Commentary

Journal of Iranian Medical Council, Volume 9, Issue no. 4
http://dx.doi.org/10.18502/jimc.v9i4.22478

Informed Consent in Dermatology: Protecting Patients or Regulatory Obstacle?

Ambika Nand Jha[1]*, Varsha Ratan Gaikwad[2], Piyush Mittal[1], Rabia Alam[3] and Ashok Kumar Gupta[1]

1. School of Pharmacy, Sharda University, Greater Noida, Uttar Pradesh, India 201310
2. Sandip School of Pharmaceutical Sciences, Sandip University, Nashik, Maharashtra, India
3. Department of Dermatology, School of Medical Sciences and Research, Sharda University, Greater Noida, Uttar Pradesh, India

*** Corresponding author**
Ambika Nand Jha, Pharm.D
School of Pharmacy, Sharda University, Greater Noida, Uttar Pradesh, India 201310
Tel: +91 8002787814
Email: nandjha99@gmail.com

Received: 20 Mar 2025
Accepted: 25 Aug 2025

Citation to this article
Nand Jha A, Ratan Gaikwad V, Mittal P, Alam R, Kumar Gupta A. Informed Consent in Dermatology: Protecting Patients or Regulatory Obstacle? *J Iran Med Counc.* 2026;9(4):1038-40.

Informed consent is a foundational element of ethical dermatological practice, ensuring respect for patient autonomy and protecting participants in clinical research. As dermatologic care evolves with expanding procedures, aesthetic interventions, and novel therapies so too do the challenges of obtaining meaningful consent. Increasingly complex regulatory environments, defensive documentation practices, and bureaucratic research oversight may obscure the core ethical intent of informed consent, turning it into a legal safeguard rather than a tool for shared decision-making. This editorial examines the tension between patient protection and administrative demands, urging a balance that preserves ethical integrity without impeding clinical innovation. In dermatology, where treatments range from laser resurfacing to biologics, informed consent must adapt to diverse patient needs. Multimedia tools, plain-language documents, and culturally tailored approaches enhance understanding, especially for procedures with nuanced risks. Digital innovations such as interactive portals with voiceovers, videos, and comprehension checks have improved patient satisfaction and decision confidence. Special attention is needed for vulnerable populations, including elderly, paediatric, low-literacy, and marginalized groups. Strategies such as caregiver involvement, large-print formats, and multilingual resources ensure inclusivity. Global variation in consent practices from individualized documentation in Western contexts to family-mediated consent in many Asian or Middle Eastern cultures highlights the need for context-sensitive, adaptable models. Ultimately, informed consent should remain a dynamic dialogue one that promotes trust, transparency, and respect. Dermatologists must embrace patient-centered tools and advocate for simplified, ethically sound frameworks that meet both clinical and regulatory standards. In doing so, they ensure that informed consent continues to empower patients rather than hinder progress.

Keywords: Comprehension, Dermatology, Ethics, Informed consent, Patient satisfaction, Trust

Informed consent represents a fundamental principle in bioethics

and clinical dermatology. Historically rooted in the Nuremberg Code (1947) and expanded by the Declaration of Helsinki (1964, latest revision 2024), informed consent mandates voluntary, informed participation in medical interventions and research. These frameworks emphasize autonomy, beneficence, and respect for persons (1). Within dermatological care, informed consent encompasses a spectrum of interventions ranging from non-invasive procedures to complex systemic therapies. Examples include phototherapy, excision of skin malignancies, cryotherapy, botulinum toxin injections, and resurfacing lasers. Informed consent must address both clinical efficacy and aesthetic implications, utilizing language accessible to patients regardless of health literacy (2). Nevertheless, implementation remains challenging. Many consent forms are saturated with medico-legal jargon and lack the clarity necessary for genuine understanding. Patients often face time constraints and insufficient counselling, which may undermine autonomy and introduce anxiety (3,4).

To address these deficits, clinicians have adopted strategies such as simplified, plain-language documents and multimedia adjuncts. Visual diagrams, explanatory videos, and interactive modules allow asynchronous review, reinforcing key procedural concepts. In phototherapy or isotretinoin counselling, visual and interactive aids have demonstrated improved comprehension and decision confidence. Digital consent platforms further facilitate multilingual, personalized content delivery, incorporating audio narration and comprehension verification tools (5,6). These innovations underscore a paradigmatic shift toward dynamic, patient-centric consent processes. In research, however, Institutional Review Board (IRB) procedures may introduce delays that obstruct timely trial initiation, particularly in novel therapeutic domains such as immunobiologics or photodynamic therapies. While ethical oversight is indispensable, procedural streamlining must be considered to prevent stagnation in clinical advancement (7). Another complicating factor is medicolegal defensiveness. To mitigate litigation risk, some institutions have adopted overly exhaustive consent forms replete with indemnity clauses. In cosmetic dermatology, particularly laser procedures, this practice may induce patient apprehension rather than clarity, thus compromising the therapeutic alliance (1). Additional considerations arise when treating vulnerable populations. Elderly individuals may require auditory or large-font materials, while paediatric patients benefit from age-appropriate visualizations and assent procedures. In dermatology camps targeting migrant or underserved populations, pictorial flipcharts in native languages have increased procedural adherence and reduced post-treatment uncertainty. Likewise, involving family caregivers in geriatric and cognitively impaired patient settings improves ethical transparency and clinical safety.

Cross-national variation in legal requirements and cultural attitudes necessitates adaptability. In Western contexts, individual consent is standard, whereas many non-Western cultures favor collective, family-mediated decision-making. Dermatologists practicing in multicultural environments must navigate these norms, while maintaining ethical rigor. Table 1 outlines key methods for enhancing the informed consent process in dermatological practice, including

Table 1. Key strategies to improve informed consent in dermatology

Identified challenge	Recommended strategy	Relevant context
Medico-legal language complexity	Plain-language consent forms	Outpatient surgery, cosmetic procedures
Limited patient comprehension	Multimedia tools and FAQs	Acne therapies, systemic drug counseling
Passive engagement	Interactive digital modules	Clinical trials, chronic disease management
Over-cautious legalism	Eliminate non-essential disclaimers	Elective aesthetic procedures
Patient vulnerability (age/literacy)	Multilingual, large-print, caregiver inclusion	Geriatric, paediatric, low-literacy settings
Bureaucratic research delays	Streamlined ethics committee protocols	Emerging dermatologic trials

adaptations for vulnerable populations and digital innovations.

Informed consent in dermatology must evolve from a static procedural requirement to a dialogic, ethically grounded interaction. Simplified communication, technological innovation, and contextual sensitivity are imperative to uphold the principles of autonomy and non-maleficence.

Future dermatology practice and policy should prioritize two actionable strategies: (1) the implementation of plain-language, multimedia consent systems tailored to vulnerable populations; and (2) the development of standardized, yet adaptable, institutional protocols that streamline ethical review without compromising patient safety. These steps will help ensure that informed consent continues to function as a cornerstone of ethical, patient-centered dermatologic care.

Funding

No external funding was received for this work.

Acknowledgement

This article does not report clinical or interventional research on human participants. Hence, IRCT registration and institutional ethics approval are not applicable.

Conflict of Interest

There was no conflict of interest in this manuscript.

References

1. Thakur S, Lahiry S. Research ethics in the modern era. Indian J Dermatol Venereol Leprol 2019;85:351-4. https://

2. Nirmal B, Sacchidanand SA. Informed consent in dermatology: What's known and what's new?. Indian J Dermatol Venereol Leprol 2014;80:58-61.

3. Steen RG. Writing for publication in a medical journal. Indian J Endocr Metab 2012;16:899-903.

4. Ananthakrishnan N, Shanthi AK. ICMR's ethical guidelines for biomedical research on human participants: Need for clarification. Indian J Med Ethics 2012;9:207-9.

5. Sil A, Das NK. Informed Consent Process: Foundation of the Researcher-participant Bond. Indian J Dermatol 2017 Jul-Aug;62(4):380-386.

6. Ravi S, Zhou AE, Sloan B, Bercovitch L, Grant-Kels JM. Navigating the Ethics of Predatory Journals and Processing Fees in Dermatology. Clin Dermatol 2024 Dec 27:S0738-081X(24)00285-2.

7. Hengy M, Hewitt M, Dekany V, Bedford-Lyon N, Daveluy S. Informed consent in dermatology: a narrative review. Int J Dermatol 2023 Apr;62(4):476-482.