Brain Bank ethical guidelines

(an unofficial translation from the Japanese original document)

September 26, 2015: Japanese Society of Neuropathology, Japanese Society of Biological Psychiatry

(February 5, 2016: Japanese Society of Pathology, minor revision)

(April 27, 2018: minor revision due to amendment of Ethical Guidelines for Medical and Health Research Involving Human Subjects and Ethical Guidelines for Human Genome / Gene Analysis Research)

(August 9, 2019: Japanese Society of Neurology, minor revision)

(June 26, 2025: minor revision due to Ethical Guidelines for Medical and Biological Research Involving Human Subjects)

Societies supporting these guidelines

Japanese Society of Pathology (February 5, 2016)

Japanese Society of Neuropsychopharmacology (June 29, 2016)

Japanese Society of Schizophrenia Research (July 4, 2016)

Japanese Neuroscience Society (July 7, 2016)

Japanese Society for Neurochemistry (July 14, 2016)

Japanese Society of Mood Disorders (July 22, 2016)

Japanese Society of Psychiatry and Neurology (September 19, 2016)

Japanese Society of Neurology (November 12, 2016)

VIII. Implementation date

I. What is the Brain Bank?

I-1. Meaning and purpose of Brain Bank

The concept of Brain Banks is founded on the will of citizens to donate the "gift of hope"[1] to future generations through the promotion of research. They aim to honor this will by appropriately managing donated postmortem brain tissue, thereby contributing to research that seeks to improve both mental and physical health. As the subjects involved are corpses and the initiative is supported by the philanthropy of bereaved families, the common themes across all processes are respect for the dignity of the deceased, consideration for the bereaved families, and adherence to social conventions.

I-2. Subjects handled by Brain Bank

The Brain Bank is an organization that conducts research aimed at contributing to the improvement of mental and physical health by collecting and providing targeted tissue and information from the subjects listed below.

a) Subjects

Subjects with and without neurological or psychiatric disorders.

b) Target tissue: Entire brain or parts of it (left and right cerebrum, cerebellum, brain stem, etc.); entire spinal cord or parts of it; and parts of other tissues (peripheral nerves and muscles, blood, cerebrospinal fluid, systemic organs such as liver, skin, etc.) that have been removed during postmortem examination in accordance with the Postmortem Examination and Corpse Preservation Act and the Guidelines for Pathologists' Autopsies.

c) Information

This includes information about the donor's antemortem health and medical condition; clinical data obtained from the donor or their physician with their consent during antemortem registration; and antemortem information such as the cause of death, obtained from the primary physician or medical institution with the consent of the bereaved family.

II. Basic policy of these guidelines

Medical research on postmortem tissue has conventionally been conducted based on the stipulation of the Postmortem Examination and Corpse Preservation Act, which states that “Corpse preservation may be conducted for setting the entire corpse or part of it with the consent of the bereaved family if deemed particularly necessary for medical research.” The use of postmortem tissue in research, and the process of obtaining consent for such use, involve ethical considerations that differ from those related to tissues collected through biopsy or surgery. This necessitates ethically and technically valid practices that fully respects the dignity of the deceased, demonstrate courtesy to bereaved families, and adhere to social conventions. Accordingly, these guidelines have been developed with the goal of providing directions for the operation of Brain Banks and the procedures for using postmortem brain tissues in research, in accordance with the principles of the Postmortem Examination and Corpse Preservation Act. The following items should be taken into account in matters concerning the Brain Bank project.

II-1. Assumption of autopsy

Pathological autopsy (including administrative autopsies conducted by local governments where permitted) is based on the principle of providing a definitive diagnosis of the cause of death as a final service to the deceased. In addition, it offers valuable information to the bereaved families and caregivers, particularly in cases involving neurological or psychiatric disorders. In Japan, the Brain Bank project is based on the performance of autopsies; therefore, an accurate neuropathological diagnosis is essential.

II-2. Brain Bank project and Postmortem Examination and Corpse Preservation Act

The process of removing and preserving a corpse through examination is referred to as “postmortem examination” and “corpse preservation” under the Postmortem Examination and Corpse Preservation Act. The requirements of this Act must be observed. However, the Act does not clearly stipulate procedures for activities following “corpse preservation” as a specimen—such as the secondary processing of samples, supplying them to external entities, or their use by researchers. From a practical standpoint, it is difficult to apply the legal requirements related to “postmortem examination” and “part of corpse” to all corpse-derived items. In reality, cases where the “specimen is limited to a small part of the corpse” are considered outside the scope of these provisions, as stated in previous administrative guidelines from the Ministry of Health and Welfare and Guidelines for Pathologists’ Autopsies (Reply from Director General of the Medical Affairs Bureau of Ministry of Health and Welfare to Governor of Saitama Prefecture on February 10,

1951/MA No. 77 and Notice from Director General of Health Policy Bureau of Ministry of Health and Welfare in 1988, HP No. 693]). Nonetheless, even in the case of processed samples, because they are derived from a corpse, their use requires not only the consent of the bereaved family but also follow socially acceptable protocols. This includes respectful treatment of the samples and strict, appropriate management in accordance with public health standards.

II-3. Postmortem examination and corpse preservation/storage locations

Brain Banks collect a wide range of brain specimen by conducting postmortem examinations on the corpses of patients who died at medical institutions other than their own. To preserve and store part of the corpse, they implement one of the following procedures: a) The corpse is transported to a Brain Bank facility and a postmortem examination is conducted; b) An Brain Bank-dispatched individual conducts the postmortem examination at the medical institution where the patient died; or c) An qualified individual at the medical institution where the patient died performs the postmortem examination. The removed target tissue is then transported to the Brain Bank. This also includes cases where other institutions cooperate in the postmortem examination and the preservation and storage of body parts based on antemortem registration, carried out jointly by other Brain Banks (see Section V). If the Brain Bank is not affiliated with a university, regional medical support hospital or specialized hospital—as stipulated in Article 17 of the Postmortem Examination and Corpse Preservation Act—or if it is not operated by an individual qualified to conduct postmortem examination under Article 18 of the same Act, then permission must be obtained from the prefectural governor, as required under Article 19 of the same Act, for the preservation of the entire corpse or parts of it. Furthermore, while the Postmortem Examination and Corpse Preservation Act stipulates that corpses or body parts must be preserved at the medical institution where the postmortem examination was conducted, it does not address their transport to other institutions, nor their storage and provision by Brain Banks. Nevertheless, in cases where the postmortem examination was performed by a qualified individual or at a qualified hospital, the management of the target tissue may be entrusted to the Brain Bank, and the target tissue may be preserved and stored[2] accordingly.

II-4. Collection of antemortem medical information

The antemortem medical information will be handled in line with the “Ethical Guidelines for Medical and Biological Research Involving Human Subjects (Notice of Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labor and Welfare, and Ministry of Economy, Trade and Industry).

III. Brain Bank ethical principles

The operation of the Brain Bank and implementation of research that uses the Brain Bank must observe the following principles to maintain ethical appropriateness.

a) Contribution to research that aids in the improvement of mental and physical health

The tissue provided to the Brain Bank must be regarded as having been entrusted by the donor and their bereaved family for the development of research aimed at improving mental and physical health. Therefore, these tissues must be managed and used appropriately to support meaningful research development.

b) Ensuring voluntary nature

The Brain Bank registration must be based on the assumption that the consent has been obtained from the bereaved family and must be carried out in a manner that respects the wishes expressed by the candidate when they were alive. No psychological pressure must be placed on the candidate or the bereaved family during the decision-making process.

c) Informed consent

Written consent must be obtained when receiving a donation after a full explanation is given to the bereaved family and they have confirmed that they fully understood the contents. Even after consent has been acquired, the latest information stipulated below must be disclosed, and consideration must be given to ensure that the above-mentioned parties are aware of the status of activities.

d) Maintaining courtesy

When collecting, supplying, or using tissue, samples, or related information for research, courtesy must be shown to both the donor (deceased) and their bereaved family. Particular attention must be given to preserving the dignity of the deceased. The use of such samples by researchers rests on the assumption that they will be handled with due respect—equivalent to the level of courtesy shown by a physician (or other qualified

individual) during a postmortem examination. When samples are used by researchers who are not physicians or are not qualified to conduct postmortem examinations, prior training by the Brain Bank is strongly recommended to ensure appropriate respect is maintained toward the samples derived from corpses.

e) Maintaining non-commercial availability

The Brain Bank must not be operated for profit. Tissue donations or the registration of an intent to donate must not involve financial benefits beyond the reimbursement of necessary for the bereaved family or the individual expressing interest in donation. Additionally, individuals involved in or cooperating with Brain Bank operations must not receive compensation exceeding a reasonable range of fees related to operational and maintenance costs, or the collection and provision of tissue.

f) Strict management of personal information

Information that could lead to the identification of Brain Bank antemortem registrants or donors, as well as any information designated as confidential by registrants, donors, or their bereaved families, must be strictly managed. Utmost care must be taken to prevent the leakage of such information.

g) Information disclosure

The Brain Bank must establish a system for the widespread disclosure of information about its activities to the public. Efforts must be made to share information and exchange opinions regarding important matters relating to Brain Bank management with researchers and the public. The method of information disclosure for research must entail to providing latest information on the internet homepage and in newsletters, in accordance with the “Ethical Guidelines for Medical and Biological Research Involving Human Subjects”.

h) Compliance with laws and regulations

The Brain Bank activities must comply with the relevant laws and regulations (Postmortem Examination and Corpse Preservation Act) and national guidelines (Guidelines for Pathologists’ Autopsies and Ethical Guidelines for Medical and Biological Research Involving Human Subjects).

IV. Standard Brain Bank operation guidelines

IV-1. Procedures for receiving donations

IV-1-A. Basic principles

1. Candidates and the bereaved family must provide consent to the purpose of the Brain Bank, which is to contribute to the improvement of mental and physical health.

2. Informed consent must be obtained from the bereaved family when accepting tissue donation.

3. The candidate's antemortem wishes must be respected when accepting tissue donation.

4. Cases where a candidate has registered an intent to not donate a sample must be respected by not accepting the tissue.

5. The bereaved family may withdraw their informed consent to tissue donation at any time. The wish to withdraw may be expressed at any time, provided the bereaved family is present; however, such withdrawal is not retroactive. In other words, there is no obligation to return samples already used in research or withdraw any published research findings derived from them.

IV-1-B. Informed consent procedures from bereaved families

1. Explanations to the bereaved family regarding the donation of tissue must consider the situation in which the bereaved family (contacted shortly after the death of the deceased member), respecting their feelings. Consideration should be given to ensuring the voluntary nature of the process by clearly informing the bereaved family of their right to refuse participation. This includes clarifying that they may choose whether to receive an explanation and that refusal will not result in any disadvantage.

2. Cases where the candidate registered an antemortem wish to donate (see Section V) should provide an explanation of the intent of the antemortem registrant to the bereaved family. In cases where a wish to donate was not registered, that wish should be communicated to the bereaved family and hospital, indicating that no sample will be donated.

3. Cases where consent is obtained from the bereaved family regarding the donation of tissue will, as a rule, involve both written and verbal explanations of the following contents and matters, with the consent obtained in writing.

(1) Significance and overview of Brain Bank (including contact information)

(2) Purpose of antemortem registration and intent of antemortem registrant in cases where candidate registered a wish to donate

(3) Tissue donation is entirely voluntary, and individuals will not face any disadvantage if they choose not to provide.

(4) Matters relating to withdrawal of consent

・Consent to donate tissue can be withdrawn at any time prior to the use of research.

・Withdrawal method

・Policy regarding handling of tissue in the event of withdrawal

(5) Scope of tissue to be donated, method of collection, and handling of tissue.

(6) Content of the information to be provided and method of acquisition

(7) Policy regarding disposal of tissue.

(8) Policy regarding use, supply, and transfer of tissue.

(9) Examples of expected uses

(10) Matters relating to non-compensation of donation and property rights related to tissue.

(11) Policy regarding recipient (research using donated tissue must undergo ethical review and approval). If the data is provided for overseas research and development or to commercial enterprises, then this should also be stated

(12) Matters relating to protection of personal information.

(13) Policy relating to disclosure of information obtained by the analysis of tissue (the potential and limitations of disclosure if information related to the health of the bereaved family is obtained unethically).

(14) Information disclosure methods and contact information

(15) Other matters required by national research ethics guidelines and ethical review committee of each institution (right to obtain and view materials related to the research

plan and research methods within the scope that does not impede the protection of personal information or the originality of the research, and the method for obtaining and viewing such material; the status of conflicts of interest relating to the research area of the researcher; and responses to suggestions)

4. The written consent obtained from the bereaved family should involve a copy of the consent form, including explanation on the content provided to the bereaved family.

5. Cases where consent is withdrawn by the bereaved family the Brain Bank must take appropriate measures such as prompt cremation of any unused brain tissue or sample parts. Explanations to the individual and bereaved family should clearly state in advance, in the event of withdrawal, the Brain Bank will follow its established policy, including cremation at the facility. Once the withdrawal process is completed, the bereaved family will be notified. Throughout this process, attention must be given to the appropriate management of personal information.

IV-2. Acquisition of antemortem information

1. When receiving tissue donation, the donor's name, date of birth, and the following antemortem information must be obtained through the bereaved family, primary physician, or medical institution.

General information such as age, sex, height, weight, and handedness; developmental, educational, family, and lifestyle history; favorite items; substance abuse; previous physical illnesses; cause of death; mental and physical condition prior to death; medical history; clinical symptoms; test results; neuroradiological images; treatment and infectious disease history.

2. The acquisition of antemortem information will be through an interview with the bereaved family and primary physician, or by viewing the medical records stored at the medical institution.

3. Sufficient consideration toward the feelings of the bereaved family will be given when interviewing them regarding antemortem information about the donor.

4. Receipt of a donation of antemortem information from a primary physician or medical institution must also have an accompanying consent form from the bereaved family regarding the acquisition of the information. Cases where the donor expressed

antemortem their wish to donate must also be included in the donor's registration application form, as required.

IV-3. Removal and corpse preservation

1. Refer to the stipulations regarding the postmortem examination and corpse preservation location (Sections II-2 and II-3).

2. Cases of a pathological autopsy require written consent from the bereaved family, as part of the autopsy consent form established by the medical facility, to conduct the autopsy.

IV-4. Corpse and tissue transportation

Cases where the corpse is transported to a Brain Bank facility for postmortem examination or cases where an individual, stipulated by the Postmortem Examination and Corpse Preservation Act and the Guidelines for Pathologists' Autopsies, transports tissue to a Brain Bank for storage after conducting a postmortem examination at a location specified by the Postmortem Examination and Corpse Preservation Act, must observe public health infection prevention measures and efforts toward maintaining conditions that are appropriate for the purpose of the research.

IV-5. Handling of tissue.

a) Tissue and sample processing and storage

1. Tissue and sample processing and storage should be conducted in a manner that matches the research objectives, for the implementation of morphological and pathological analyses such as neuropathological diagnoses.

2. Tissues and samples must be processed, stored, and managed in an anonymous state.

3. Efforts should be made to store tissues and samples for as long as possible. When submitting a research plan related to the collection and supply of tissue, cases in which a storage period is specified should set a target of 10 years, accompanied by a statement stating that the tissues and samples will continue to be stored beyond that period.

4. Thorough quality control will be ensured by appointing a quality control officer for tissue removal, as well as tissue and sample processing and storage. Education and

training will be provided regularly to technicians involved in tissue removal, including tissue and sample storage, in cooperation with related institutions.

5. Cases where the relevant institution struggles to store and manage the tissues and samples, or when another institution is better suited to do this, consideration will be given to their effective use through transfer to another Brain Bank. Such a transfer requires confirmation that this action does not violate the wishes of the donor or bereaved family. Additionally, a material transfer agreement (MTA) with the transfer recipient must be established to ensure appropriate storage and management of the tissues and samples.

b) Information storage and management

1. Antemortem information relating to the donor will be anonymized and stored.

2. The anonymization of tissue and the management of the correspondence table that is created for the anonymization will be conducted under the purview of a personal information manager who is bound by confidentiality.

3. Cases where tissues and samples are transferred to another Brain Bank will also be involved in the transfer of the antemortem information and correspondence table. In the process of transfer, matters related to the appropriate storage and management of the antemortem, and the correspondence table must be included in the MTA.

c) Disposal of tissue.

1. In cases where disposal is inevitable due to tissue or sample deterioration, issues with tissue management, and other issues, will involve conducting disposal in an appropriate manner as specified by the facility, with consideration given to the fact that the tissue is derived from a corpse, to prevent infection and leakage of personal information.

IV-6. Supply of samples

1. Samples should be supplied fairly, based on written standards.

2. The supply of samples requires the submission of a research plan by the recipient institution and confirmation of the following items.

(1) The samples will be used for research that contributes to the improvement of mental and physical health.

(2) An academic review committee must confirm the ethical and scientific validity of the research plan including a third party of the Brain Bank.

(3) The ethics committee of the recipient institution must approve the relevant research plan.

(4) The tissue is expected to be handled in an appropriate manner from the standpoint of the dignity of the deceased and protection of personal information.

(5) The research structure must be designed to deal with biohazards.

(6) As a rule, the recipient institution must report on the usage history on a regular basis. In cases where the sample is no longer expected to be used, it must be returned to the Brain Bank.

(7) Individuals wishing to use resources must not engage in activities that go against Brain Bank activities, including antemortem registration.

3. When supplying samples, an MTA must be concluded with the recipient institution to ensure their appropriate use. The MTA must include provisions, as necessary, to restrict or prohibit the transfer of samples to third parties.

4. Care must be taken when supplying samples to maintain a condition that matches the research purpose. Additionally, respect must be shown to the deceased who provided the sample; courtesy must be shown to the bereaved family; and consideration must be given from a public health standpoint.

5. The Brain Bank should record the recipient and provide sample content, donor's clinical information, and information on the analysis results, with these records stored for as long as possible. When collecting tissues and sample supplies for the submission of a research plan, cases specifying the storage period for the information pertaining to the tissues and samples should have a target of 10 years, with a statement indicating that the tissues and samples will be stored beyond that period. Similarly, the recipient institution will record the name of the Brain Bank providing the samples, name of the manager, sample and information content, and the process for obtaining them, storing the records for a period of five years from the date of the report on the completion of the relevant research.

6. Cases where an invention is made through research using samples provided by the Brain Bank, and the inventor seeks to obtain intellectual property rights such as a patent for the

invention, are subject to consultation with the Brain Bank, with consideration given to the public nature of the Brain Bank, and voluntary nature of philanthropic action.

7. Following the completion of the research period using samples provided by the Brain Bank, or after the researchers have achieved and published certain research findings, the information obtained should ideally be provided to the Brain Bank, whereupon the Brain Bank and its users will be allowed to utilize the information for secondary use.

IV-7. Brain Bank management structure

a) Establishment, management system, audit

1. A representative must be appointed, and appropriate facilities, equipment, and personnel must be established to support public operations of the project. In cases where multiple institutions or departments within an institution collaborate to operate a Brain Bank, particular consideration should be given to ensuring unified and responsible management.

2. The establishment of a Brain Bank should have a clearly defined framework for operation by preparing a statement of purpose, project plan, and budget plan in writing.

3. The establishment should be approved by the ethics committee of the affiliated institution, and a system for third-party audits should be established, such as regular reports to the ethics committee.

b) Operational structure

1. A system is established for ensuring the safe and prompt supply of samples and providing education and training.

2. A system is established for properly managing personal information, providing education and training.

3. Transparency is ensured in operations, and efforts are made to publicize the project content.

4. Efforts are made to secure stable financial resources to ensure project continuity.

5. Procedures are clarified for quality assurance and reliability.

V. Brain Bank antemortem registration procedures

1. The introduction of an antemortem registration system is recommended from the standpoint of the sustainable development of Brain Banks in harmony with society. As a rule, antemortem registration is intended for people who understand its purpose and have the capacity to make their own decisions and give consent[3]. When providing explanations relating to antemortem registration to the candidate, consideration should be given to ensuring the voluntary nature of the process, clearly explaining to the candidate their right to refuse, including whether they want to receive an explanation, and clarifying that they will not be disadvantaged in any way. As a rule, a coordinator other than the primary physician will be involved in the process of acquiring informed consent to carefully judge whether an individual has the capacity to make their own judgment and provide consent.

2. As a rule, cases where an application from a candidate is received for antemortem registration to register their wish to donate tissue will involve both the written and verbal explanation of the following contents and matters, with the application being received in writing.

(1) Significance and overview of Brain Bank (including contact information)

(2) Registration of the wish to donate or not is optional, and the registration will not change the provision of therapeutic benefits.

(3) Consent of the bereaved family is required for donation. Even in the case of registration of a wish to donate, the donation may not occur because of the disapproval of the bereaved family or medical reasons.

(4) Matters relating to withdrawal of antemortem registration

・The wish to register can be withdrawn based on the application of the candidate or changed at any time.

・Withdrawal or change method

(5) Matters related to acquisition of clinical information for antemortem registration

・Registration of the wish to donate should involve the provision of clinical information from the candidate, primary physician, and medical institution.

・Content of information to be provided and method of acquisition

(6) Expected range of tissue that may be donated, method of tissue collection and its handling

(7) Matters relating to acquisition of antemortem information

・Clinical information should be provided postmortem by the bereaved family, primary physician, and medical institution.

・Content of information to be provided and method of acquisition

(8) Policy for tissue handling and its disposal

(9) Policy regarding use, supply, and transfer of tissue.

(10) Examples of expected uses

(11) Matters relating to non-compensation of donation and property rights related to tissue.

(12) Policy regarding recipient (research using donated tissue must undergo ethical review and approval). If data is provided for research and development from overseas or to commercial enterprises, then this should also be stated

(13) Matters relating to protection of personal information.

(14) Policy relating to disclosure of information obtained by tissue analysis (potential and limitations of disclosure if health-related information is accidentally obtained.).

(15) Information disclosure methods and contact information

3. Antemortem registration of the wish to donate should involve efforts to obtain consensus through the candidate, primary physician, and medical institution, for providing not only the candidate's name, date of birth, and contact information, but also the following clinically required postmortem information.

General information such as age, sex, height, weight, and handedness; developmental, educational, family, and lifestyle history; favorite items; substances of abuse; previous physical illnesses; cause of death; mental and physical condition immediately prior to death; medical history; clinical symptoms; test results; neuroradiological images; treatment and infectious disease history.

VI. Review

An important aspect of establishing and operating the Brain Bank is fostering a shared understanding across society, including stakeholders, their families, medical and welfare workers, and relevant academic fields such as pathology, neuropathology, anatomy, forensic medicine, clinical psychiatry, neurology, and neuroscience. In the future, ethical guidelines will be reviewed for each relevant field and revised as necessary. A review will also be conducted as needed, or approximately five years after implementation, considering overall circumstances.

VII. Definition of terms

Bereaved family: The definition of bereaved family in these guidelines, as well as the interpretation of the scope of a bereaved family, is determined by the ethical review committee of each institution, with reference given to the definition of relatives in the "Guidelines for the Implementation of the Act on Organ Transplantation" (established on October 8, 1997, partially revised on May 1, 2012), as well as the "Ethical Guidelines for Medical and Biological Research Involving Human Subjects" (partially revised on March 27, 2023), and "Guidance for the Ethical Guidelines for Medical and Biological Research Involving Human Subjects" (partially revised on April 1, 2024).

Tissue: Material in the stage prior to processing and adjustment, to be supplied to researchers as a sample. Given the nature of the Brain Bank, this mainly refers to brain tissue but can broadly include other organs, spinal cord, cerebrospinal fluid, body fluids, and peripheral organs, depending on the research purpose.

Sample: Material that is supplied from the Brain Bank to researchers and used according to a specific research plan. This generally refers to tissue, in the stage of use, that has been processed and adjusted for individual research applications, such as removing or extracting part of the tissue or fixing it.

Notes

Note 1: "Gift of Hope" is used as a slogan for expressing the purpose of the Brain Bank in many countries.

Note 2: Result of the review by the Law Ethics Committee of the Ministry of Education, Culture, Sports, Science and Technology Strategic Research Program for Brain Sciences refers to “Research on development of a brain base aimed at securing research resources for overcoming mental and neurological disorders.”

Note 3: These guidelines do not restrict the collection and registration of cases from the antemortem stage, which is conducted with the understanding and cooperation of the patients themselves (or individual who makes decisions on their behalf depending on their ability to make decisions) and with the approval and supervision of the ethics committee at each institution. Even in such cases, postmortem examination and the handling of tissues and samples are based on the premise of consent from the bereaved family.

VIII. Implementation date

These guidelines were implemented from September 26, 2015, onwards (this was approved by the Japanese Society of Pathology on February 5, 2016, following minor typographical revisions. April 27, 2018: This was approved by the Japanese Society of Biological Psychiatry following minor revision due to the amendment of Ethical Guidelines for Medical and Health Research Involving Human Subjects and Ethical Guidelines for Human Genome / Gene Analysis Research. June 24, 2018: This was approved by the Japanese Society of Neuropathology. June 26, 2025: This was approved following minor revisions based on the Ethical Guidelines for Medical and Biological Research Involving Human Subjects.)