

Personal data protection (publication consent)

대한의학학술지편집인위원회 부회장
Annals of Dermatology, 대한피부과학회지 편집장
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학술지 논문 출판 시 환자의 개인정보 보호에 관한 권고안 제정

2017.11.30. 의학학술지편집인협의회 출판윤리위원회

- 최근 ICMJE와 많은 학술지에서 환자의 개인정보를 보호하려는 시도가 강화되면서 일부 학술지에서는 이미 관련 내용을 투고규정에 포함 또는 개정하고 있다. 출판윤리의 저변확대를 위해 의학학술지편집인협의회 출판윤리위원회에서는 각 회원 학술지 편집인께 출판물에 불필요한 환자의 개인정보가 드러나지 않도록 개인정보 보호와 관련된 투고규정의 개정을 포함한 윤리적, 제도적 장치를 보완해 줄 것을 요청한다.
- 환자는 사생활을 보호받을 권리가 있으며, 개인정보는 반드시 필요한 경우가 아니면 공개해서는 안 된다. **출판물에 환자의 이름, 이름의 머리글자, 병록번호, 사진, 가계 등 식별 가능한 정보는 어느 형태로든 출판할 수 없다. 불필요한 환자의 세부개인정보는 가능한 생략한다.** 단, 과학정보로서 환자의 개인정보 노출이 필수불가결한 경우에는 출판 전 환자 또는 환자의 법정대리인에게 이를 설명하고, 서면으로 동의서를 취득해야 한다. 또한 이때 환자의 개인정보가 출판물뿐만 아니라, 인터넷 등을 통해 공개될 가능성이 있음을 고지해야 한다.
- 학술지 편집인은 대상자 동의서 취득을 포함한 환자의 개인정보 보호 관련 규정을 반드시 학술지 투고규정에 포함시키고, 게재 논문에도 정보에 입각한 환자(또는 법정대리인)의 자발적 서면 동의 취득을 표시해야 한다. 학술지 편집인은 개별적 관련 규정에 따라 취득한 서면 동의서를 보관하거나 혹은 보관과정에서 환자의 개인정보 식별이 우려되는 경우 저자가 서면 동의서를 보관하도록 하고, 대신 동의서를 규정에 따라 취득하여 보관하고 있음을 증명하는 내용을 논문에 표시하도록 한다. 한편, 환자의 익명성을 유지하기 위한 보호 과정에서 편집인은 원 자료의 과학적 의미를 왜곡시키지 않도록 주의해야 한다. 즉, 학술지는 사례발표를 포함한 사람을 대상으로 하는 연구를 보고할 때는 대상자(환자) 동의서와 관련한 규정을 투고규정에 반드시 포함시켜야 하며, 대상자 동의서를 취득한 경우에는 게재하는 논문에 이를 적시하여야 한다.
- <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/protection-of-research-participants.html>

각국의 개인정보보호법

- EU: General Data Protection Regulation(GDPR) 2016/679 <https://eugdpr.org>
- 미국: The Health Insurance Portability and Accountability Act of 1996 (HIPAA) <https://www.hhs.gov/hipaa/index.html>
- 캐나다: Personal Information Protection and Electronic Documents Act <https://www.priv.gc.ca/en/privacy-topics/privacy-laws-in-canada/the-personal-information-protection-and-electronic-documents-act-pipeda/>
- 인도: Information Technology Act and related Privacy Rules <http://www.meity.gov.in/content/information-technology-act>
- 한국: 개인정보보호법 <https://www.privacy.go.kr/main/mainView.do>

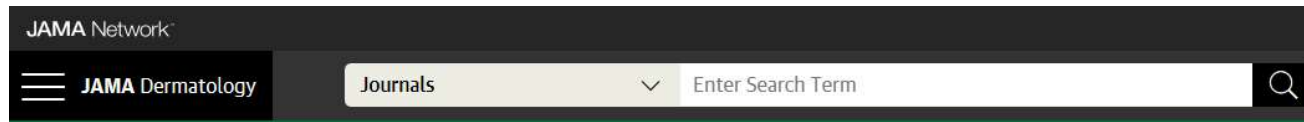
개인정보 보호법

- 모든 부분에서 개인정보보호를 명문화하고, 이의 철저한 준수와 함께 제도 보완을 요구하고 있으며, 개인의 동의가 철회되면 즉시 개인 정보의 사용을 중단하도록 함.
- 학술지: 개인의 동의 없이 가계도나 개인정보가 노출될 수 있는 사진 등을 게재하지 못하며, 게재할 경우에도 완성된 논문의 형태에서 그대로 사용되는 것을 보여주고 동의를 구할 것을 요구. 특히 소아의 경우 부모나 법적 대리인의 동의를 필수적으로 구하도록 함.

Journals' Best Practices for Ensuring Consent for Publishing Medical Case Reports: guidance from COPE

- The publication of case reports is a common practice in medical journals, and increasingly in basic science journals when an article illustrates a specific scientific point (e.g., a genetic phenotype). There is no doubt that case reports are valuable in the academic literature. However, they pose a specific ethical challenge for journals because, by their very nature, individuals in reports are highly identifiable. Hence, journals must ensure that proper consent for publication has been obtained and that the individual(s) who is being reported on is aware of the possible consequences of that reporting.
- [Best Practices for Ensuring Consent for Publishing Medical Case Reports guidance from COPE.pdf](#)

Requirements for Reporting by JAMA Network



from the study participants (ie, oral or written) and whether participants received a stipend. Editors may request that authors provide documentation of the formal review and recommendation from the institutional review board or ethics committee responsible for oversight of the study.

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Patient Identification

A signed statement of informed consent to publish patient descriptions, photographs, video, and pedigrees should be obtained from all persons (parents or legal guardians for minors) who can be identified (including by the patients themselves) in such written descriptions, photographs, or pedigrees and should be submitted with the manuscript and indicated in the Acknowledgment section of the manuscript. Such persons should be offered the opportunity to see the manuscript before its submission.^{2(pp229-232)}

Omitting data or making data less specific to deidentify patients is acceptable, but changing any such data is not acceptable. Only those details essential for understanding and interpreting a specific case report or case series should be provided. Although the degree of specificity needed will depend on the context of what is being reported, specific ages, race/ethnicity, and other sociodemographic details should be presented only if clinically or scientifically relevant and important.² Cropping of photographs to remove identifiable personal features that are not essential to the clinical message may be permitted as long as the photographs are not otherwise altered. Please do not submit masked photographs of patients. Patients' initials or other personal identifiers must not appear in an image.

Patient Permission Form:

The Patient Permission form for publication of identifying material is available [here](#). Translated versions in Arabic, Chinese, French, German, Hindi, Italian, Japanese, Portuguese, and Spanish are available on request.

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Patient Consent Form



Consent for Publication of Identifying Material in JAMA Network Journals

I give my permission for the following material to appear in the print, online, and licensed versions of JAMA Network Journals and for the JAMA Network Journals to grant permission to third parties to reproduce this material.

Title or subject of article or photograph, video, or audio:

I understand that my name will not be published but that complete anonymity cannot be guaranteed.
Please check only 1 box below after reading each statement.

- I have read the manuscript or a general description of what the manuscript contains and reviewed all photographs, illustrations, video, or audio files (if included) in which I am included that will be published.
- I have been offered the opportunity to read the manuscript and to see all photographs, illustrations, video, or audio files (if included) in which I am included, but I waive my right to do so.

Signed

Date

Print name

If you are granting permission for another person, what is your relationship to that person?

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The NEW ENGLAND JOURNAL of MEDICINE

Identifiable Patients

Authors should remove information from photographs and manuscripts that might identify a patient. Where this is impossible, submissions must be accompanied by a written release from the patient. One option is the [NEJM Release Form for Photographs of Identifiable Patients](#).

CONSENT FORM

**Patient's consent for the publication of material relating to him or her in
*The NEW ENGLAND JOURNAL of MEDICINE***

Description of article, content or photograph (the "Material"): _____

Name of author submitting the Material: _____

Contribution number (if known): _____

To be completed by the patient:

I give my consent for all or any part of the material referenced above to appear in publications of the Massachusetts Medical Society ("Society") in any media worldwide, including *The New England Journal of Medicine* and any derivative works or products. I understand that the Material may depict my medical conditions.

I understand that:

- My name will not be published with the Material by the Society and the Society will endeavor to maintain my anonymity. I understand, however, that it is possible that someone may recognize me from the images and/or accompanying content.
- The use of the Material relating to me may include, without limitation, publication in the printed and electronic editions of Society publications, on websites, in sublicensed or reprinted editions (including foreign language editions), and in other derivative works or products.
- I grant and release to the Society all rights, title, and interest that I may have in the Material. I understand that I will not receive, and am giving up any claim to receive, any payment or royalties in connection with the use of the material
- The Material may be edited, modified, and retouched.

PATIENT:

Signed: _____ Date _____

Print name: _____

Address: _____

If you are not the patient, what is your relationship to him/her

Witness: _____ Date: _____

Patient Consent Forms and Patient Details

- Written consents must be retained by the author and copies of the consents or evidence that such consents have been obtained must be provided to Elsevier on request. For more information, please review the Elsevier Policy on the Use of Images or Personal Information of Patients or other Individuals, <http://www.elsevier.com/patient-consent-policy>. Unless you have written permission from the patient (or, where applicable, the next of kin), the personal details of any patient included in any part of the article and in any supplementary materials (including all illustrations and videos) must be removed before submission.

The *Journal of the American Academy of Dermatology (JAAD)* seeks to ensure that patient privacy is protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

While *JAAD* accepts institution and private entity HIPAA patient sign-off for photo/image use, it also provides this [document](#) as a template for use by *JAAD* manuscript authors.

It is important to disclose to patients that images submitted to *JAAD* may be utilized in various forms of publication and mediums by the Journal, including but not limited to teaching, research, scientific meetings, other professional journals, medical books, broadcasts, advertising, and other similar purposes. These materials may appear in print and online and the public may have access to them.

Care must be taken by authors submitting images to ensure that images are de-identified to the greatest extent possible, while preserving the teaching nature of the image/s.

Patient consent and confidentiality

When publishing personal information about identifiable living patients, we require a signed copy of our patient consent permission form. This form is available as a pdf and in multiple languages.

Authors should seek the patient's consent to publication before submitting any article. Please save and print the form, then show the patient the version of the article that you are submitting and, if they give permission for publication, please ask them (or, as appropriate, their next of kin - in which case please explain this on the form) to sign the form. Then send the completed form to us. You can do this in either one of two ways:

- Scan the signed and completed form into your computer and then email it to us as an attachment;
- Scan the signed and completed form into your computer and then upload it to our online editorial office as a 'Supplementary file for Editors only' when submitting.

Patient consent form (click here to download in multiple languages)



[Patient_Consent_Form_Korean.pdf](#)

[Deceased_Patient_permission_Form.pdf](#)

Images of Patients

Our policy on obtaining consent for publication of pictures or videos of patients is a subset of our general policy on patient confidentiality. If there is any chance that a patient may be identified from a photograph or other static or moving image, or from its legend or accompanying text, we need the patient's written consent to publication by BMJ.

- Images - such as x rays, laparoscopic images, ultrasound images, pathology slides, or images of undistinctive parts of the body - or multimedia files (e.g. video, audio) may be used without consent so long as they are anonymised by the removal of any identifying marks and are not accompanied by text that could reveal the patient's identity through clinical or personal detail.
- An exception to this policy of needing consent for recognisable photographs of individuals is when we use photographs from picture agencies to illustrate news stories and other articles. We state where these photographs have come from and we rely on the fact that the agencies and their photographers have obtained the relevant permissions from the people shown in the photographs. If we doubt that someone photographed could have given consent - owing for example to severe mental illness or learning disability - we will use our discretion and avoid using such images.

Non-identifiable images

- Formal consents are not required for the use of entirely anonymized images from which the individual cannot be identified- for example, x-rays, ultrasound images, pathology slides or laparoscopic images, provided that these do not contain any identifying marks and are not accompanied by text that might identify the individual concerned.
- If consent has not been obtained, it is generally not sufficient to anonymize a photograph simply by using eye bars or blurring the face of the individual concerned.
- <https://www.elsevier.com/about/policies/patient-consent>

Retractions Cases

Authors couldn't find a patient to give consent for case report. Then the patient found the report.

When a group of authors decided to write up a curious case of a 35-year-old woman with a mysterious mass that took 11 years to be diagnosed, they tried repeatedly to contact the patient for her permission. When they couldn't reach her, they published the paper anyway, removing any identifiable information.

But the report apparently included enough details for the patient to recognize herself — and when she read the paper, she asked the authors to retract it.

That's the story according to the publisher of the 2016 case study, which recently retracted it with this notice:

Medicine

Wolters Kluwer

Study of child with rare cancer retracted due to lack of parental consent

Researchers in Ireland have retracted a case study about a rare type of cancer in a child because – contrary to what they claimed in the paper – they had not obtained the necessary permission from the parents.

Diagnostic Pathology



medRxiv

In the June 2016 article, the authors stated they had received “written informed consent” from the parents to publish the case. But according to the retraction notice — issued just a few months later in October — that was not the case.

Here's the retraction notice for “Paediatric Ewing-like sarcoma arising from the cranium – a unique diagnostic challenge,” which for legal reasons, the publisher has withdrawn from public view:

This article [1] has been retracted by the authors because, contrary to the statement in the article, they did not obtain the necessary written informed consent from the patient's parents to publish this case. The article is no longer available online in order to protect the patient's privacy. The authors have agreed to the retraction.

개인정보 보호 관련 체크리스트

- 학술지 투고 규정에 개인정보 보호와 관련한 설명이 포함되어 있나?
- 논문에 식별 가능한 개인정보가 포함되어 있는가?
- 과학적 목적으로 식별 가능한 개인정보를 포함한 경우 출판 전 환자 또는 환자의 법정대리인에게 이를 설명하고, 서면으로 동의서를 취득하였는가?
- 환자의 출판 동의서를 원고와 함께 제출하였는가?