Questions and Answers to
"Guidelines on Privacy Protection in Journal Publication and Conference Presentations Including Case Reports" by *The Japanese Society of Psychiatry and Neurology*

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This document is a question-and-answer (Q&A) for the "Guidelines on Privacy Protection in Journal Publication and Conference Presentations Including Case Reports" (hereinafter, the JSPN Privacy Guidelines) published by *The Japanese Society of Psychiatry and Neurology* (hereinafter, the JSPN) on January 20, 2018 in light of revisions to the Act on the Protection of Personal Information (hereinafter, the Privacy Act).

The JSPN Privacy Guidelines and this Q&A are intended to present the current views and policies of the JSPN and may be subject to revisions in response to new laws, guidelines and their interpretations that are set forth by the government or academic associations.

Q1. Does consent need to be obtained in writing?

A1. Ideally, an informed consent form should be prepared, and its details should be clearly and thoroughly explained to the patient, after which the patient's written informed consent is obtained. However, an oral informed consent may be considered valid provided that a record of oral informed consent is documented in writing.

Explanations

Informed consent forms should be prepared at each facility, but it is important that the following conditions are met.

1. The aim of the case report is to improve healthcare or contribute to public health, academia, or education.
2. The patient is not subjected to any disadvantages in the care provided whether the patient provides consent, declines from doing so, or withdraws consent at any time.
3. Ensures anonymity and protection of privacy.

A sample informed consent form and explanations are attached. The attached form should be edited as appropriate to suit the conditions and requirements at each facility.

According to the Privacy Act, oral consent can be considered valid (Guidance for the appropriate handling of personal information by health and long-term care providers (hereinafter, the Privacy Act Guidance), p.14). The record of informed consent orally obtained should be documented in patient medical charts.

Q2. What are the procedures necessary in making a case report without obtaining the patient's consent in a case deemed to correspond to an exception in the JSPN Privacy

Guidelines?

A2. Authors presenting a case report in a JSPN publication or conference must specify which exception to the JSPN Privacy Guidelines applies to the case report at the time of submission, and the JSPN will accordingly make the decision as to whether it meets the conditions for an exception.

Q3. Is the consent of the patient concerned necessary for a case series?

A3. Yes, as a general rule, the consent of the person concerned is necessary. However, in certain cases, the informed consent procedure may be simplified in studies conducted as medical research approved by the ethics review board with permission of the director of the institution.

Explanation

A case report is defined as a "report of an individual case presented in in-facility case study conferences, workshops and conferences to present the case outside the facility, or to other medical practitioners through publication in medical journals in the aim of sharing medical information in p. 4 of the "Ethical Guidelines for Medical Research Using Human Subjects" (hereinafter, Ethical Guidelines for Medical Research) Guidance.

When the details of the research are presented in a case series in which multiple cases are presented together as a novel medical finding, the study must conform to the Ethical Guidelines for Medical Research. The JSPN "Guidelines on 'Case Reports Treated as Research Requiring an Ethical Review'" requires an ethical review of "[studies] that involve the use of clinical data such as medical records to accumulate cases." In such cases, informed consent must be obtained as a general rule, but the process may be simplified in certain cases by an opt-out procedure (disclosing information related to the study) to provide an opportunity for the subject to decline as per the provisions of the Ethical Guidelines for Medical Research. In such a case, the research protocol must be approved by the institutional review board and permission must be received from the dean/director of the research institution.

Q4. Is it appropriate to obtain only the consent of the patient or the legal representative for patients who are hospitalized under the Act on Mental Health and Welfare for the Mentally Disabled (e.g., emergency hospitalization, hospitalization for medical care and protection, involuntary hospitalization) or under the Medical Treatment and Supervision Act?

A4. The patient's consent suffices when the patient is deemed to have the capacity to adequately understand the outcomes that may result from providing consent. When the patient is deemed to lack the capacity to make the judgment and a legal representative has been appropriately appointed, the consent of the said legal representative will suffice.

Explanation

Emergency hospitalization, hospitalization for medical care and protection and involuntary hospitalization under the Act on Mental Health and Welfare for the Mentally Disabled or hospitalization under the Medical Treatment and Supervision Act are involuntary in many cases. However, although the two capacities of making judgment on treatment and hospitalization and making judgment on understanding the implications and outcomes of providing consent to become a case report subject may interact and influence each other, they are separate phenomena. Furthermore, in certain cases, the patient may be deemed incapable of making an informed decision at a certain time period, but may then recover their capacity to do so at a later time, and informed consent may be obtained from the patient at that time. Therefore, it is necessary to obtain the patient's consent as much as possible.

When the patient is deemed to lack the capacity of making informed decisions, the consent of the representative is required. However, in appointing the representative, it is important to note that the patient and the appointed representative may have conflicting interests; thus, it is important to consider their relationship in appointing the appropriate representative.

The Ethical Guidelines for Medical Research specify that as much as possible, effort should be made to obtain the informed consent of the patient even if the informed consent of the representative has been obtained (p. 24). Moreover, these policies can provide guidelines for case reports.

Q5. What if the patient is deceased?

A5. If the details of the publication or presentation are deemed to contain personal information of the bereaved family, the family's informed consent is required. If it does not contain personal information of the bereaved family, the case report can be made without the family's consent in certain cases with due consideration for the patient's living will and dignity.

Explanation

The Privacy Act defines personal information as "information related to a living individual" (The Privacy Act Article 2, Paragraph 1). As a general rule, information of a deceased person is not generally considered personal information. However, when the information pertaining to a deceased person is related to information pertaining to living persons, such as the bereaved family, then it corresponds to information related to the said living individual (The Privacy Act Guidance, p.6). Note that in this case, said information must be treated with caution as personal information of the bereaved family.

In the case that the information does not require to be treated as personal information of the bereaved family, the Privacy Act does not apply to the information on the deceased person. However, even in this case, effort should be made to use the deceased person's information with due consideration for the individual's living will and dignity.

Q6-1. Is it unnecessary to obtain informed consent as long as an effort is made to anonymize the case such as changing the profession, sex, or other characteristics?

A6-1. Accurate description is a requirement to ensure scientific and academic integrity. Therefore, the JSPN does not allow case reports with changes to factual details.

Q6-2. Is it appropriate to use a different name for the subject in a case report and write beside this name “pseudonym” so as to avoid revealing their identity?

A6-2. Rather than using pseudonyms, case reports in the JSPN should use abbreviations such as “Case A” such that it is clear that the names have been systematically anonymized.

Q6-3. Does the use of alphabet letters for proper nouns to avoid revealing the subject’s identity compromise factuality?

A6-3. For example, proper nouns can be renamed in alphabetical order such as “A,” “B” or “C” such that it is evident that the names were systematically changed. This does not provide grounds for alteration of facts. Using the first letter of the actual name is not recommended because it would involve greater chances of revealing the individuals’ identity than would the systematic method of assigning letters alphabetically.

Q6-4. Is it unnecessary to obtain informed consent if multiple cases are combined into one?

A6-4. For pedagogic purposes, the presentation of fictional cases may be allowed. However, this is not true for case reports. When “multiple cases are combined” or “an actual case is modified,” data about existing cases will be retained in some form, which makes it difficult to completely prevent the risk of revealing their identities. Therefore, in publishing or presenting a case report without obtaining informed consent, it is ideal to present a “fictitious” case and to explicitly indicate that the said case is fictitious.

References:

Ethical Guidelines for Medical and Health Research Involving Human Subjects (abbreviated as the Ethical Guidelines for Medical Research) http://www.lifescience.mext.go.jp/files/pdf/n1443_01.pdf

Ethical Guidelines for Medical and Health Research Involving Human Subjects Guidance (abbreviated as the Ethical Guidelines for Medical Research Guidance)

http://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/0000166072.pdf

Act on the Protection of Personal Information (abbreviated as the Privacy Act)
https://www.ppc.go.jp/files/pdf/290530_personal_law.pdf

Guidance for the Appropriate Handling of Personal Information by Health and Long-term care Providers (abbreviated as the Privacy Act Guidance)
https://www.ppc.go.jp/files/pdf/iryoukaigo_guidance.pdf

Questions and Answers related to the “Guidance for the Appropriate Handling of Personal Information by Health and Long-term Care Providers” (Case studies) (abbreviated as the Privacy Act Guidance Q&A)
https://www.ppc.go.jp/files/pdf/iryoukaigo_guidance_QA.pdf

Guidelines on Patient Privacy Protection in Medical Article Publication and Conference Presentations of Conference Presentations and Medical Reports including Case Reports (The Japanese Society of Psychiatry and Neurology) (abbreviated as the JSPN Privacy Guidelines)
https://www.jspn.or.jp/modules/info/index.php?content_id=583

Note:

These guidelines cover case reports to which Japanese laws and regulations apply. Case reports to which the laws and regulations of other regions apply must comply with the relevant laws and regulations.