Risk of *Over*Documentation of Informed Consent Needs to be Considered Among Dermatology Journals

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Informed consent protects patient autonomy and well-being in clinical research, case reports included. Yet, several article retractions at the request of the involved patients have been reported.[1,2] Many journals stipulate that written informed consent from the patient must be submitted to the journal for a case report manuscript to be reviewed (Table 1), regardless of whether patient identifiability is plausible.

While ensuring the documentation of informed consent and transfer to a third-party publisher may sound like a liability-free action, this action has a risk of *over*identification—one that potentially is more harmful than images alone, by linking sensitive case history to a name and date. Dermatologists should consider the risks of transferring a patient's name and date of signature without knowledge of the publishers' safeguards in place to protect that data. While this may seem theoretical, the incidence of unauthorized access of personal health identifiers doubled between 2011-2013. Most reported data breaches are from large healthcare corporations, but breaches of security have occurred among journal publishers. Notably in 2012, Elsevier was infiltrated by hackers who developed editorial accounts, reviewed manuscripts, and steered over 10 articles to acceptance.[3] In 2019, the same publisher acknowledged a "misconfigured" server setting that left user passwords and data subsequently open to the public with an unknown quantity of potentially identifiable documentation exposed.[4]

Yet publishers, too, must be protected from risks, including retractions and liability. How can we reconcile these competing risks? We suggest following the guidance in the Department of Health and Human Services' documentation for institutional review boards, which provides exceptions for informed consent documentation in research including 45 CFR 46.117(c): *(i) The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality*[5] Scenarios in which case reports are not generally identifiable clearly meet this exception criteria for documenting informed consent. Scenarios in which a patient is clearly identifiable are more nuanced, but we would argue that informed consent documentation should be stored within the patient's electronic medical record. Then, it is incumbent upon the senior author to document that they have obtained the patient's informed consent, with recognition of the various risks of patient identification. The senior author would subsequently be contractually bound to maintain the informed consent within a compliant manner, including an office or institutional contact, to whom the publisher may reach out for confirmation of documentation.

We advocate for all leading dermatology journals to consider the risk of *over*documentation of informed consent. A facial image and medical history may be identifiable to a close acquaintance, but the risk of sensitive health information linked to a specific name and date broadens the risk of identifiability. Following the spirit of 45 CFR 46.117(c), the optimal method to safeguard patient privacy, as already set forward by *JAAD, JEADV, AJCD,* and *JID,* is to contractually bind the senior author of a manuscript to maintain documentation of informed consent, with provision as legally necessary to the publisher.

Table 1. *Top dermatology journals by impact factor and their specific informed consent language.*

Journal	Impact Factor (2024)	Informed Consent Language
Journal of the American Academy of Dermatology	13.8	"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 upon request only…While institution and private entity HIPAA patient sign-off for photo/image use is acceptable, the journal also provides this document as a template for use by *JAAD* manuscript authors. The journal no longer requests copies of these forms be submitted with manuscripts but does require authors to attest in the author questionnaire that they have consent on file and can produce copies of the signed consent forms if requested by the journal."[6]
JAMA Dermatology	10.9	"A signed statement of informed consent to publish

Journal	**Impact Factor (2024)**	**Informed Consent Language**
		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."[7]
British Journal of Dermatology	10.3	"Patient consent for publication, including for use in social media, is required for all case reports and all clinical images whether or not the patient is identifiable."[8]
Journal of the European Academy of Dermatology and Venerology	9.2	"For papers containing information or images that could identify individuals, authors must obtain a consent form signed by the patient, parents or guardian, acknowledging the potential for publication and their awareness of the content. The signed consent form should be securely filed in the patient's case notes and the manuscript submitted to *JEADV* should include this statement in the Ethics Statement section indicating that specific consent for publication was obtained: 'The patients in this manuscript have given written informed consent to publication of their case details**.'** The journal editorial office will not collect or archive consent forms from authors but reserves the right to inquire about their presence."[9]
American Journal of Clinical Dermatology	7.3	"Please keep [the journal] consent form in the patient's case files. The manuscript reporting this patient's details should state that 'Written informed consent for publication of their clinical details and/or clinical images was obtained from the patient/parent/guardian/ relative of the patient. A copy of the consent form is available for review by the Editor of this journal.'"[10]
Journal of Investigative Dermatology	6.5	"All clinical investigation must have been approved, or granted a waiver of approval, by the author's Institutional Review Board or Research Ethics Committee, and written informed consent must have been obtained from all patients and control participants. All patients referred to in human studies should be identified by number, not by name. Identifying information should not be published in written descriptions, photographs, or pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) has given written informed consent for publication. In addition, retrospective studies must have Institutional

Journal	Impact Factor (2024)	Informed Consent Language
		Review Board approval. Approvals and patients' and participants' consent should be stated in the Methods section of the manuscript. The editors reserve the right to reject manuscripts that fail to meet these criteria, and to ask for proof of Institutional Review Board approval…Include a statement affirming that patients consented to publication, if their image or case history is used. For images, this statement should be included at the end of the figure legend."[11]

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