POINT OF VIEW

Proposing a Universal Informed Written Consent for Publication of Case Reports or Case Series

Atanu Chandra[1*], Rupak Chatterjee[2], Sugata Dasgupta[3], Nandini Chatterjee[4], Jyotirmoy Pal[5]

Received: 17 August 2025; *Accepted:* 29 December 2025

Abstract

Case reports and case series play a pivotal role in advancing medical knowledge by highlighting rare conditions, novel treatments, and unique clinical presentations. Despite their importance, ethical considerations surrounding patient autonomy, privacy, and confidentiality remain central to their publication. Informed written consent is a cornerstone of this process, yet the current system for obtaining consent is fragmented and inconsistent across journals. Authors are often required to secure new, journal-specific consent forms for each submission, creating unnecessary administrative burdens and risking patient dissatisfaction or noncompliance. This inefficiency may ultimately hinder the timely dissemination of valuable clinical insights. With the rise of open-access publishing and the broader reuse of published material under Creative Commons licenses, the limitations of traditional anonymization techniques further underscore the need for robust and standardized consent practices. This article proposes the development of a universal informed written consent form that could be accepted across all medical journals. Such a form, developed collaboratively by journals, ethical committees, and legal experts, would simplify the publication process, protect patient rights, and maintain ethical integrity. Adoption of a universal consent framework represents a critical step toward safeguarding patient dignity while facilitating the responsible advancement of medical science.

Journal of The Association of Physicians of India (2026): 10.59556/japi.74.1318

Introduction

Case reports and case series are a valuable means of advancing medical knowledge. These reports provide insights into rare conditions, innovative treatments, and unusual presentations, contributing to the knowledge base for personalized health care and serving as an important educational resource. However, ethical considerations are paramount, particularly the need for informed written consent from patients.[1] Informed consent is crucial in maintaining patient privacy and autonomy.[2] Case reports must ensure patient confidentiality by excluding unnecessary details and identifiable features from images. Even with direct identifiers removed, obtaining consent for the publication of both the report and associated images is essential, as clinical details and images can still potentially reveal individuals' identities.[3] Despite its importance, the current process for obtaining informed written consent for case report publication is fragmented and inconsistent across journals. This article proposes the development of a universal informed consent form that can be accepted across all journals, simplifying the process for authors and ensuring ethical standards are maintained.

Why is Informed Written Consent Necessary for Publication?

The Committee on Publication Ethics (COPE) and the International Committee of Medical Journal Editors (ICMJE) have provided guidelines for publishing case reports.[1,4,5] These guidelines generally require that patient consent be obtained before publication. Authors must inform patients that their case will be publicly accessible and that, despite efforts to anonymize, there is still a risk of identification. With the shift to online and open-access publishing, and the use of Creative Commons licenses that allow free reuse of material, including patient photographs, there is a concern about the potential for patients' images to be repurposed in different contexts without proper consent. Techniques such as blurring or covering the eyes have proven insufficient for ensuring anonymity.[6] Additionally, once published, consent cannot be withdrawn. Patients should be given the chance to review the manuscript and any accompanying images as part of the consent process. In the context of case reports and series, it ensures that patients understand the nature of the publication, how their information will be used, and the potential risks of making their case details public. The primary goal is to respect patient autonomy, confidentiality, and dignity.[4,7] For minors, deceased patients, or those unable to give consent, additional considerations are necessary. In such cases, consent must be obtained from legal guardians, next of kin or legally authorized representatives. For minors, the consent should include assent from the child, where appropriate, along with the consent from the guardian. For deceased patients, the consent must respect the patient's previously expressed wishes if known, and should be obtained from the family.

Challenges with the Current Consent Process Applicable to Different Journals

A major issue with the current consent process for publishing case reports is the inconsistency among journal requirements. Different journals often have varied formats, content specifications, and wording for consent forms, creating confusion and adding administrative burdens for authors.[8] When a manuscript is submitted to multiple journals, authors frequently need to secure new consent forms tailored to each journal's specific guidelines, even if consent was previously obtained in another format. This repetitive process is both time-consuming and impractical.

[1]Associate Professor, Department of Internal Medicine, Calcutta National Medical College, Kolkata; [2]Senior Resident, Department of Tropical Medicine, Calcutta School of Tropical Medicine; [3]Professor, Department of Critical Care Medicine; [4]Professor, Department of Internal Medicine, IPGMER and SSKM Hospital; [5]Professor, Department of Internal Medicine, College of Medicine and Sagore Datta Hospital, Kolkata, West Bengal, India; *Corresponding Author

How to cite this article: Chandra A, Chatterjee R, Dasgupta S, *et al.* Proposing a Universal Informed Written Consent for Publication of Case Reports or Case Series. J Assoc Physicians India 2026;74(5):95–96.

For example, if a manuscript is first submitted to a high-impact journal and rejected, it might then be sent to a second and third journal before being accepted. Each journal might require a different consent form, forcing authors to repeatedly approach patients or their representatives for new consents. Additionally, the process of repeatedly seeking consent can strain relationships with patients or guardians, who may become reluctant or refuse to sign multiple forms, particularly if they are facing health issues. If patients become unreachable between submissions, obtaining updated consent becomes difficult, potentially halting the publication process. Conflicting guidelines among journals can also create confusion and raise ethical and legal risks if specific consent forms do not align with legal standards. The time and cost involved in managing multiple consent processes further complicate the situation. Implementing a universal, standardized consent form could address these issues, streamlining the publication process and ensuring consistent patient privacy protection.

Proposal for a Universal Informed Consent Form

To resolve the challenges associated with the current consent process, the development and adoption of a universal informed consent form is essential. This standardized form would be created in collaboration with major medical journals, ethical bodies, and legal experts to ensure it meets diverse requirements and adheres to best practices across the field.

The universal consent form would feature several essential components to ensure comprehensive and consistent consent across case reports.[1,5] It would include sections for recording patient details, such as demographics and relevant medical history, while maintaining privacy. The form would also provide a clear description of the scope of the report, detailing what patient information will be included, how it will be used, and the extent of its disclosure. Explicit language would outline the implications of consenting to publication, including the handling of information and images, potential future reuse, and associated risks. Special provisions would address unique cases, such as obtaining consent from minors, with sections for parental or guardian consent and minor assent and securing consent from relatives or legal representatives for deceased patients. Additionally, the form would include a revocation policy detailing the conditions under which consent can be withdrawn and its implications. Finally, it would ensure compliance with all relevant legal and ethical standards, including privacy laws and regulations such as the General Data Protection Regulation (GDPR).

Conclusion

The need for a universal informed written consent form for the publication of case reports and series is clear. The current fragmented approach is inefficient, frustrating for authors, and could potentially discourage the publication of valuable medical cases. By implementing a standardized consent form accepted across all journals, we can ensure ethical standards are maintained while making the publication process smoother and more practical for authors. Collaboration among medical journals, ethical committees, and other stakeholders is necessary to bring about this change, ultimately benefiting both medical research and patient care.

Author's Contributions

All the authors prepared the manuscript with adequate planning and execution. All had contributed to review of literature, critical revision of content, and final approval of the manuscript. All authors are in agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Orcid

Atanu Chandra https://orcid.org/0000-0002-3809-8926
Sugata Dasgupta https://orcid.org/0000-0003-0014-893X
Nandini Chatterjee https://orcid.org/0000-0002-7729-812X
Jyotirmoy Pal https://orcid.org/0000-0001-7769-9655

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