff

The term "staff" shall mean an individual who is engaged in the business of handling personal information (including staff provided by the rules of employment of the Hospital and temporary staff) under the direction and supervision of the Hospital organization.

(7) Intern

The term "intern" shall mean a student from schools, training centers or medical related organizations such as the Japan Pharmaceutical Association (hereinafter the "Training organizations") for the purpose of training doctors, pharmacists, health nurses, midwives,

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radiology therapists, clinical laboratory (health laboratory) technicians, physical therapists, occupational therapists, orthoptists, dieticians, emergency life-saving technicians, or medical technologists for medical office work, who is entrusted to undertake internship in the Hospital.

(8) Trainee

The term "trainee" shall mean an individual who holds a license as a doctor, pharmacist, health nurse, midwives, radiology therapist, clinical laboratory (health laboratory) technician, physical therapist, occupational therapist, orthoptist, dietician, or emergency life-saving technicians and receives on-the-job training in the Hospital.

Article 3 Scope of the Detailed Regulations

The meaning

- 1) These regulations shall apply to staff members provided by the rules of employment of the Hospital and (including temporary staff), interns and trainees.
- 2) In addition to what is provided for in the preceding paragraph, these regulations shall also apply to all individuals who enter the Hospital for the purposes of the medical examination, research, education or business, and may be able to obtaining personal information.

Section 2 Responsibilities

Article 4 Responsibility of the Hospital

The Hospital shall recognize the importance of the protection of personal information and shall take necessary measures on the prevention of the infringement of the rights and interests of the individual concerned regarding handling of personal information.

Article 5 Responsibility of the Staff

- 1) The staff must handle personal information, in accordance with the spirit of the law, provided by related regulations, the Hospital's Personal Information Protection Regulations and these Detailed Regulations.
- 2) The staff must abide by confidentiality of the medical profession under the criminal law, confidentiality of the medical profession under the related laws corresponding to the Hospital work, and the rules of employment, and shall not disclose the personal information acquired with respect to his or her work to another person without a justifiable ground or use such information for an unjust purpose.

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- 3) The provision of the preceding paragraph will continue to apply after retiring from employment (including the termination of the contract).

Article 6 Responsibility of the Interns and the Trainees

- 1) The interns and the trainees, in accordance with the spirit of the law, provided by related regulations, the Hospital's Personal Information Protection Regulations and these Detailed Regulations, shall not disclose the personal information acquired with respect to his or her training to another person without a justifiable ground or use such information for an unjust purpose.
- 2) A person who shall undertake internship, on-the-job training, and tour at the Hospital must submit the letter of commitment on the protection of personal information with the prescribed application to the Chief Administrator.
- 3) The provision of the preceding paragraph will continue to apply after completing the internship and on-the-job training.

Article 7 Other Responsibilities

- 1) A person other than those specified in Article 5 and 6, in accordance with the spirit of the law, provided by related regulations, the Hospital's Personal Information Protection Regulations, and these Detailed Regulations, shall not disclose the personal information acquired to another person without a justifiable ground or use such information for an unjust purpose.
- 2) A person who falls under the provision of the preceding paragraph at the Hospital must submit the letter of commitment on the protection of personal information with the prescribed application to the Chief Administrator.
- 3) The provision of the preceding paragraph will continue to apply after the end of permitted period.

Section 3 Management System

Article 8 Personal Information Protection Chief Administrator

- 1) The Hospital shall have a Personal Information Protection Chief Administrator (hereinafter the "Chief Administrator") and the director of the Hospital shall serve as the Chief Administrator.
- 2) The Chief Administrator shall perform appropriate administrative tasks for the proper management of the retained personal information in the Hospital.

Article 9 Personal Information Protection Administrator

- 1) The Hospital shall have Personal Information Protection Administrators (hereinafter the “Administrators”) and the head of each department of the Hospital shall serve as the Administrator.
- 2) The Administrators shall perform appropriate administrative tasks for the proper management of the retained personal information relating to the responsible tasks.

Article 10 Personal Information Protection Committee

- 1) The Hospital shall have Nippon Medical School Hospital Personal Information Protection Committee (hereinafter the “Committee” in this article) in order to deliberate important matters relating to personal information.
- 2) The Committee shall deliberate the following matters.
 - i. Matters relating to the basic measures regarding the protection of personal information
 - ii. Matters relating to handling of personal information referred by the Chief Administrator
 - iii. Other important matters relating to the protecting of personal information
- 3) Necessary matters regarding the Committee shall be provided by the “Nippon Medical School Hospital Personal Information Protection Committee Detailed Regulations”.

Section 4 Handling of Personal Information

Article 11 General Principles for the Collection of Personal Information

- 1) Personal information must be collected legitimately and fairly.
- 2) The purpose of utilization of personal information must be clearly specified, and information should be collected only to the necessary to accomplish the specified purpose.
- 3) Matters relating to ideology, belief, and religion, and personal information relating to matters which may lead to social discrimination must not be collected.
- 4) Personal information must be collected directly from the individual concerned. When personal information is collected directly from the individual concerned, the person collecting must notify, disclose or explicitly specify the individual concerned the following matters in advance or immediately after collecting information. However, that, this shall not apply in the case where it is otherwise provided in laws and regulations.
 - i. The purpose of utilization of personal information

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- ii. The purpose and the intended recipient if you plan to provide personal information to a third party
- iii. The rights listed in a) to e) below relating to the retained personal data and specific methods to exercise these rights
 - a) The right to request notification of the purpose of utilization of the said data
 - b) The right to request disclosure of the said data
 - c) The right to correct, add, or delete the contents of the said data if the said data is found to be incorrect
 - d) The right to request discontinuation of the use of or deletion of the said data
 - e) Procedures to exercise the rights listed in a) to d) above
- 5) In the case of collecting personal information from someone other than the individual concerned, he or she must either be notified or disclosed the matters listed in the items of the preceding paragraph. However, that, this shall not apply in the case where it is otherwise provided in laws, where information is collected from an information provider with the consent of the individual concerned knowing that information will be provided to the Hospital under the item 2 of the preceding paragraph, and where entrusted by a third party to handle personal information.

Article 12 Restriction on Use of Personal Information

The use of personal information shall be within the scope of the purpose of utilization and limited to the extent necessary for performance of work. However, that, this shall not apply in the following circumstances.

- i. Cases when the consent of the individual concerned has been obtained
- ii. Cases in which the usage of personal information is based on laws and regulations
- iii. Cases in which the usage of personal information is necessary for the protection of the life, body, or property of the individual concerned and in which it is difficult to obtain the consent of the individual concerned
- iv. Cases in which the usage of personal information is specially necessary for improving public health or promoting the sound growth of children and in which it is difficult to obtain the consent of the individual concerned
- v. Cases in which the handling of personal information is necessary for cooperating with a state organ, a local government, or an individual or a business operator entrusted by either of the former two in executing the affairs prescribed by laws and regulations and in which obtaining the consent of the individual concerned is likely to impede the execution of the affairs concerned

Article 13 Restriction of Provision to a Third Party

Personal information shall not be provided to a third party without obtaining the prior consent of the individual concerned. However, that, this shall not apply in the following circumstances.

- i. Cases in which the usage of personal information is based on laws and regulations
- ii. Cases in which the usage of personal information is necessary for the protection of the life, body, or property of the individual concerned and in which it is difficult to obtain the consent of the individual concerned
- iii. Cases in which the usage of personal information is specially necessary for improving public health or promoting the sound growth of children and in which it is difficult to obtain the consent of the individual concerned
- iv. Cases in which the handling of personal information is necessary for cooperating with a state organ, a local government, or an individual or a business operator entrusted by either of the former two in executing the affairs prescribed by laws and regulations and in which obtaining the consent of the individual concerned is likely to impede the execution of the affairs concerned

Article 14 Restriction of Access

- 1) The Administrators shall restrict access to personal information to the minimum staff members, as warranted by the confidentiality and nature of the retained personal information, required to achieve the purpose of utilization.
- 2) Unauthorized staff members shall not access personal information.
- 3) Staff members shall not access personal information for non-operational purposes even in the case of having the power to access.
- 4) The Administrators shall separately specify access to personal information.

Article 15 Restriction of Copying and Distribution etc. of Personal Information

Staff members shall follow the instructions of the Administrators when handling of personal information for operational purposes in any of the following activities.

- i. Copying of retained personal information
- ii. Distribution of retained personal information
- iii. Distribution to outside parties or distribution of media containing retained personal information
- iv. Other inappropriate management of retained personal information

Article 16 Maintenance of the Accuracy

When any incorrect personal information etc. is discovered by staff members, staff members shall promptly correct errors, etc. and endeavor to keep accurate and updated information as instructed by the Administrators.

Article 17 Management of Media

Staff members shall store personal information media in a designated location as instructed by the Administrators.

Article 18 Disposal etc.

- 1) When disposing personal information, personal information must be made anonymous or disposing must be entrusted to appropriate waste disposers.
- 2) Remove personal information before disposing computers by using special software etc., and storage media such as floppy disks, CDs, and MOs etc. must be physically destroyed before disposal.
- 3) Remove personal information using special software etc. before giving computers to other people.
- 4) Personal information used to manage the employment of the interns and the trainees shall be disposed of in the same manner as above.

Article 19 Personal Information Handling Records

As warranted by the confidentiality and nature of the personal information, the Administrators shall create ledgers, etc. and record the status of personal information use, storage, and handling.

Section 5 Educational Training

Article 20 Educational Training

- 1) The Administrators shall provide staff members adequate training opportunities in appropriate management and handling of personal information.
- 2) The Administrators shall provide explanation and guidance relating to the management of personal information to the interns and the trainees.

Section 6 Operation Outsourcing etc.

Article 21 Operation Outsourcing etc.

- 1) When outsourcing operations related to the handling of personal information, all necessary security measures shall be taken to avoid selection of parties lacking the capacity to appropriately manage personal information.
- 2) When outsourcing operations related to the handling of personal information, contracts shall be concluded containing the following matters.
 - i. Obligations to protect the confidentiality of personal information
 - ii. Restrictions and/or conditions on re-outsourcing
 - iii. Restrictions on copying, and bans on falsification and processing of personal information
 - iv. Duty to inform the Hospital an unauthorized disclosure or other incident involving personal information and the matters relating to the responsibility of the outsourcer
 - v. Destruction of personal information and return of digital media at the conclusion of outsourcing
 - vi. Contract cancellation procedures and other necessary measures in the event of violations
- 3) When temporary staffs handle personal information, temporary staffs must submit a written pledge relating to the compliance of the proper handling of personal information.

Section 7 Disclosures, Correction, Suspension, Deletion of the Retained Personal Data

Article 22 Notice of the Purpose of Utilization

When a person makes a request for notification of the purpose of utilization of such retained personal data as may lead to the identification of the individual concerned, he or she will be notified without delay. However, that, this shall not apply in the case where it is otherwise provided in laws and regulations.

Article 23 Disclosure of the Retained Personal Data

- 1) When a person makes a request for disclosure of such retained personal data as may lead to the identification of the individual concern, the retained personal data will be disclosed without delay. However, that, this shall not apply in the case where it is otherwise provided in laws and regulations.
- 2) When any incorrect information is discovered as a result of the disclosure in the preceding paragraph and in the case that the person requests a correction or deletion of

such information, such information shall be corrected or deleted without delay, and the individual concerned will be notified its results and the content of the correction to the extent possible.

Article 24 Response to Refusal of Usage and Provision

- 1) Upon receipt of any request from an individual to cease usage or deletion of such retained personal data as may lead to the identification of the individual concerned, on the ground that the retained personal data is being handled for an unintended purpose or has been acquired by improper means, and where it is considered that the request is justifiable, the request will be responded without delay. However, that, this provision shall not apply to cases in which it costs large amount or otherwise difficult to discontinue using or to erase the retained personal data and in which necessary alternative measures are to protect the rights and interests of the individual concerned.
- 2) Upon receipt of any request from an individual to discontinue providing to a third party such retained personal data as may lead to the identification of the person, on the ground that the retained personal data is being provided to a third party in violation of laws and regulations, and where it is considered that the request is justifiable, provision of the retained personal data to a third party shall be discontinued without delay. However, that, this provision shall not apply to cases in which it costs large amount or otherwise difficult to discontinue providing the retained personal data concerned to a third party and in which necessary alternative measures are to protect the rights and interests of the individual concerned.

Article 25 Procedures for Disclosure

- 1) When an individual makes a request to notify disclosure, correction or deletion of personal information under the provision of the four preceding articles, he or she must submit a form specified separately.
- 2) In the case of a request provided in the preceding paragraph is made by an agent, the individual concerned may be asked to submit a letter of attorney signed and sealed by the individual concerned or a document evidencing authority delegated to the agent.
- 3) For the request for a notification or disclosure under the provision of the Paragraph 1, a service charge is charged per retained personal data specified separately.

Section 8 Security Issue Responses

Article 26 Incident Reporting and Recurrence Prevention Measures

- 1) In the event of unauthorized disclosure or other incidents that pose security problems for personal information (hereinafter the "Incident" in this chapter), staff members shall, upon learning of the incident, immediately report to the Administrators responsible for the management of such personal information.
- 2) The Administrators shall identify the chain of events leading to the incident and the extent of damage, etc. and shall report to the Chief Administrator.
- 3) The Chief Administrator shall take necessary measures to prevent the expansion of damage and incident recovery in cooperation with the Administrators.
- 4) The Chief Administrator shall analyze the factors resulting in the incident and shall take such measures to prevent further recurrence in cooperation with the Administrators

Article 27 Public Announcements, etc.

The Chief Administrator shall, as warranted by the nature and impact, etc. of the incident, publicly announce the facts of the incident and measures to prevent recurrence, and determine responses, etc. to the individuals whose information was involved in the incident.

Section 9 Inspection etc.

Article 28 Inspection

The Administrators shall inspect on a regular and as-necessary basis the digital recording media, processing channels and storage methods, etc. for personal information under his/her responsibility for management and when deemed necessary, shall report findings to the Chief Administrator.

Article 29 Evaluation and Review

The Administrator shall evaluate measures for the appropriate management of personal information in response to inspection findings etc. and, when deemed necessary, shall be reviewed and report to the Chief Administrator.

Section 10 Audit

Article 30 Audit

- 1) The Chief Administrator shall appoint the Audit Controller, and the Audit Controller shall be responsible for performing regular audits of the status of the implementation of personal information protection.
- 2) The Audit Controller shall perform appropriate audits and shall report findings to the

Chief Administrator.

- 3) In cases of violation of laws and these regulations relating to the management of personal information in the Hospital is revealed in audit results, the Chief Administrator shall instruct the parties involved to take necessary action for improvement.

Section 11 Complaints and Inquiries

Article 31 Response to Complaints and Inquiry Counter

The Chief Administrator shall receive complaints and inquires relating to the handling of personal information at the “Medical Inquiries”, and must notify the contact information of the “Medical Inquiries” to the patients and the users.

Section 12 Miscellaneous

Article 32 Handling of Laws and Regulations

In addition to those stipulated in these Detailed Regulations, matters concerning protection of personal information shall be governed by laws and related statutes.

Article 33 Enactment of Internal Regulations etc.

The Chief Administrator may establish detailed regulations and internal regulations in order to take necessary measures on matters concerning protection of personal information relating to the responsible tasks.

Article 34 Abolition of the Regulations

The Abolition of these regulations shall be deliberated on in the Committee and requires approval of the director of the Hospital.

Supplementary Provisions

These Regulations shall come into force from April 1, 2005

Supplementary Provisions

These Regulations shall come into force from July 1, 2012

Supplementary Provisions

These Regulations shall come into force from December 1, 2012

**Notification of Request for Consent and Refusal Relating to Changes (Additions) in
the Purpose of Utilization of Personal Information**

(Name of the medical institution) Nippon Medical School Hospital

To the Director of the Nippon Medical School Hospital

I have received the notification of changes (additions) in the purpose of utilization of my personal information held by your hospital as follows.

Items and scope of changes
in the purpose of utilization

(Filled in by the medical institution)

Newly added contents of the
purpose of utilization

(Filled in by the medical institution)

Below is my answer concerning the above changes (additions) in the purpose of utilization.

I agree / disagree with the changes / additions in the purpose of utilization.

Note

Date: _____

The Patient (sign): _____

Dear. _____

**Changes (Additions) in the Purpose of Utilization of Your Personal Information
Held by the Hospital**

Your personal information held by the Hospital is handled appropriately within the scope of utilization as we have been notifying you through notices in the Hospital. However, recently it became necessary to make changes (additions) in the purpose of utilization as stated below.

Therefore, please respond in the affirmative or negative of the changes (additions) in the purpose of utilization of your personal information by filling out the attached "Notification of Request for Consent and Refusal relating to Changes (Additions) in the Purpose of Utilization of Personal Information" and return it to the Hospital.

Items and scope of changes
in the purpose of utilization

Newly added contents of the
purpose of utilization

Date: _____

(Name of the medical institution) Nippon Medical School Hospital

Director _____

Doctor-in-charge _____ Department _____