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Special Feature Article

Response to the New Ethical Guidelines at National Center of Neurology and Psychiatry: Focusing on the Case of the Mental Illness Registry

Hideki OI

Department of Clinical Data Science, Clinical Research & Education Promotion Division,
National Center of Neurology and Psychiatry

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Abstract

The new ethical guidelines came into effect on June 30,2021. The main revisions are as follows: (1) the introduction of the principle of "central ethical review" (one research, one review), (2) the establishment of "research collaborating institutions," and (3) the establishment of "e-consent" (electronic informed consent).

Regarding (1), a central ethical review could be conducted based on a request from the head of the research institution, and the operation of such a review was limited to cases where the institution did not have its own ethical review committee. In addition, the ethical review committee was positioned as an advisory body to the head of the research institution who then had the final responsibility. Under the new ethical guidelines, as in the case of the Clinical Trials Act, the principal investigator will apply to the ethical review committee, and after its review, the head of the research institution will grant permission for the research to be conducted at each research institution.

Concerning (2), when new samples and information were obtained for research purposes, it was necessary to develop a system similar to that of a researcher/research institution, such as applying for ethical review, attending research ethics education, and managing conflicts of interest. Under the new ethical guidelines, it is possible for an institution to be positioned as a "research collaborating institution", which is not a

researcher/research institution, even in cases where samples and information are newly obtained or provided.

As for (3), the new ethical guidelines recognize the use of information and communication technology to obtain informed consent for research participation. It is expected that multimedia-based explanations and electronic signatures would facilitate research participation from remote locations.

In this paper, I would like to introduce the response to the new ethical guidelines at National Center of Neurology and Psychiatry, focusing on the case of the Mental Illness Registry, and to consider strategies for the smooth implementation of the new ethical guidelines and further promotion of non-interventional clinical trials.

Keywords: mental illness registry, ethical guidelines, central ethical review, research collaborating institutions, e-consent

Introduction

The "Ethical Guidelines for Medical and Health Research Involving Human Subjects" (hereinafter referred to as the "Guidelines for Medical and Health Research") were announced on March 23, 2021 and came into effect on June 30 of the same year.³⁾ The main revisions were: (i) introduction of the principle of "collective review" (one review per research), (ii) establishment of "research collaborating institutions," and (iii) introduction of "e-consent" (electromagnetic consent).

Regarding (i), central ethical review had been possible based on the request of the head of the research institution in the past, but its operation was limited to cases where the institution did not have its own ethical review committee.

In addition, the ethics review committee was an advisory body to the head of the research institution, and that head was considered to be ultimately responsible. Under the Guidelines for Medical and Health Research, the principle is to conduct a batch review. As in the case of the Clinical Trials Act, the principal investigator collectively applies to a single ethics review committee, and each research institution obtains permission for implementation from the head of the research institution after the batch review. The ethics review committee, as an independent entity, is responsible for reviewing the research plan, the principal investigator is responsible for conducting the research, and the head of the research institution is responsible for supervision, thereby

clarifying the division of responsibility among the three parties.

Regarding (ii), for an institution that obtains new samples and information for research purposes, that institution is positioned as a research institution, and is required to maintain a system as a research institution, including application for ethics review, participation in research ethics education, and conflict of interest (COI) management. Exceptionally, only in the case of providing existing samples and information, the scheme was permitted without the responsibility of the researchers/research institutions. In the Guidelines for Medical and Health Research, it is now possible to be positioned as a "research collaborating institution" that is not a researcher or research institution, even when acquiring or providing new samples and information.

Regarding (iii), the use of information and communication technology (ICT) to obtain consent for participation in research was approved. The use of multimedia-based explanation of consent and electronic signatures is expected to facilitate participation in research from remote locations.

In this article, we will introduce the National Center of Neurology and Psychiatry's response to the Guidelines for Medical and Health Research, focusing on the mental illness registry,

and consider how to smoothly implement the Guidelines for Medical and Health Research and further promote non-interventional research.

I. Overview of the Mental Illness Registry

The Agency for Healthcare Research and Quality (AHRQ) defines a patient registry as "a patient registry that uses observational research methods to assess specific outcomes in a population defined by a particular disease, condition, or exposure. A patient registry is defined as "an organized system for collecting uniform data (e.g., clinical information) using observational research methods to evaluate specific outcomes in a population defined by a particular disease, condition, or exposure, and serving a predetermined scientific, clinical, or policy purpose."¹⁾ In the field of psychiatry, the definition includes a large cohort on mood disorders,²⁾ a large sample of patients with psychotic symptoms (schizophrenia, schizoaffective disorder, bipolar disorder),⁷⁾ and a longitudinal study of subjects with specific mutations (deletions or duplications in 16p11.2 and 1q21.1) involved in the development of autism spectrum disorders and neurodevelopmental disorders,⁶⁾ but all of them are from overseas. In Japan, "Research to

develop new diagnostic and therapeutic methods by establishing and integrating a mental illness registry (project number: 18dk0307081h0002)" (PI: Kazuyuki Nakagome) was adopted by the Comprehensive Research and Development Project on Disability Measures (Mental Disorders) of the Japan Agency for Medical Research and Development in FY2018. The National Center of Neurology and Psychiatry and Japanese Society of Psychiatry and Neurology are playing central roles in operations throughout Japan and management of the registry.

1. Overall Concept of the Mental Illness Registry

The overall concept of the mental illness registry is shown in Figure 1. In this study, in addition to the "layer 1" clinical information of the subject's basic information [demographic information, diagnosis, allergies, family history, past medical history, history of suicide attempts, history of smoking, problem drinking, substance abuse, educational background, occupation, schooling and employment status, marital status, family structure, care giver status, medical history, examination (brain imaging and function, blood chemistry, ECG/X-rays, and abnormal findings), prescription history (5 years), history of non-medication treatment, behavioral

restrictions, and receipt of disability welfare services], "layer 2" clinical information on emotional valence, cognitive function, social function, sleep, QOL, and biomonitoring information by wearable devices reflecting functional domains are added.

The "layer 2" is classified into "layer 2a," which collects QOL, emotional valence, and sleep items electronically from the research subjects themselves in a self-administered form, and biological monitoring information such as heart rate, respiration rate, active time, sleep duration, sleep score, and stress-related values calculated from heart rate and other factors through wearable devices, and "layer 2b," which collects evaluation results from physicians and evaluators of mental symptoms, cognitive function, social function, etc., from various medical institutions. Furthermore, information such as subject identification code (primary ID), unique ID (secondary ID), and donor ID (tertiary ID) are used to link the biological samples and information [biological samples: 20 mL blood (serum, plasma), 10 mL spinal fluid, brain tissue, biological information: information obtained from analysis of biological samples, and brain neuroimaging (3D-T1, 3D-T2, rsfMRI, DTI, NRC), EEG (clinical data, biological information by portable EEG), polysomnography (clinical data), ECG

(clinical data), and information from analysis] with the clinical information in layers 1 and 2 to follow the longitudinal course.

Based on the aggregated big data, we will identify an analysis method to extract a homogeneous population, and promote personalized treatment and standardization of psychiatric care based on elucidation of the etiology and pathology of the patients. In collaboration with the Japanese Society of Psychiatry and Neurology, the Japan Psychiatric Hospitals Association, the Japanese Association of Newro-Psychiatric Clinics, patient and family associations, and companies, we are also working on the selection of data collection items, patient registry management, informed consent, secondary use, and third party use, including not only domestic companies but also foreign companies, from a broad perspective.⁵⁾

2. Management of Samples and Information in Mental Illness Registry

Figure 2 shows the management of clinical information and catalog information of biological samples and information in the mental illness registry. Data sources and collection methods in the mental illness registry vary. The clinical information in layers 1 and 2 (a and b) and the catalog information in layer 3 (biospecimens

and information) are stored and managed in an "integrated database" that integrates data from the same research subjects using a unique ID (secondary ID). The data center established in the academic research organization (ARO) function of the National Center of Neurology and Psychiatry manages the integrated database, cleans the data, creates datasets for data utilization, and prepares and stores documents and records related to these activities.

The information for layer 1 is collected from discharge and outpatient summaries in electronic medical records (input screens are created in advance using a template function), or CSV data extracted from discharge summaries and outpatient summary creation tools from a Web system called the "basic information input system" are imported into the integrated database. The information in layer 2a is automatically collected in the integrated database by the electronic patient-reported outcomes (ePRO) product through the personal information management system and ePRO database. Biomonitoring information from smartwatches and other devices will be imported into the integrated database from an external database, from which the extracted data were entered. For the collection of layer 2b information and layer 3 catalog information, case report

form (CRF) information in electronic media is registered in the data center as electronic data capture (EDC), and then imported into the integrated database. For the utilization of registry data, the data center will assign a provisional ID (tertiary ID) for clinical information and give it to the client (researcher, company, etc.). For biological samples and information, the data center will create a table of correspondence between the research subject identification code (primary ID) and provisional ID (tertiary ID) for the research institution that owns the samples and information, and the samples and information to which the provisional ID (tertiary ID) is assigned by the research institution will be given to the client (researcher, company, etc.).

As security measures of the system, each database is built on Amazon Web Services (AWS) servers in Japan (in compliance with domestic laws), and data are encrypted in the infrastructure layer so that third parties cannot read the data even if the AWS servers are physically damaged. Information immediately associated with specific individuals, such as names, telephone numbers, and e-mail addresses, is stored only in the personal information management system, and can only be viewed by personnel at the ePRO office (set up independently from researchers

and the data center), who require direct contact with the subjects themselves.

3. Operation and Management System of the Mental Illness Registry

The operation and management system of the mental illness registry is shown in Figure 3. First, the "Council for the Promotion of the Mental Illness Registry" (hereinafter referred to as the "council") will be established, and the council will be the registry holder to establish, operate, and manage the mental illness registry. A steering committee will be established to determine the management and activity policies of the council, and will be responsible for the overall management of the registry.

The members will consist of institutions and individuals who agree with the activities of the mental illness registry and have been approved by the steering committee (general members), and organizations that are willing to support the activities of the council and have been approved by the steering committee (corporate members). The principal investigator of "Research for the development of new diagnostic and therapeutic methods through the establishment and integration of a mental illness registry (Principal investigator: Kazuyuki Nakagome)," which is research related to the establishment of the mental illness

registry, will serve as the president of the council. At present, applications for the provision of samples and information for research using data collected in the registry may only be made by members of the promotion council.

The steering committee will be chaired by the president of the council and consists of three members recommended by the Promotion Committee on Psychiatric Research of the Japanese Society of Psychiatry and Neurology, two members recommended by principal investigators, one member recommended by the Japanese Psychiatric Hospital Association, one member recommended by the Japanese Association of Neuropsychiatric Clinics, and two members comprising patients and their families. Matters to be resolved by the steering committee include: determination of management policy, determination of activity policy, income and expenditure of the council, appointment and dismissal of the chairperson and members of the Information Review Committee, appointment and dismissal of the executive director of the mental illness registry office, progress management of the mental illness registry, and matters concerning the adoption of clinical trials and clinical research utilizing the mental illness registry and management of the progress thereof.

The rules for the utilization of data will be established by the information provision review committee, and the review system will be established after approval by the steering committee. When an application for data utilization is submitted by a client (researcher, company, etc.), the steering committee will request the information provision review committee to review the application, and upon receiving a report on the results, the committee will determine whether the data can be utilized. The client submits a report on the progress of the research to the steering committee office once a year, and the information provision review committee reviews the annual report from the client as necessary. The information review committee consists of: the director of the psychiatric department of the National Center of Neurology and Psychiatry, one person with expertise in medicine, dentistry, pharmacology, or clinical trials at the National Center of Neurology and Psychiatry, and three persons recommended by the ethics committee of the Japanese Society of Psychiatry and Neurology.

II. Handling of the "Collective Review" (one study, one review)

Table 1 shows the status of central ethical review in the mental illness registry. The Ethics Committee of the

National Center of Neurology and Psychiatry has been working on central batch ethics review since before implementation of the Guidelines for Medical and Health Research, based on its participation as a research development subcommittee in the "Development of Infrastructure for a Central Ethics Committee for Non-interventional Research" project for the central clinical trial review committee and central ethics review committee infrastructure development project of the Japan Agency for Medical Research and Development in FY2019. The research involved in the establishment of a psychiatric disease registry was conducted by the following research groups.

The research on the construction of a mental illness registry was the first project to undergo central batch ethics review by the Ethics Committee of the National Center of Neurology and Psychiatry. After a new ethics application was submitted on November 5, 2019, and after two rounds of ethics review and "approval with conditions" review results, compliance with the conditions for approval was confirmed and approval was granted on January 22, 2020. Subsequently, permission to conduct the research was obtained from the head of the research institution on January 28, 2020.

In the initial ethics reviews, those reviews for Nagoya University, Akita University, Hokkaido University, and Keio University were conducted in batches, after which permission was obtained from each research institution. After implementation of the Guidelines for Medical and Health Research, the "Request form for Ethical Review," which was previously required to be submitted as a document issued by the head of each research institution, was abolished, and the form was replaced by a batch application for ethics review from the principal investigator, as specified in the Guidelines for Medical and Health Research.

III. Response to "Research Collaborating Institutions"

Table 2 gives an overview of the "research collaborating institutions" specified as a new track in the Guidelines for Medical and Health Research. Research collaborating institutions can be regarded as other than researcher/research institutions even when acquiring and providing new samples and information, and are not required to apply for ethical review, participate in research ethics education, or manage conflicts of interest (COI), as required of researchers/research institutions.

In cases that fall under the category of "minor invasiveness" as defined in the

Guidelines for Medical and Health Research Part 2 (2) "Invasiveness," such as additional QOL surveys and small additional blood sampling, the institution can provide data as a research collaborating institution. In the mental illness registry, it is expected that the research collaborating institution scheme will lead to the collection of a large number of samples and more information in the future. The "Guidelines for Medical and Health Research" states: "For example, when MR imaging without contrast media is performed for research purposes, if the injury and burden caused to the research subject's body by the imaging is considered to be small, and if the research subject's body and mind are not burdened by restrictions on behavior for a long period of time, the imaging may be considered minor invasiveness." Therefore, in the case of prospective MR imaging, if the physical or mental burden on the research subject is significant, it does not fall under the category of minor invasiveness, and the institution should be positioned as a research institution rather than a research collaborating institution.

In addition, physicians in research collaborating institutions are obliged to report adverse events and are not allowed to obtain informed consent (although they are required to confirm

that consent has been obtained). In the case of collecting samples and information from research collaborating institutions in the mental illness registry, the e-consent (electromagnetic consent) specified in the Guidelines for Medical and Health Research should be utilized, and informed consent should be obtained by connecting the research institution and research collaborating institutions via telecommunication lines.

IV. Utilizing of e-consent (electromagnetic consent)

The Guidelines for Medical and Health Research clearly state "e-consent," and Table 3 shows specific examples of identification (identity verification, authentication) in the case of non-face-to-face contact. In the mental illness registry, as described in the document for the management of samples and information in Figure 2, informed consent for the overall research is first obtained in writing at the medical institution, and consent for data entry into ePRO is also obtained in the ePRO product at the time of collection for layer 2a information.

The specific procedure is as follows: (i) each medical institution enters the email address of the research subject along with the research subject identification code (primary ID); (ii) an email is sent to the registered research

subject's email address for them to accept the registration; (iii) the research subject clicks on the URL in the email, enters the password and marks the check box for "I agree to use the input and log into the mental illness registry," and clicks "Complete Registration" (consent to use ePRO products); (iv) an e-mail is sent to the registered research subject's e-mail address confirming completion of registration, and the user name (ePRO registration number: 6 digits) in the email should be recorded; (v) the research subject clicks on the URL in the e-mail, enters the user name (6 digits) and password set by the research subject him/herself, and clicks "Login"; (vi) the home screen of ePRO input is displayed; (vii) the subject clicks the "Edit" button of the layer 2a information item to be answered, and then answers the question.

Although various discussions and examinations are in progress regarding e-consent (electromagnetic consent) using digital devices, this system of consent for the use of ePRO products in the mental illness registry has the potential to lead to the identification of individuals (personal authentication) in the case of non-face-to-face contact.

Conclusion

This article outlines the National Center of Neurology and Psychiatry's response to the Guidelines for Medical

and Health Research, focusing on the case of the mental illness registry. The main revisions to the Guidelines for Medical and Health Research were: (i) introduction of the principle of "collective review" (one research, one review), (ii) establishment of "research collaborating institutions," and (iii) introduction of "e-consent," which promote multi-institutional, non-interventional, prospective observational studies, such as those related to establishment of the mental illness registry, as well as studies related to the secondary use and third-party provision of aggregated data.

We hope to build a large patient registry across a wide range of diagnostic categories with the understanding of larger numbers of the public, patients, and research personnel, to realize personalized medicine in the field of psychiatry, to contribute to the social participation and well-being of many patients with mental disorders and their families by promoting the standardization of psychiatric care, and develop novel medical technologies such as drugs, medical devices, and regenerative medical products by elucidating the pathophysiology of homogeneous groups of patients.

Editor's note: This special feature article was based on the symposium held at the 117th Annual Meeting of the

Japanese Society of Psychiatry and Neurology, with Chieko Kurihara (Quantum Science and Technology) as a representative.

There are no conflicts of interest to disclose in connection with this article.

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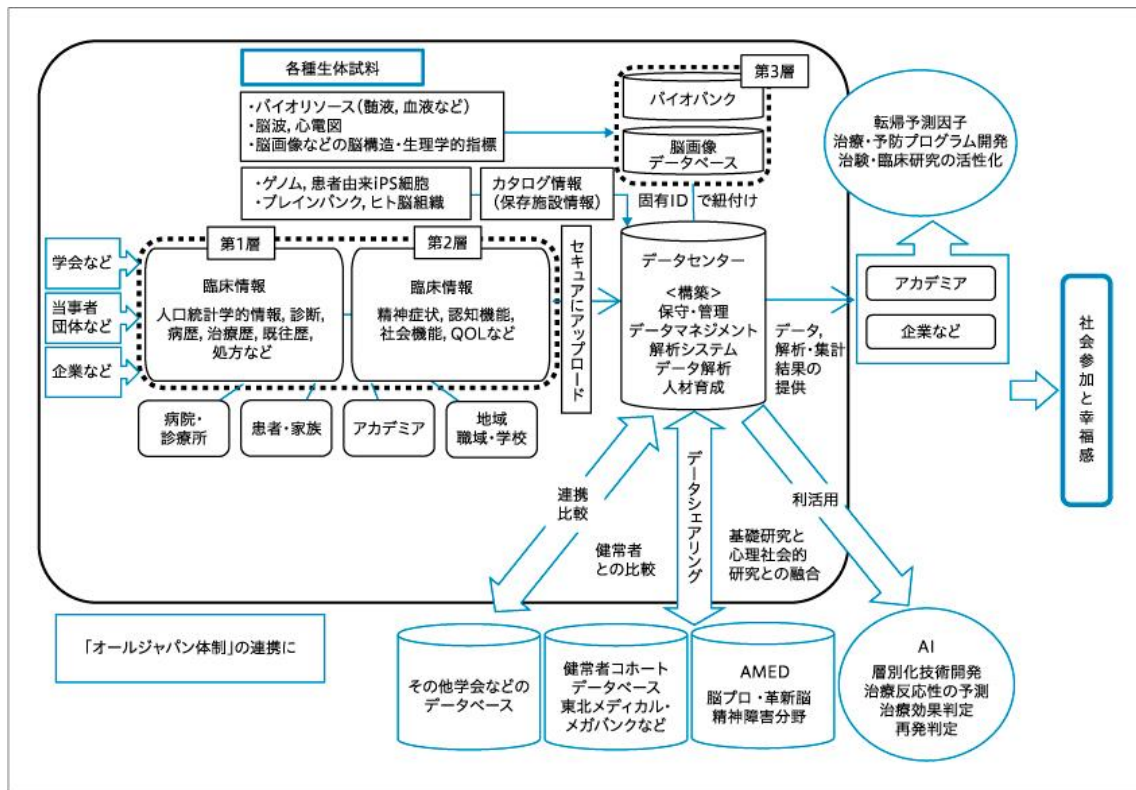


図1 精神疾患レジストリの全体構想
(文献5より改変して引用)

Figure 1. Overall Concept of the Mental Illness Registry
(Adapted from Reference 5)

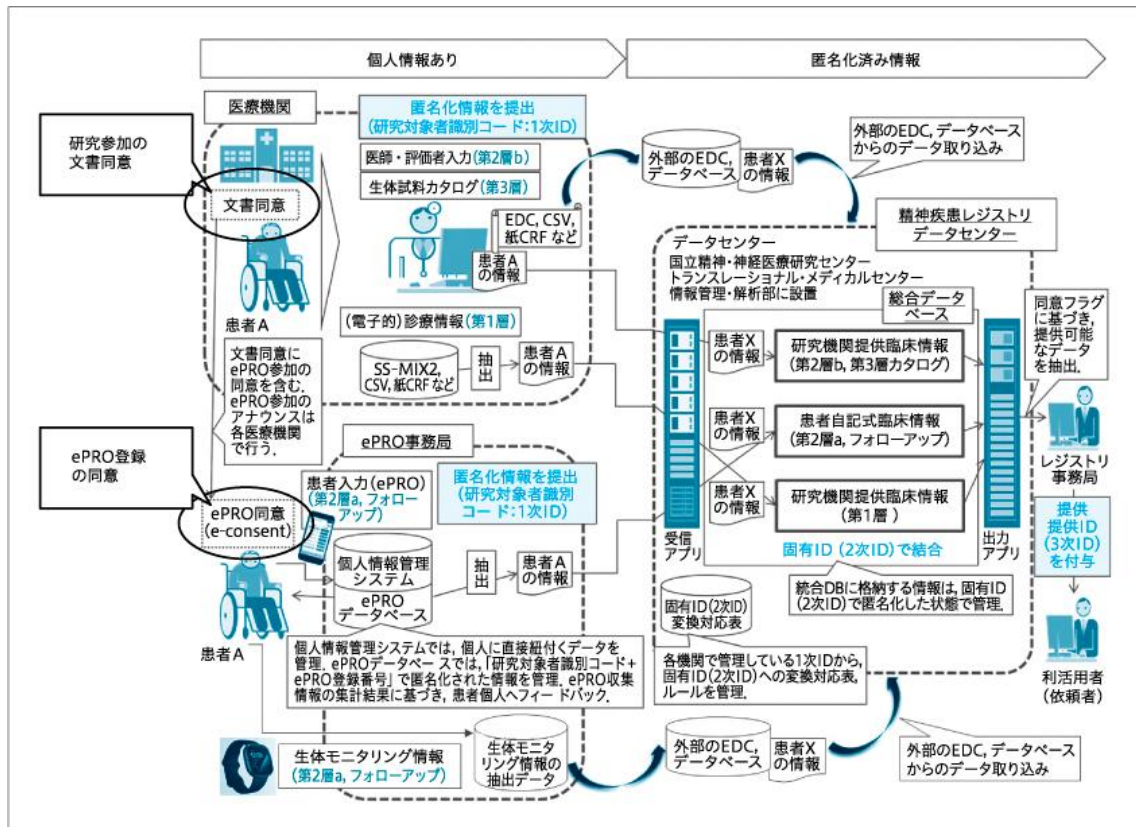


図2 精神疾患レジストリにおける試料・情報の管理

Figure 2. Management of Samples and Information in the Mental Illness Registry

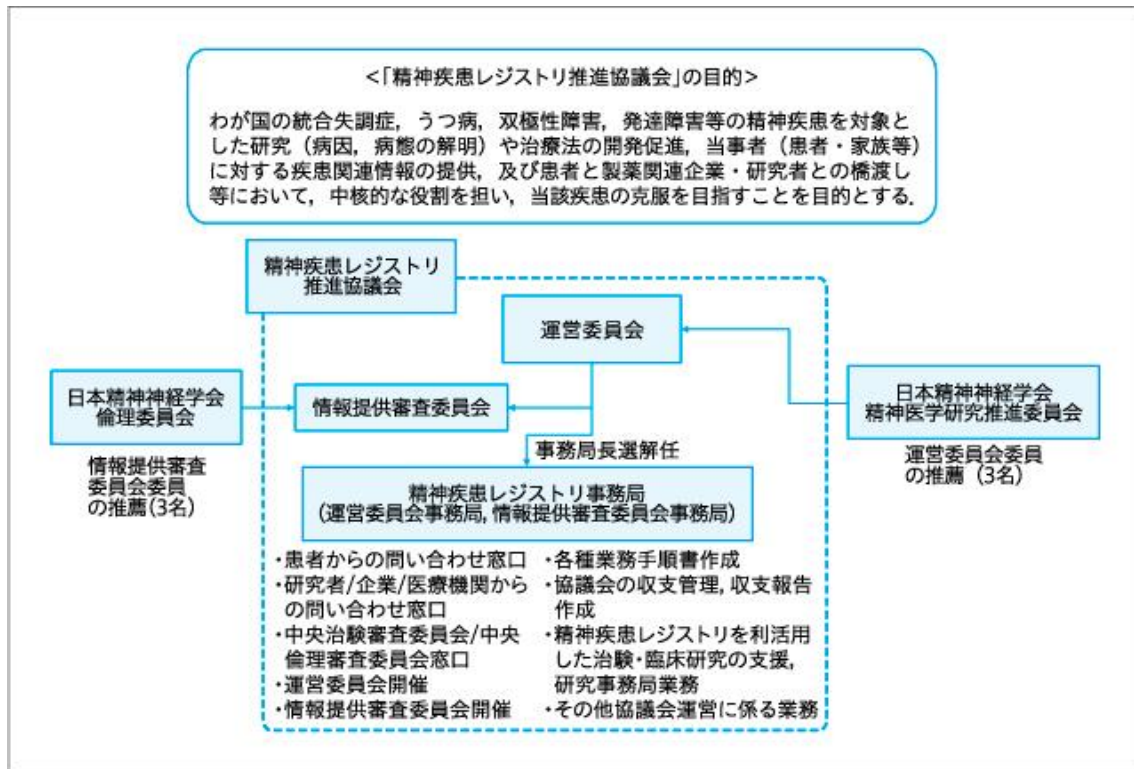


図3 精神疾患レジストリの運営・管理体制

Figure 3. Operational and Management Structure of the Mental Illness Registry

表 1 中央一括倫理審査：精神疾患レジストリ（AMED・パイロット）

2019年11月5日（火）：新規倫理申請（国立精神・神経医療研究センター倫理委員会）

2019年12月17日（火）：第1回 会議体倫理委員会審査

2020年1月10日（金）：第2回 会議体倫理委員会審査（条件付き承認）

承認条件への対応⇒2020年1月22日 承認

【中央一括倫理審査の状況】

	倫理審査委託依頼書	倫理審査結果通知書	機関長の実施許可日
国立精神・神経医療研究センター	—	2020年1月22日	2020年1月28日
名古屋大学	2019年11月22日	2020年1月28日	2020年2月20日
秋田大学	2019年12月7日	2020年1月28日	2020年3月4日
北海道大学	2019年12月17日	2020年1月28日	2020年3月23日
慶應義塾大学	2019年12月23日	2020年1月28日	2020年2月4日
関西医科大学	2020年9月29日	2020年11月26日	2020年12月23日
奈良県立医科大学	2020年10月28日	2020年11月26日	2020年12月22日
千葉大学	2020年12月25日	2021年1月14日	2021年6月16日
獨協医科大学	(不要)*	2021年8月5日	2021年8月26日

*2021年6月30日の生命科学・医学系指針施行に伴う倫理審査書式の変更のため

Table 1. Central Batch Ethical Review: Mental Illness Registry (AMED pilot)

Tuesday, November 5, 2019: New ethics application (National Center of Neurology and Psychiatry Ethics Committee)

Tuesday, December 17, 2019: First conference ethics committee review

Friday, January 10, 2020: 2nd conference ethics committee review (approval with conditions)

Response to conditions for approval ⇒ Approved on January 22, 2020

[Status of central batch ethics review]

Ethics review commission request form

Ethics review result notification form

Date of approval for implementation by the head of the institution

National Center of Neurology and Psychiatry - January 22, 2020/ January 28, 2020

Nagoya University - November 22, 2019/ January 28, 2020/ February 20, 2020

Akita University - December 7, 2019/ January 28, 2020/ March 4, 2020

Hokkaido University - December 17, 2019/ January 28, 2020/ March 23, 2020

Keio University - December 23, 2019/ January 28, 2020/ February 4, 2020

Kansai Medical University - September 29, 2020/ November 26, 2020/ December 23, 2020

Nara Medical University - October 28, 2020/ November 26, 2020/ December 22, 2020

Chiba University - December 25, 2020/ January 14, 2021/ June 16, 2021

Dokkyo Medical University - (Not required)* / August 5, 2021/ August 26, 2021

* Due to changes in ethics review forms following the enforcement of the Guidelines for Medical and Health Research on June 30, 2021.

表 2 研究協力機関：精神疾患レジストリでの活用

<p>これまでの倫理指針</p> <p>研究にかかわる人は、ほぼ「研究者等」に該当し、その所属先は「研究機関」(研究目的で新たに試料・情報を採取する場合)</p> <ul style="list-style-type: none"> ・既存試料・情報の提供のみを行う者、および委託を受けて研究に関する業務の一部に従事する者(委託契約に基づく)を除く <p>倫理審査申請, 研究倫理教育の受講, 利益相反(COI)管理など, 研究機関としての体制整備が求められる</p>
<p>生命科学・医学系指針：新たなトラック</p> <p>新規に試料・情報の取得・提供を行う場合であっても, 研究者/研究機関ではない位置づけが可能となった.</p> <ul style="list-style-type: none"> ・QOL 調査の追加や少量の追加採血など「軽微な侵襲」に該当する場合は, 研究協力機関としての位置づけにおいて提供が可能 ・「研究協力機関」では, 研究者としての責務を負わなくてよい ・「研究協力機関」の医師は, 有害事象報告の義務は負うが, インフォームド・コンセントの取得はできない(同意取得の確認のみ)

Table 2. Research Collaborating Institutions: Utilization in the Mental Illness Registry

Ethical Guidelines to Date

The person involved in the research is almost always a "researcher, etc." and belongs to a "research institution" (when new samples/information are collected for the purpose of research).

- Excluding those who only provide existing samples/information and those who are engaged in a part of the work related to research under commission (based on a commission contract).

The research institution is required to have a system in place to apply for ethics review, attend research ethics education sessions, and manage conflicts of interest (COI).

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It allows the researcher/institution to be positioned as a non-researcher even when

acquiring/providing new samples/information.

In the case of "minor invasiveness" such as additional QOL surveys or small additional blood sampling, it is possible to provide such information in the position of a research collaborating institution.

"Research collaborating institutions" are not required to assume the responsibilities of researchers.

Physicians at the "collaborating institution" are obliged to report adverse events, but cannot obtain informed consent (only confirmation of consent).

表 3 e-consent (電磁的同意): 非対面での本人確認 (身元確認, 当人認証)

「本人確認」に関して、本人確認とは、手続きを実施する人物が、実在する本人であることを確認することである。非対面の場合、研究者などによる、研究対象者などの身元確認または当人認証の実施が該当し、具体例は以下が考えられる。

①身元確認	<ul style="list-style-type: none"> ・自己申告 ・身分証明書の提示を受ける など
②当人認証	<ul style="list-style-type: none"> ・単要素認証 (例えば、ID と紐付けて、パスワード等の単一の要素を用いる方法) ・多要素認証 (例えば、ID と紐付けて、「知識 (パスワード、秘密の質問など)」「所持 (スマートフォンの SMS・アプリ認証、ワンタイムパスワードのメール送付、トークン、クレジットカードなど)」「生体 (顔・指紋など)」などのうち複数の要素を組み合わせる方法)

(文献 4 より改変して引用)

Table 3. e-consent: Non-face-to-face identification (identity verification, authentication)

"Identification" refers to the confirmation that the person who performs the procedure is the actual person himself/herself. In the case of non-face-to-face procedures, the identification or authentication of the identity of the research subject by a researcher, etc., may include the following specific examples:

(1) Identification

- ・Self-reported identification
- ・Proof of identity, e.g., by asking the subject to present his/her ID card

(2) Identity authentication

- ・Single-factor authentication
(e.g., a method using a single factor such as a password linked to an ID)
- ・Multi-factor authentication
(e.g., a method that combines multiple elements out of "knowledge (password, secret

question, etc.)," "possession (SMS/app authentication on smartphones, one-time password sent by e-mail, token, credit card, etc.)," and "biometric (face, fingerprint, etc.)" in connection with ID

(Adapted from Reference 4)