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Center for Informed Consent Integrity

Informed Consent: A Monthly Review

June 2025 :: Issue 78

The Center for Informed Consent Integrity engages consent as the bulwark of human rights, fundamental freedoms, responsible science, and effective governance. Consent must be exercised in open, non-coercive, supportive, documented contexts and grounded in evidence-based, accessible, understandable and materially complete information. We publish this digest as a key program in our Center's 2030 program of work.

Informed Consent: A Monthly Review aggregates and distills key content and analysis around informed consent and assent from a broad spectrum of peer-reviewed journals and grey literature, and from various practice domains and organization types including international agencies, INGOs, governments, academic and research institutions, consortiums and collaborations, foundations, and commercial organizations. We directly monitor a wide range of journals and other sources, and utilize *Google Scholar* as a key tool in developing each edition.

As indicated by the thematic sections listed below, our intent is to present a comprehensive digest, including selected content that is arguably controversial and which warrants close scrutiny. We may include "Editor's Notes" or other notations to identify and sometimes challenge such content. We welcome reader comment on any content we include.

Informed Consent: A Monthly Review is a service of the Center for Informed Consent Integrity (CICI), a program of the GE2P2 Global Foundation. The Foundation is solely responsible for its content. Comments and suggestions should be directed to:

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No new content was identified for the following established categories:

BIOBANKING
COMPASSIONATE USE/EXPANDED ACCESS
HUMANITARIAN CONTEXT

Please note that while we strive to identify the primary subject area for the categorization of content, we also recognize that many articles are relevant across other subject areas. We encourage readers to review the entire digest and to utilize the search function on our website where articles are posted and cross tagged. We maintain a glossary, an inventory of assessment and other tools, as well as standards and guidance documents, also on the Center's website.

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GENERAL/OTHER

Optimizing Informed Consent—A Call to Action

Viewpoint

Nancy E. Kass, Ann Meeker-O'Connell, Stephanie R. Morain, Matthew A. Crane

JAMA Health Forum, 2 May 2025; 6(5)

Excerpt

People who volunteer to participate in clinical trials regulated by the US Food and Drug Administration (FDA) play an integral role in advancing scientific knowledge about medical products. These clinical trials are intended to generate reliable evidence that informs product development and, ultimately, patient care—an essential task given the vast gap in evidence for clinical care.1 When implementing clinical research, investigators should provide information about a planned trial to potential participants in a clear, comprehensible way, both out of respect for the individuals who consider volunteering and so that those individuals can make informed decisions about whether they wish to volunteer.

…, we intend to identify additional ways to improve how the research community designs and obtains informed consent, in partnership with potential research participants, researchers, and others in the clinical trial and clinical practice communities… We also plan to continue supporting the research community in applying recommendations from our guidance or appropriate alternative approaches to improve informed consent, including through future demonstration projects that provide examples of clear, understandable, and informative consent documents and processes. Finally, given the multiregional nature of clinical trials, we are working with global partners—in partnership with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use—to promote the comprehensibility and brevity

of informed consent. We hope that a strategic and collaborative focus on informed consent will help to fulfill this fundamental ethical commitment to potential research participants.

Contemporary human rights violations in female sterilization care: legal and ethical considerations when coerced patients do consent

Liana Woskie, Mindy Jane Roseman

Monash Bioethics Review, 13 May 2025

Open Access

Abstract

In this piece we examine three forms of coercive or otherwise involuntary care that can occur with patient consent. To do so, we examine: (1) uninformed consent, (2) contingency-based consent and (3) constrained-market consent, amongst female sterilization patients. While there is broad recognition that "coercion" in sterilization care can manifest beyond instances of overt force and clarity on what constitutes coercion within clinical care, this has not translated to accountability. The current practice of identifying coercion through discrete civil cases may facilitate a narrow understanding of its contemporary prevalence; one that does not align with definitions of coercion supported by international human rights entities. We use three acute, and widely recognized, examples—hysterectomies in ICE detention facilities, India's sterilization camp deaths and birth control quotas for Uyghur women—as an entry point to highlight less overt contemporary forms of coercive sterilization care, pairing each example with data that explores prevalence at a broader population level. These data suggest less visible forms of coercion may persist relatively unchallenged—raising the ethical case for a functional approach to the measurement of coercion. In turn, we argue the relevant question may not be "when is coercion ethically justified in public health," but rather, why is coercion already the status quo?

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BIOMEDICAL RESEARCH

Informed Consent Documents from Psychedelic Clinical Trials: A Descriptive Ethical Analysis

Katherine Cheung, Caleigh Propes, Marianna Graziosi, Kyle Patch, David B. Yaden

AJOB Empirical Bioethics, May 2025

Abstract

Background

Classic psychedelics, such as psilocybin and LSD, evoke certain kinds of altered states of consciousness. Specific features of the experience, such as its allegedly ineffable nature, have been discussed as posing challenges to the informed consent process. A growing call for tailored informed consent documents (ICDs) in the psychedelic bioethics literature raises the question of how closely ICDs used in contemporary psychedelic trials reflect the concrete suggestions and proposals offered by psychedelic bioethicists.

Methods

In this article, we review ICDs from psilocybin clinical trials in the United States. Using a content analysis approach, we provide a systematic qualitative description of the ICDs which comprise our final sample (N=28; 28 clinical trials across 13 unique sites). Coders demonstrated good reliability (κ=.683).

Results

Qualitative analyses revealed that most of the coding aligned with expectations based upon the psychedelics bioethics literature, such as the emphasis on Mental Health Risks and Physical Risks in ICDs. Notably, psychedelic-specific codes (e.g., Inef ability, Therapeutic Touch) did not appear as frequently in ICDs.

Conclusions

Scholars in psychedelic bioethics have called for the inclusion of a variety of potential risks and benefits in ICDs. It will be important to continue debating which elements are worth including in ICDs such that potential research participants are presented with the most salient factors relevant to their decision about joining a study. We provide a table of best practices applied by our sample of ICDs.

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SOCIAL SCIENCE RESEARCH

Informed Consent in Qualitative Research: Lessons on Relationality from a Technologically Dense Classroom

Book Chapter
Fride Haram Klykken
Reframing Qualitative Research Ethics, 20 May 2025 [Emerald Publishing Limited]
Abstract
This chapter examines the challenges that informed consent poses in qualitative research. Drawing on examples from a video ethnography in a technologically rich classroom in Norway, this chapter highlights limitations of the current emphasis on anticipatory approaches to informed consent. I explore how a nuanced processual understanding of informed consent can be added to these established procedures so as to navigate the intricate dynamics of conducting ethical research in a relationally constituted world. This chapter illustrates how, from a relationally situated approach, explicit and implicit negotiations of informed consent can be incorporated throughout the research process. Informed by sociomaterial and material feminist theories, this chapter reflects on the iterative and material effects of contemporary informed consent practices. Encouraging a rethinking of the role of informed consent within qualitative research, I argue that engaging in informed consent practices is not only about formal procedures or written agreements but also entails a continuous relational negotiation that needs attention throughout the research process. In conclusion, I advocate that institutions and researchers should advance responsible research ethics by acknowledging ethical complexity, promoting trust, and building diverse and responsive ethical resource networks.

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ARTIFICIAL INTELLIGENCE

From black box to clarity: Strategies for effective AI informed consent in healthcare

Research paper
M. Chau, M.G. Rahman, T. Debnath
Artificial Intelligence in Medicine, 24 May 2025
Abstract
Background
Informed consent is fundamental to ethical medical practice, ensuring that patients understand the procedures they undergo, the associated risks, and available alternatives. The advent of artificial intelligence (AI) in healthcare, particularly in diagnostics, introduces complexities that traditional informed consent forms do not adequately address. AI technologies, such as image analysis and decision-support systems, offer significant benefits but also raise ethical, legal, and practical concerns regarding patient information and autonomy.
Main body

The integration of AI in healthcare diagnostics necessitates a re-evaluation of current informed consent practices to ensure that patients are fully aware of AI's role, capabilities, and limitations in their care. Existing standards, such as those in the UK's National Health Service and the US, highlight the need for transparency and patient understanding but often fall short when applied to AI. The “black box” phenomenon, where the inner workings of AI systems are not transparent, poses a significant challenge. This lack of transparency can lead to over-reliance or distrust in AI tools by clinicians and patients alike. Additionally, the current informed consent process often fails to provide detailed explanations about AI algorithms, the data they use, and inherent biases. There is also a notable gap in the training and education of healthcare professionals on AI technologies, which impacts their ability to communicate effectively with patients. Ethical and legal considerations, including data privacy and algorithmic fairness, are frequently inadequately addressed in consent forms. Furthermore, integrating AI into clinical workflows presents practical challenges that require careful planning and robust support systems.

Conclusion

This review proposes strategies for redesigning informed consent forms. These include using plain language, visual aids, and personalised information to improve patient understanding and trust. Implementing continuous monitoring and feedback mechanisms can ensure the ongoing effectiveness of these forms. Future research should focus on developing comprehensive regulatory frameworks and enhancing communication techniques to convey complex AI concepts to patients. By improving informed consent practices, we can uphold ethical standards, foster patient trust, and support the responsible integration of AI in healthcare, ultimately benefiting both patients and healthcare providers.

“Does Black Box AI In Medicine Compromise Informed Consent?”

Research Article

Samuel Director

Philosophy & Technology, 13 May 2025

Open Access

Abstract

Recently, there has been a large push for the use of artificial intelligence in medical settings. The promise of artificial intelligence (AI) in medicine is considerable, but its moral implications are insufficiently examined. If AI is used in medical diagnosis and treatment, it may pose a substantial problem for informed consent. The short version of the problem is this: medical AI will likely surpass human doctors in accuracy, meaning that patients have a prudential reason to prefer treatment from an AI. However, given the black box problem, medical AI cannot explain to patients how it makes decisions, yet such an explanation seems to be required by informed consent. Thus, it seems that doing what is best for patients (treatment via AI), even if patients want to permit this, might be prohibited by medicine’s commitment to informed consent. Conflicts between beneficence and autonomy are not new, but medical AI poses a novel version of this conflict, because this problem is one in which even if the patient says they want to use their autonomy to receive better care, the commitment to autonomy (via informed consent) seems to block them from doing so. Given this dilemma, should we abandon informed consent, or should we not use medical AI? My thesis is that we can have our cake and eat it too; we can use opaque AI in clinical medicine and retain our commitment to informed consent, although it may require revising our understanding of informed consent. Specifically, it will require us to distinguish between two levels of consent (higher-order and first-order consent).

Ethical approval and informed consent in mental health research: a scoping review

Leona Cilar Budler, Gregor Stiglic

AI and Society, 1 May 2025

Abstract

Although there is a wide range of scientific papers introducing artificial intelligence techniques in the mental health field, there is a lack of literature assessing the reporting of ethical concerns in such studies. In addition, it is not yet known whether the authors seek ethical approval or informed consent while performing such research. This study aimed to investigate the extent to which studies in the mental health domain that utilize chatbots either ignore or incompletely disclose patient consent and ethical approval from the responsible review boards. A scoping literature search was performed in PsychARTICLES, PubMed, and Web of Science using both MeSH terms and free-text keywords. Following PRISMA-ScR guidelines, we also contacted study authors to verify missing information about ethical approval or informed consent, enhancing the transparency and rigor of our analysis. Among the 27 studies reviewed, 13 reported obtaining ethical approval, and 16 reported collecting informed consent. The remaining studies did not provide such information. These findings underscore the ethical complexities surrounding AI in mental health, especially regarding the collection, storage, and use of sensitive patient data. There is a correlation between sample size and the acquisition of ethical approval, particularly in studies published in journals with low-impact factors. Future research should investigate the role of journal policies in influencing ethical practices. In addition, training programs could be developed to educate researchers on the importance of ethics, particularly in studies with smaller sample sizes.

Whose Reality? Consent Boundaries and Free Speech Arguments in the Politics of Generative AI

Sara Concetta Santoriello

Politikon: The IAPSS Journal of Political Science, 28 April 2025

Abstract

Generative AI enables creation of increasingly realistic deepfakes that challenge content authenticity assessment. This research examines how anti-woke opinion leaders frame deepfake technology within broader cultural discourse. Through narrative analysis of statements and media between 2018 and 2024, we identify significant inconsistencies in these figures' approaches to consent and bodily autonomy. While championing unrestricted speech when deepfakes target women, minorities, or political opponents, these commentators often advocate for regulation when personally affected. This selective application of principles reveals how deepfake technology disproportionately impacts minoritized groups while reinforcing existing power hierarchies. The research exposes fundamental tensions within anti-woke discourse between freedom of expression and protection from exploitation. Ultimately, deepfakes serve as a lens through which to understand broader ideological inconsistencies around technological governance, highlighting the urgent need for consent-based approaches to synthetic media regulation.

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GENOMIC MEDICINE/GENE EDITING

Informed consent for forensic genetic population studies: *Status quo* and a call for harmonization

Martin Bodner, Walther Parson

Forensic Science International: Genetics, June 2025

Abstract

Donor-signed informed consent is a fundamental prerequisite for ethically correct analysis and publication of genetic data in forensic population studies, including quality assessment of datasets and their inclusion into frequency databases. While considerations on the requirement and content of informed consent have been published, little information is available with regard to the actual nature of the documents currently in use. This study investigated 50 recent informed consent forms submitted to EMPOP and STRidER from a broad range of contributors across worldwide legislations, irrespective of the quality of the associated genetic data.

The common ground of the informed consent forms, their specific content and differences, and the extent to which they contain suggested components are outlined. This evaluation of authentic informed consent form diversity adds to the discussion on formal aspects to be covered at the time of sampling and may expedite future harmonization of informed consent in forensic population studies, assuring ethical principles in the application of precious sample sets for a broad range of investigations across genetic disciplines.

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HEALTH DATA/DATA

Evaluation of a DIC Broad Consent Cohort

Observational Study

Marvin O Kampf, Hans-Ulrich Prokosch, Christian Gulden, Detlef Kraska, Thomas Ganslandt, Susanne A Seuchter

Studies in Health Technology and Informatics, 15 May 2025

Abstract

This single-center retrospective observational study accesses potential differences between adult patients who were admitted to the University Hospital Erlangen between March 2021 and December 2023 (hospital cohort) and adult patients who have given consent to use their documented data for research purposes (broad consent cohort). Demographic and clinical data (ICD-10 diagnoses) were extracted from the university hospitalt's FHIR research data repository and analyzed in pseudonymized form. The two cohorts comprise 98,564 and 1,678 patients respectively and were compared concerning representativity of the BC cohort. The results suggest that the ongoing stepwise rollout of the consent obtainment process creates biases in clinical and demographic characteristics. For as long as these biases persist, we suggest researchers to prefer federated over centralized approaches to data analysis, where broad consent is not required and the analyses can be based on the total hospital cohort.

Ownership and Gatekeeping vs. Safeguarding and Consent: How Migrant Parents Navigate Child Data Management Complexities

Conference Proceedings

Rui Huan, Kopo M. Ramokapane, Awais Rashid

2025 IEEE Symposium on Security and Privacy, May 2025 [USA]; pp 2209-2227

Abstract

Parents pursuing opportunities abroad increasingly find themselves raising children in new cultural and legal environments. This responsibility extends to complying with unfamiliar regulations and safeguarding their children’s data which is often complex and a challenging task. In this study, we examine how migrant parents perceive, manage, and safeguard data related to their children. Through interviews with 17 migrant parents and guardians in the UK, we uncover nuanced and evolving perspectives on data ownership and management. Migrant parents express significant concerns about losing control over data shared locally and with extended families abroad, with fears of misuse that could harm their children or jeopardize their immigration status. We discuss their data management strategies and approaches to navigating changing concepts of data ownership and consent. Our findings underscore the need for culturally sensitive support to help migrant families safeguard their children’s data and highlight directions for future research into the complexities of cross-border data sharing and its implications.

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TECHNOLOGY/OTHER MEDIATION

Picturing informed consent: Exploring participatory visual methods to enhance meaningful consent conversations with young people

Research article

Jennifer A. Thompson, Emilia Gonzalez, Mónica Ruiz-Casares

Research Ethics, 20 May 2025

Open access

Abstract

Informed consent (IC) is a cornerstone of ethical research, ensuring participants are informed and provide voluntary agreement to participate. Yet IC remains complex, especially in research with young people, and practical examples for engaging youth meaningfully in IC processes are limited. Participatory visual methodologies engage youth as knowledge producers to think creatively, express diverse perspectives, and engage in dialog. This study explores how participatory visual methodologies can involve youth in IC by inviting them to create and discuss visual representations of its key concepts. Grounded in literature on research ethics with young people, we ask: How do young people in Cameroon represent some of the core concepts within IC visually, and what kinds of conversations emerge around these representations? To address these questions, we conducted workshops with 56 young people (10–16 years old) in Cameroon's Southwest and Northwest Regions. Participants took photos to represent and discuss the benefits and risks of research, voluntary participation, and confidentiality as key elements of IC, and created visual representations of IC forms. Findings show that incorporating visual elements in IC prompted participants to critically engage with IC, facilitating a deeper contextualized and nuanced understanding and meaningful dialog about both the notion of consent and the study they are potentially consenting to. This study presents a case on adolescents and IC in an African context, emphasizing the importance of social and cultural factors in IC and contributing to literature that largely focuses on younger children in Western settings. Integrating participatory visual methods reframed IC as a collaborative, group-centered process rather than a researcher-driven, one-time event. These findings highlight the potential of participatory visual approaches to deepen youth engagement in research ethics, contributing to more equitable and locally relevant research practices.

Video-assisted education for informed consent in percutaneous nephrolithotomy: a prospective study on patient comprehension

Research

Mucahit Gelmis, Yasar Pazir, Ufuk Caglar, Ahmet Halis, Caglar Dizdaroglu, Furkan Gunay, Sedat Cakmak, Faruk Ozgor

World Journal of Urology, 15 May 2025

Abstract

Purpose

The prevalence of urinary stone disease is increasing due to climate change, dietary habits, and obesity. Percutaneous nephrolithotomy (PCNL) remains the preferred treatment for large kidney stones. The informed consent process is essential for patient understanding; however, conventional verbal and written methods may be inadequate. This study aimed to evaluate the effectiveness of video-assisted education in improving informed consent for PCNL.

Methods

This randomized controlled study was conducted from January to July 2023. Eighty patients scheduled for PCNL were randomly assigned to either a written-consent-only group or a video-assisted consent group that received both written consent and a seven-minute 3D-animated video. Comprehension was assessed using a

17-question knowledge assessment questionnaire before and after the consent process. Improvements in knowledge and differences in comprehension were compared.

Results

The video-assisted consent group showed significantly greater comprehension improvement than the written-only group, benefiting patients across all education levels. Multivariate analysis confirmed the strong association between video education and knowledge gain, though older age was linked to lower improvement. Despite its effectiveness, two patients withdrew due to increased anxiety, underscoring the need to balance understanding with emotional reassurance.

Conclusion

Video-assisted informed consent significantly improves comprehension in PCNL patients, particularly in those with lower education levels. However, an increased awareness of surgical risks may contribute to preoperative anxiety. Future research should refine video content, assess long-term outcomes, and explore strategies to balance comprehension with emotional reassurance.

Uses of augmented reality in surgical consent and patient education – A systematic review

Research Article

Thomas Evans, Adam Turna, Thomas D. Stringfellow, Gareth G. Jones

PLOS Digital Health, 28 April 2025

Open Access

Abstract

Augmented reality (AR) allows the real environment to be altered with superimposed graphics using a head-mounted-display (HMD), smartphone or tablet. AR in surgery is being explored as a potential disruptive technology and could be used to improve patient understanding of treatment and as an adjunct for surgery. The aim was to explore this use of AR and assess potential benefits for consent and patient education. A systematic review was conducted using PRISMA-SCR guidelines. 4 major bibliographic databases were searched using the terms: '(augmented reality OR mixed reality) AND surgery AND (consent OR patient education)'. Included papers evaluated an AR intervention on consenting patients for enhancing surgical consent or education about a procedure. Non-English language papers and studies which did evaluate an intervention were excluded. Three reviewers screened all abstracts and full text papers for inclusion. The review protocol was prospectively registered with PROSPERO (ID: CRD42020207360). 52 records were identified. Following removal of 13 duplicates, 21 were removed after abstract screening leaving 17 articles for full assessment. One article was a letter and 8 did not evaluate interventions, leaving 8 articles published between 2019 and 2023. 3 papers were randomised controlled trials comparing AR enhanced processes to standard consent, 2 cohort studies evaluated patient satisfaction with AR interventions and there was one randomised crossover trial of AR against traditional consent consultation. The Cochrane risk of bias tool was used most studies were deemed as high risk of bias. Patient satisfaction and understanding were improved using AR. However, advantages over other enhanced techniques are less clear. Using AR to enhance written literature was shown to require less mental effort from patients and was preferred to standard resources to understand complex surgery. The few randomised trials are limited by bias and lack of power calculation, highlighting the need for further research.

How Making Consent Procedures More Interactive can Improve Informed Consent: An Experimental Study and Replication

Marije Aan Het Rot, Ineke Wessel

Journal of Empirical Research on Human Research Ethics, February-April 2025

Abstract

Prospective research participants do not always retain information provided during consent procedures. This may be relatively common in online research and is considered particularly problematic when the research

carries risks. Clinical psychology studies using the trauma film paradigm, which aims to elicit an emotional response, provide an example. In the two studies presented here, 112-126 participants were informed they would be taking part in an online study using a variant of this paradigm. The information was provided across five digital pages using either a standard or an interactive format. In both studies, compared to the control condition, participants in the interactive condition showed more retention of information. However, this was only found for information about which they had been previously asked via the interactive format. Therefore, the impact of adding interactivity to digital study information was limited. True informed consent for an online study may require additional measures.

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YOUNG PERSONS

Empowering Voices: Implementing Ethical Practices for Young Children's Assent in Digital Research

Amanda M. Mirabella, Ilene R. Berson, Michael J. Berson
Education Sciences, 3 May 2025
Open Access
Abstract
This article examines how young children express informed assent in research settings that incorporate digital tools, participatory methods, and play-based approaches. Drawing on data from three studies involving kindergarten and first-grade children (ages 5 to 7) in the southeastern United States, this cross-case analysis explores how children navigated their participation using multimodal and relational strategies. Conceptual play theory, social semiotics, and participatory research frameworks guided the analysis, emphasizing assent as an evolving, co-constructed process rather than a singular verbal agreement. Through video recordings, field notes, and action-oriented transcripts, we investigated how children expressed comfort, curiosity, and agency across diverse contexts—including virtual reality storytelling, video-cued reflection, and interactive eBooks. Findings illustrate that assent was negotiated through gesture, movement, silence, humor, and peer interaction, often extending beyond adult-defined research routines. Children reinterpreted their roles, shaped the pace of sessions, and co-constructed meaning through play and dialogue. This retrospective synthesis of three previously conducted studies offers practical and ethical insights for researchers working with young children, including the importance of ongoing assent checkpoints, developmentally appropriate explanations, and flexible research environments. We argue that ethical research with children must prioritize multimodal communication, child-led pacing, and relational trust to support authentic and meaningful participation. By reframing assent as a dynamic and multimodal process, this research contributes to emerging conversations about ethical responsiveness, agency, and inclusive practices in early childhood research.

Consensus on Adolescent and Young Adult HIV Research Consent in Low- and Middle-Income Countries

Consensus Statement
Suzanne Day, Sonam J. Shah, Ujunwa F. Onyeama, Lauren Fidelak, Ucheoma Nwaozuru, Stuart Rennie, Abdulhammed Opeyemi Babatunde, Weiming Tang, Elzette Rousseau, Chisom Obiezu-Umeh, Kelechi Prince Chima, Nadia A. Sam-Agudu, Erin C. Wilson, Seema K. Shah, Susan Nkengasong, Titilola Gbaja-Biamila, Bill G. Kapogiannis, Linda-Gail Bekker, Juliet Iwelunmor, Oliver Ezechi, Joseph D. Tucker
JAMA Network Open, 29 April 2025; 8(4)
Open Access

Key Points

Question

What are practical strategies to improve informed consent processes for adolescents and young adults (AYAs; aged 10-24 years) in HIV research studies in low- and middle-income countries?

Findings

This consensus statement addresses critical questions about empowering AYAs, involving parents in the research process, and developing policies to increase AYA inclusion in research based on data from a comprehensive scoping review, a crowdsourcing open call, and a diverse global group of people.

Meaning

This consensus statement provides a framework to enhance inclusion of AYAs in HIV studies in low- and middle-income countries.

Abstract

Importance

Many adolescents and young adults (AYAs) in low- and middle-income countries (LMICs) are excluded from HIV research because of challenges with informed consent for study participation, which makes it difficult to understand and improve the lives of AYAs living with HIV and AIDS in a wide variety of settings.

Objective

To help increase the inclusion of AYAs in HIV research, we developed a consensus statement on practical strategies for improving AYA consent in HIV research in LMICs.

Evidence Review

The VOICE (HIV Youth Informed Consent & Ethics in Research) Working Group included AYAs, researchers, community organizers, advocates, research ethics committee members, parents of AYAs, and bioethicists who drafted initial statement items using data from a global open call and scoping review. An adapted Delphi process was then used to develop consensus statement items. The process involved 3 rounds of online Likert-scale questionnaires and a hybrid (online and in-person) consensus summit in Lagos, Nigeria, in 2022, with the total study period lasting from August 23, 2021, to February 10, 2023.

Findings

Thirty-five people participated in the final round of the Delphi process, including 14 individuals younger than 35 years (40.0%), 25 HIV researchers (71.4%), and 32 people who worked in an LMIC (91.4%). Twenty-five items reached a predefined threshold for consensus (≥80% agreement). Strong consensus emerged for formal mechanisms (eg, cocreation, crowdsourcing, or youth advisory boards) for AYA engagement in and education about research as well as for strategies to enhance parental and guardian involvement in HIV research when safe and appropriate. Capacity strengthening can allow AYAs to review research protocols, join ethical review committees, and advocate for regulatory change. Two items in the statement (alternatives to parental consent and raising awareness among research ethics committees about AYA-independent consent) required further refinement to reach the agreement threshold for inclusion.

Conclusions and Relevance

Greater engagement of both AYAs and parents may help to enhance consent processes and increase the inclusion of AYAs in LMIC HIV research studies. The resulting consensus statement provides practical strategies for implementing improved consent processes for AYA research participation at the organizational, community, and policy levels, which may help foster greater inclusion of AYAs in HIV research and address existing data gaps.

Conclusions [taken from the full statement]

In this consensus statement study of strategies to improve AYA consent processes for HIV research in LMICs, we identified a set of 25 practical approaches by which consent processes might be improved. Improving consent processes is the first (albeit not the only) step toward improving inclusion of AYAs in HIV research, which is essential to ensure the collection of data for informing treatment and prevention strategies that are effective and safe for AYAs. The strategies proposed in this consensus statement may be relevant to a wide range of other research topics beyond HIV, with potential to inform and improve research practices in other

areas involving AYAs, such as mental health, sexual and reproductive health, and beyond. Further collaboration will be needed to assess the utility of this guidance in diverse LMIC settings.
The finalized consensus statement, including the preamble, glossary of terms, and open-access resources, are available in the eResults in the Supplement.

Ethical Considerations in Pediatric Surgery: Discussing Informed Consent, Parental Rights, and Decision-Making in Complex Cases

Sahir Prasenjit Telang
Journal of New Century Innovations, 12 April 2025
Abstract
Ethical aspects in pediatric surgery represent a special area of medical practice where the interests of the child, parents, and medical professionals intersect. The purpose of this study is to analyze modern approaches to informed consent, parental rights, and decision-making in complex clinical situations. The study involved 450 pediatric surgeons and 320 parents from five multidisciplinary hospitals in Europe and Central Asia. The obtained data showed that only 37% of doctors involve children over 12 in the decision-making process, despite the recommendations of international organizations. In 64% of cases, doctors encountered disagreements from parents, and 17% of such situations required intervention from the ethics committee or judicial authorities. Significant cultural differences were also identified: in Central Asia, parental opinion dominance was noted in 83% of cases, compared to 51% in European clinics ($p<0.01$). The results highlight the need to develop unified protocols, improve the effectiveness of ethics committees, and implement medical ethics programs in the educational process. Strengthening the role of joint decision-making, taking into account the child's opinion, can improve the ethical stability and quality of medical care in pediatric surgery.
Editor's note: The Journal of New Century Innovations is published in Uzebekistan.

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CAPACITY TO CONSENT

Informed Consent in Vulnerable Populations: The Case of Detained Persons with Attention Deficit Hyperactivity Disorder

Research Article
Stéphanie Baggio, Leonel da Cunha Gonçalves, Patrick Heller, Hans Wolff, Laurent Gétaz
Journal of Empirical Research on Human Research Ethics, 8 May 2025
Abstract
Informed consent (IC) is a critical component in research involving human participants, yet participants' understanding of consent information remains underexplored, particularly in vulnerable populations. This study aimed to assess whether attention deficit hyperactivity disorder (ADHD) was associated with understanding and willingness to sign the IC among detained individuals. This secondary analysis used data from a randomised trial conducted in a Swiss prison (n = 183). Statistical analyses included regression models. There was no significant difference in understanding of the IC between the groups with and without positive screening for ADHD (mean score = 5.2 vs. 4.9 respectively, p = .468). Acceptance of signing the IC was comparable between groups (83.3% ADHD vs. 84.9% non-ADHD, p = .814). Our findings suggest that ADHD did not significantly impair the understanding of the IC or the decision to participate in research among detained individuals. However, the level of understanding was overall low, highlighting the need for tailored approaches to improve understanding in vulnerable populations.

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CULTURAL/HERITAGE/RELIGIOUS/COUNTRY CONTEXT

Exploring knowledge and attitudes toward electronic informed consent among clinical trial participants in China: a cross-sectional study

Ying Wu, Xing Liu, Xiaoying Ge, Xin Tan, Weiwei Yu, Xiaomin Wang

BMC Medical Ethics, 26 May 2025

Open Access

Abstract

Background

With the extensive integration of digital technology into clinical research, intelligence, virtualization, and decentralization have gradually transformed into emerging clinical research modes, the electronization of informed consent has become indispensable to the development of clinical trial informatization, and the inclination to use electronic informed consent (eIC) has grown. The knowledge and perceptions of research participants, as objects of informed consent acquisition, regarding eIC are crucial. However, few studies have empirically explored such issues.

Methods

This cross-sectional study was conducted at three general hospitals in south-central China from July to September 2022. An online survey questionnaire was adapted and administered via WeChat to investigate the issues of interest.

Results

A total of 388 valid questionnaires were included in the analysis. The results showed that the overall response rate for the knowledge section of the questionnaire exceeded 70%. Of the respondents, 53.1% had heard of the term “electronic informed consent,” but only 43.2% had used eIC. The majority of respondents (68%) expressed a preference for using eIC and demonstrated a positive attitude toward it. However, some participants expressed concerns regarding the security and confidentiality (64.4%), operational complexity (52.3%), and effectiveness of online interaction (59.3%) in eIC. Statistically significant relationships were observed between participants’ attitude scores and their age, gender, type of participation, and frequency of involvement in clinical research. Additionally, a positive and statistically significant correlation was found between participants’ knowledge scores and their attitude scores.

Conclusion

The results of this study indicate that most participants have a good understanding of eIC-related knowledge and hold a positive attitude toward its implementation. However, they also express concerns about data protection and privacy security in eIC. These findings provide a foundation for developing targeted strategies to enhance the adoption and acceptance of eIC among diverse populations.

Family consent to deceased organ donation in China: a participatory qualitative study

Original research

Haiyan He, Chaojie Liu, Ying Huang, Wei Ouyang, Zirui Xin, Hanan Khalil, Aijing Luo, Wenzhao Xie

Journal of Medical Ethics, 22 May 2025

Abstract

Background

Organ donation improves patient survival and quality of life, yet family refusal is a major barrier. This study aimed to explore the role of family discussions in shaping attitudes and decisions about organ donation in China, while also examining the influencing factors at the individual, family, community and societal levels.

Method

Participatory interviews with family members were conducted based on the social-ecological model (SEM). A snowball sampling strategy was adopted to recruit volunteer interviewers. Of 52 interviewers, 25 completed the family group interviews, involving 94 participants in total. Interviews were audio-recorded and transcribed verbatim within 24 hours. Two researchers coded the data in line with SEM. Themes were identified through an inductive process.

Results

Four themes were identified out of family discussions about deceased organ donation: (i) individual perceptions on the value of lives and organ donation (value of organ donation, death attitudes, knowledge about organ donation), (ii) family consensus and conflicts (family structure, family altruism), (iii) collective conformity (conformity, individualism, negativity bias) and (IV) culture and social environment (traditional beliefs, incentive policy, education, media promotion).

Conclusion

This study is the first to systematically examine the factors influencing deceased organ donation in the Chinese family context. Obtaining family consent for organ donation appears to be challenging in Chinese families due to limited knowledge and traditional beliefs. Incentive policies that benefit the family are crucial. While media promotion is effective in increasing awareness of organ donation, education and family discussions are critical in alleviating fears and misunderstandings about deceased organ donation.

Too uncertain to consent, too supportive to refuse: the sociocultural dilemma of hesitant organ donors in Kazakhstan

Original Research

Aidos Bolatov, Aruzhan Asanova, Aigerim Abdiorazova, Yuriy Pya

Frontiers of Public Health: Public Health Education and Promotion, 19 May 2025

Abstract

Background

Understanding the factors influencing posthumous organ donation decisions is essential for developing effective strategies to increase donor registration. While previous studies have explored reasons for consent and refusal, less attention has been given to individuals who defer the decision to their families (Decision Left to Close Relatives, DLCR). This study examines the sociodemographic, institutional, and cultural factors influencing donation preferences, with a focus on the DLCR group as a transitional category between consent (LC) and refusal (LR).

Methods

A cross-sectional survey was conducted among 1,333 participants in Kazakhstan. Donation preferences were categorized into Lifetime Consent (35.3%), Lifetime Refusal (21.4%), and DLCR (43.4%). Participants completed measures assessing knowledge, attitudes, and perceived barriers to organ donation. Principal Component Analysis (PSA) identified two key dimensions of perceived barriers: institutional and cultural barriers. Linear regression and mediation analyses were performed to examine predictors of attitudes toward organ donation.

Results

The DLCR group held intermediate attitudes toward donation, significantly higher than LR but lower than LC ($p < 0.001$), moreover, 44.4% of the DLCR group had a favorable attitude toward organ donation. A critical finding was the high level of uncertainty about how to declare donation status among DLCR participants, significantly higher than in both LC and LR ($p < 0.05$). PCA revealed that DLCR individuals were institutionally closer to LC but culturally aligned with LR, suggesting that cultural concerns are the stronger barrier preventing proactive consent. Among DLCR participants, knowledge positively predicted donation attitudes ($\beta = 0.223$, $p < 0.001$), while cultural and religious barriers had the strongest negative effect ($\beta = -0.290$, $p < 0.001$). Language preference also emerged as a factor, with Russian speakers demonstrating significantly more favorable attitudes than Kazakh speakers. Specialization (medical vs. non-medical) had no direct effect

on donation attitudes ($p = 0.777$), but it influenced attitudes indirectly through institutional ($\beta = -0.223$, $p < 0.001$) and cultural barriers ($\beta = 0.194$, $p = 0.003$).

Conclusion

Both procedural uncertainty and cultural-religious factors influence the hesitation of DLCR individuals to commit to donation, with cultural concerns having a stronger effect. Language preference also shapes attitudes, reflecting broader sociocultural framings. Reducing uncertainty and addressing cultural misconceptions, particularly among the DLCR group, may be key to increasing donor registration.

Knowledge and associated factors of patients towards informed consent in obstetric and gynecologic surgical procedures at Debre Markos Comprehensive Specialized Hospital, Ethiopia

Addisu Andualem Ferede, Mamaru Getie Fetene, Endinew Beka, Worku Taye Getahun, Aysheshim Asnake Abneh

Frontiers of Surery: Obstetrics and Gynecological Surgery, 7 May 2025

Abstract

Background

Informed consent is a principle in medical ethics that a patient must have adequate information and understanding before making decisions about their medical care. It is essential for both clinicians and patients in surgery and should be seen as a usual activity. Knowledge is one of the main intervention tools to improve patient comprehension in informed consent of surgical patients. In Ethiopia, little is known about the knowledge level and its determinant towards obstetric and gynecologic surgical informed consent. Due to this reason, this study aimed to assess the level of knowledge and determinants of surgical informed consent among patients undergone obstetric and gynecologic surgery at Debre Markos Comprehensive Specialized Hospital.

Methods

An institutional-based cross-sectional study was conducted from November 28 to December 30, 2023, among 298 post-operative women admitted to Debre Markos Comprehensive Specialized Hospital. Data were collected using a pretested structured interviewer-administered questionnaire using a systematic random sampling technique. The collected data were entered into Epi-Data version 4.6 and then exported to SPSS statistical software version 25 for analysis. A multivariable logistic regression analysis was employed to estimate the effect of independent variables on the outcome variable. An adjusted odds ratio (AOR) with 95% Confidence interval was computed to report the presence of association between the dependent and independent variables. Statistical significance was determined at a P-value of <0.05.

Results

A total of 298 women participated in the study. The overall good knowledge of women regarding obstetrical and gynecologic surgical informed consent was 42.3% (95%CI: 36.7, 47.9). Urban residence (AOR= 2.32, 95%CI: 1.08, 5.03), educational status of women (AOR= 4.85, 95%CI: 1.99, 11.78), elective type of surgery AOR= 1.8, 95%CI: 1.14, 4.07), and having previous history of surgery (AOR= 7.2, 95%CI: 4.02, 15.15) were the identified determinant factors affecting knowledge of women towards obstetric and gynecologic surgical informed consent.

Conclusion

More than half of the study participants lack overall good knowledge regarding obstetrical and gynecologic surgical informed consent. Residence, educational status, schedule of surgery, and previous history of surgery were the identified determinant factors affecting the knowledge of women towards obstetric and gynecologic surgical informed consent.

Surgical consent, perception of the patients who underwent a surgical operation in the Kurdistan region, Iraq

Dawan Jamal Hawezy

BMC Medical Ethics, 2 May 2025

Open Access

Abstract

Introduction

Patient satisfaction is a significant measure of healthcare service quality as the patient is the center of any surgical procedure. Patient satisfaction refers to the extent to which a patient's expectations of optimal care align with their perception of the care received. Patient satisfaction during informed consent is enhanced when written informed consent is accompanied by verbal consent in the preoperative period. Satisfied patients are more inclined to adhere to therapy, engage actively in their care, utilize healthcare services, willingly partake in decision-making, and remain with a healthcare provider. This research examines the practical and ethical considerations of obtaining informed consent during surgical procedures. To better understand and make informed decisions, this study aims to assess the efficacy of present consent methods and pinpoint obstacles patients encounter.

Methodology

A cross-sectional study was conducted from April to December 2024. Data were gathered by second-year students from Koya University's Faculty of General Medicine by interviewing postoperative patients who had undergone general surgical procedures. The results were entered into a Google form and analyzed using SPSS27.

Results

In interviews with participants, 430 out of 572 patients (75%) indicated trust in their surgeons performing the surgery, while 525 patients (91%) expressed respect for their surgeons' opinions. However, 41% (239 patients) reported not reading the informed consent form, and a similar percentage denied that the details of the form were explained by the medical staff responsible for the surgery as there are some medical terms or situations in the form that are challenging to assume if not explained.

Conclusion

Compared to others, participants with a higher educational level sought extensive time from the responsible surgeons to discuss every detail of the surgery before signing the informed consent, with a statistically significant difference observed. A similar difference was noted between private and public hospitals.

Patients' perceptions and understanding of preoperative informed consent: A qualitative thematic analysis from Tanzania

Research Article

Steven Michael, Willbroad Kyejo, Allyzain Ismail, Sunil Samji, Eric Aghan, Columba Mbekenga, Athar Ali

SAGE Open Medicine, 28 April 2025

Open Access

Abstract

Background

Informed consent, grounded in the ethical principle of autonomy, represents a patient's agreement to undergo a procedure. Given its critical role in protecting human rights and autonomy, obtaining informed consent before any surgery or procedure is now a mandatory practice. However, many studies question whether informed consent is conducted genuinely, ensuring proper understanding of the information disclosed, or merely serves as a medicolegal formality. This has led to increased malpractice, misunderstanding, anxiety, and overall postoperative dissatisfaction.

Objective

This study aimed to explore patients' perceptions and experiences regarding the informed consent process for elective surgeries, identifying key challenges and areas for improvement.
Methods
This descriptive qualitative study was conducted at Aga Khan Hospital using individual in-depth interviews. Fourteen patients who had undergone elective surgery were recruited. Baseline data were presented in tables, and inductive thematic analysis was used to interpret the qualitative data.
Results
Seven themes emerged from the data: Consent as a legal formality, autonomy, and decision-making, insufficient information, time constraints and lack of opportunities for questions, use of medical jargon, patients' desired information, and overall satisfaction with care. Despite patients' higher levels of education and the hospital's patient-centered care approach, many felt the information provided was insufficient, superficial, and difficult to understand.
Conclusion
The study found a significant gap between the information patients desired and what was provided. Insufficient information, coupled with the use of medical jargon and time constraints, adversely affected the informed consent process. Enhancing clarity in communication and allowing adequate time for discussions could improve patient understanding and satisfaction.

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RELATIONAL, CULTURALLY-CONDITIONED, DECOLONIZED CONSENT

Editor's Note:
We recognize a growing literature which argues [in whole or in part] that norms requiring the individual, prior, free, express and informed consent of persons to be involved in research must accommodate notions which integrate terms such as 'community-driven', 'decolonized', or 'culturally-appropriate' and which insist that consent processes "prioritize local/indigenous values and protocols." As an editorial policy, we have decided to group such literature together in this section of the digest.

More broadly, we recognize that this literature raises critically important issues around consent integrity. Our Center for Informed Consent Integrity is actively developing a position on this matter, mindful of core guidance in research involving human participants overall, and selected instruments such as the Universal Declaration on Bioethics and Human Rights [2005] which notes:

> Article 12. Respect for cultural diversity and pluralism
> The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

We will keep readers advised of our progress. If you have an interest in participating in our working group, please contact Paige Fitzsimmons [paige.fitzsimmons@ge2p2global.org].

Informed Consent and Cultural Dignity: Rethinking Research Ethics through the Havasupai Tribe Case - Toward Collective Consent Models

Carolina Ruiz
Law, History and Society, 19 May 2025
Abstract
This article examines the limitations of Western individualistic informed consent frameworks through a critical analysis of the Havasupai Tribe v. Arizona State University Board of Regents case and its broader implications. By exploring the tension between Western legal paradigms and Indigenous collectivist worldviews, this research demonstrates how prevailing consent models systematically fail to recognize

cultural dignity and communal harm as fundamental rights. This article situates this failure within a historical pattern of research abuses against Indigenous populations while drawing parallels across multiple domains: Fourth Amendment jurisprudence, digital privacy regulation, and international approaches to Indigenous research ethics. Through these comparisons, the analysis reveals systemic deficiencies in how American legal frameworks conceptualize meaningful consent for vulnerable populations with collective identities. Based on comparative analysis of international models and examination in emerging challenges in genetic and digital research, the article proposes comprehensive reforms including cultural impact assessments, collective consent mechanisms, and ongoing consent processes that honor Indigenous sovereignty. This contribution advances a more nuanced ethical framework that protects cultural dignity while acknowledging the inherently communal nature of harm in Indigenous contexts and emerging technological landscapes.

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RIGHTS/LEGAL/LEGISLATIVE

Legal Issues in Caring for the Adolescent Student—Consent and Privacy

Book Chapter
Kristen Reilly, Ashley Ebersole
Clinical Considerations in School-based Health, 24 May 2025 [Springer]
Abstract
For patients who are minors (younger than 18), laws governing their care may be different than those for adults. The legal issues that most commonly arise concern consent (who can provide consent and for what care?) and confidentiality (what information can be shared and with whom?). This chapter will summarize the legal framework within the United States, discuss considerations for a school-based provider, and review relevant patient cases.

The Issue of Informed Consent of the Surrogate Mother in Context of Surrogacy Arrangements – Autonomy and Dignity

Zsófia Nagy, Andrea Erdősová
STUDIA IURIDICA Cassoviensia, 27 March 2025
Abstract
Since assisted reproductive techniques have widespread in medical science, bioethical principles and legal implications surrounding commercial surrogacy arrangements, particularly focusing on the position of surrogate mothers have emerged. With the rise of in vitro fertilization and the growing prevalence of surrogacy in the latter half of the 20th century, the contractual nature of these arrangements has sparked significant ethical and human rights concerns. The article delves into the complexities of parental filiation, the potential exploitation of surrogate mothers, and the critical importance of informed consent and patient autonomy in this context. The analysis of these issues could shed light on the ethical and legal discourse surrounding commercial surrogacy and collaborate to the discourse of the relevancy of the informed consent of the surrogate mother in surrogacy arrangements.

Editor's note: STUDIA IURIDICA Cassoviensia is published by Jozef Safarik University [Slovakia] Faculty of Law

Regulatory Frameworks, Compliance and Healthcare Responsibilities on Informed Consent in Nigeria

Chukwunye Augusta Ojeih, Olumide Ogidan, Adetutu Adewole

African Journal of Law, Ethics and Education, 2025

Abstract

Informed consent is a cornerstone of healthcare ethics and law in Nigeria. However, ensuring regulatory compliance and healthcare provider accountability remains a challenge. This paper examines the tripartite relationship between regulatory frameworks, institutional compliance, and healthcare provider responsibilities in obtaining informed consent; it analyzes existing laws, policies, and guidelines to identify gaps. It further scrutinizes the role of healthcare institutions and providers in ensuring effective informed consent practices, highlighting the challenges and opportunities for promoting patient autonomy and dignity in Nigeria's healthcare system. This study ultimately argues that a multifaceted approach, incorporating regulatory reform, institutional accountability, and provider responsibility is essential for ensuring the integrity and efficacy of informed consent in Nigeria's healthcare sector.

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MEDICAL/SURGICAL

The experiences of clinical staff approaching families for organ donation consent: A systematic review and thematic synthesis of qualitative studies

Review Article

L.H.M. Pengel, V. Mazarello-Paes, D. Paredes-Zapata, G.C. Oniscu, C. Gouveia Gaglianone, L. Zhu, Y. Wang, N. Dhanda, J. Tocher, L. Aviles

Transplantation Reviews, July 2025

Open Access

Abstract

Healthcare professionals (HCPs) play an essential role in organ donation (OD) particularly when approaching families to discuss consent to OD. We synthesized the evidence on experiences of HCPs when approaching potential organ donor families. Fourteen electronic databases were searched to identify studies describing HCP experiences or associations between HCP experiences and consent rates. Methodological quality was assessed by independent reviewers using the Mixed Methods Appraisal Tool. Qualitative data were analysed using thematic synthesis, while quantitative data were summarized by narrative review. Ninety-two studies were included. HCP experiences were conceptualised as a paradox due to the challenges to negotiate the boundaries between life and death. Organisational and personal aspects broadly shape the experiences of professionals. Studies suggest that staff experiences can be improved by training and education, however, quantitative studies did not show a strong association between OD training and improved consent rates. The complexities of the family approach were evident in the variety of interactions between HCPs and the donor family, which may explain why there is no uniform approach across settings and countries. The review highlights the challenges faced by professionals when negotiating policy and practice and informs recommendations to support staff involved in the OD process worldwide.

The association of patient and clinician demographics and concordance with medicaid sterilization consent form validity

Research Paper

Lisa Jackson-Moore, Kim Malloy, Gene Urrutia, Kristen A. Berg, Emily S. Miller, Margaret Boozer, Tania Serna, Jennifer L. Bailit, Suzanna Larkin, Kavita Shah Arora

Journal of the National Medical Association, 23 May 2025

Abstract

Objective(s)

To evaluate the association between patient demographics, clinician demographics, and concordance of patient-clinician demographics and Medicaid sterilization consent form validity, defined as the waiting period having elapsed.
Study Design
Secondary analysis of a large, multi-center retrospective cohort study. This analysis included patients with Medicaid insurance desiring postpartum permanent contraception across three study sites. Our primary outcome was Medicaid sterilization consent form validity. Patient demographics were abstracted from the electronic medical record. Clinician demographics were obtained both through self- and peer-report. Descriptive, random effects modeling, and multivariable logistic regression analyses were utilized.
Results
Of the 1644 patients delivered by 124 clinicians in our cohort, 840 (51 %) had a valid Medicaid sterilization consent form. Descriptively, patients who were Black, unmarried, and not college educated were more likely to have valid forms ($p < 0.001$). The religious affiliation of the clinician ($p < 0.001$), but no other clinician characteristics, was associated with form validity. In multivariable models, patients who were of a different racial identity than their clinicians were more likely to have a valid form (aOR 1.32, 95 % confidence interval (CI) 1.05–1.66).
Conclusion(s)
While unable to determine the causes of our findings, the differential proportion of Medicaid sterilization consent form validity based on patient characteristics is concerning. Differences in form validity based on patient-clinician racial and ethnic concordance is deserving of further study.

Informed consent and ethics committee involvement in case reports and case series: cross-sectional meta-research study

Research
Matea Valešić, Marta Čivljak, Livia Puljak
BMC Medical Ethics, 19 May 2025
Open Access
Abstract
Background
Although the research should guarantee the protection of privacy and personal data, case reports and case series frequently lack the involvement of the ethics board and informed consent that includes the required information. This study aimed to analyze the reporting about informed consent and ethics committees in case reports and case series.
Methods
This cross-sectional meta-research study analyzed case reports and case series published in 2021, indexed in PubMed, and available as open-access articles. Extracted variables included authorship details, country, journal name, number of cases, and documentation of informed consent and ethics committee approval.
Results
This study analyzed 2053 case reports and case series. Most articles (86%) reported a single case. Statements about informed consent were reported in 79% of cases. Informed consent was primarily obtained from patients (74%). Statements about an ethics committee were reported in 46% of articles. In 24% of articles, it was reported that approval was obtained from an ethics committee. Case reports were significantly more likely to include a statement on informed consent than case series. On the contrary, case series were significantly more likely to report ethics committee statements than case reports.
Conclusion
The findings reveal inconsistencies in ethics reporting, with 46% of articles mentioning ethics committee involvement and varying justifications for exemption. While 79% of articles reported informed consent, further improvements in transparency and standardization are needed. Clear guidelines on ethical approval

requirements and consent documentation should be established to enhance the quality and ethical rigor of case reports.

> *Editor's note: The authors refer to cases as the following in the article: "Case studies, case reports, and case series are descriptive studies that illustrate innovative, unusual, or atypical features found in patients in clinical practice."*

Patient perception of consent processes for epidural analgesia in induction of labour: a qualitative study

Danna Nitzani, Jacqueline Nicholls, Katherine Maslowski, Robert Craig, Sohail Bampoe, Melissa Whitten, Anne Lanceley

Anaesthesia, 12 May 2025

Abstract

Introduction

Women undergoing induction of labour often utilise epidural analgesia. Obtaining consent for labour epidural presents a unique challenge for the obstetric anaesthetist, who must comply with the legal standards of consent. This study explores how women perceive the consent process for epidural analgesia during induction of labour.

Methods

This was a qualitative, single-centre, interview-based study. Fourteen women who received an epidural for labour analgesia were interviewed using a semi-structured interview guide. Data were analysed using thematic analysis.

Results

Four themes described women's experience of the consent process. Understanding alternatives, risks and benefits; for example, time constraints hindering the effective communication of information around epidural analgesia, including alternative analgesic options. Timing of information; for example, the value of information was diminished by pain, fatigue and the imminence of the procedure. Timing of consent; for example, physiological and psychological demands of labour negatively impacted patients' ability to engage with the consent process. Anaesthetists' assessment of patient understanding; for example, confirmation of patient understanding by anaesthetists was lacking.

Discussion

Women's experiences of the consent process for induction of labour suggest that in the context of the pain and exhaustion of labour, inadequate and untimely information provision and dialogue between women and their anaesthetists can undermine the implementation of lawful consent.

Investigating the Level of Awareness Regarding Informed Consent Among the Post-Operative Patients in Surgical Ward

Faiza Shoaib, Amir Sultan, Noshaba Faiz, Samin Rani

Journal of Medical & Health Sciences Review, 10 May 2025

Abstract

Background

The concept of informed consent is an important aspect of biomedical ethics, which is obtained in written form, but in some cases, it may be verbal, especially for non-invasive and relatively non-risky interventions. The study was conducted with the aim of evaluating the level of awareness among post-operative patients regarding informed consent.

Methodology

The study design was cross-sectional descriptive and was conducted in the surgical ward of a tertiary care hospital in Swat, Pakistan from December 2023 to January 2024. The sample size of the study was 180 using

the purposive sampling technique, while a valid and reliable questionnaire was used for data collection. Descriptive statistics were used through SPSS 22.0. The study was approved by an ethical review committee, and informed consent was obtained from every respondent.

Results

The finding reveals that the majority of the participants were female 112 (55.7%), the age group 36–45 years was 75 (37.3%), and people belonged to village 189 (94%). The maximum number of patients level of awareness was good (58%), while the remaining 42% had a poor level of awareness. The majority of the patients know the type of surgery 181 (90%), alternative treatment to the surgery 123 (61.2%), number of hours to be nothing per oral (NPO) 190 (94.5%), time of surgery 197 (98%), and overall satisfaction regarding informed consent 201 (100%).

Conclusion

The study found that patients lack awareness about the surgeon, procedure process, advantages and disadvantages, procedure importance, anesthesia type, and complications, highlighting the need for enough information regarding their procedure.

A Modular Form of Informed Consent for the OPHL Surgeries

Book Chapter

Leone Giordano, Davide Di Santo, Andrea Galli, Mario Bussi

Atlas of Open Partial Horizontal Laryngectomy, 6 May 2025 [Springer]

Abstract

Open Partial Horizontal Laryngectomies (OPHLs) are well-established procedures for the treatment of laryngeal cancer. OPHLs have the advantage of being “modular,” such as they can be tailored to patients’ specific disease extent, and they can be intraoperatively extended according to unexpected tumoral infiltration. A modular informed consent form (ICF) should be implemented in such kind of surgery, being tailored to the patient as well and including any possible variation in the scheduled surgical plan. Furthermore, OPHLs may not be easy to understand for patients; in particular, their peculiar modularity may cause confusion. At the same time, the alliance between surgeon and patient is fundamental for postsurgical rehabilitation. To improve communication and cooperation, an information form should be provided to the patient days before the surgery. Both ICF and IF would improve communication and agreement between surgeon and patient and prevent any possible misunderstanding and litigation.

Valid consent in the acute hospital setting: perspectives of nursing and medical professionals from a survey-based study

Original Article

Charmaine Zahra, Motheo Kobua, Živa Kovic, Mary Fogarty, Catherine Buckley, Jane Murphy, Julie Walshe, Paul Zambra, Declan Byrne, Una Geary, Marie E. Ward

Irish Journal of Medical Science, 2 May 2025

Open Access

Abstract

Background

In healthcare, consent refers to the act of granting permission or agreement for treatment and care, investigation, receiving or utilising a service, or participating in research or teaching. Consent should be an ongoing process that involves clear communication about the proposed intervention, including its nature, benefits, and potential risks.

Aim

This survey-based study gathered experiences from junior doctors and nurses in a large acute teaching hospital about current consent practices and suggestions for improvement.

Method

Two surveys were developed and distributed to junior doctors in 2022 and nurses in 2023.
Results
The response rate for junior doctors (n = 58) was 21% (interns) and 57% (senior house officers) and 10% of the total nursing population responded (n = 184). Descriptive statistics and content analysis were used to analyse the results. Both junior doctors and nursing professionals believed there were areas for improvement in terms of consent processes and practices including in relation to better information for patients and more education and training for healthcare professionals.
Conclusions
The process of informed consent is central in the planning and provision of safe, effective person-centred healthcare as it encompasses healthcare professionals and patients communicating about and together deciding on and agreeing to medical interventions. This survey-based study looked at the experiences, attitudes, and perceived needs of junior doctors and nursing professionals in relation to the informed consent process in clinical practice at an acute hospital and informed the development of recommendations for improvement.

Optimizing the Performance of the Surrogate Informed Consent Process for Critical Care Research

R. Avallone Mantelli, C. Glaros, C. Tietbohl, K. Torres, D.C. Files, M.F. Mart, M.A. Matthay, K.E.A. Burns, D. Matlock, M. Wynia, M. Moss

American Journal of Respiratory and Critical Care Medicine, May 2025

Abstract
Rationale
Research in intensive care units (ICUs) is essential to improving care for critically ill patients; however, patients are often unable to consent for themselves. Surrogates are often required to participate in the informed consent process for critical care research, though how to best engage surrogates in this process remains unclear. This study seeks to identify best practices for conducting surrogate consent for critical care research.
Methods
We conducted a mixed-methods study including quantitative surveys with open-ended questions, focus groups, and semi-structured interviews with principal investigators (PIs), research coordinators (RCs), surrogate decision makers who had been approached about a critical care research clinical trial, and when possible, the patient who had been critically ill.
Results
In total, 230 individuals (105 RC, 90 PI, 27 surrogates, 8 patients) completed surveys, and 61 participated in focus groups or interviews. In both surveys and focus groups/interviews, participants across all groups believed that RCs (as opposed to PIs) should conduct the consent process, as RCs are not considered to be authority figures and have fewer perceived conflicts of interest that could influence surrogates decision-making. Surrogates appreciated it when research staff waited until an optimal time to initiate contact and were given physical space and a defined period to consider their decision before follow up with them. When compared to PI/RCs, surrogates and/or patients attributed more importance to seeing the research team as an additional resource in explaining the progress of the patient's care and were appreciated having additional team members whom they perceived as advocating for adherence to clinical protocols for their loved ones ($p<0.0001$ and $p=0.0016$). Compared to PI/RCs, surrogates thought the written consent was more important and were less concerned with its length, ($p=0.001$ and $p<0.0001$). In general, all participants felt that phone and electronic consent was less effective than in-person consent, though these modalities could facilitate the process for distant surrogates. Consent timing, respect for surrogate decision-making autonomy, and clear communication of the patient's presumed wishes were additional significant themes.
Conclusions
Our study highlights the need for better guidance for carrying out the surrogate consent process in ICU research and identifies several themes that could serve to develop recommendations including designating

trained RCs as primary facilitators, improving consent timing and setting, and for implementing accessible consent documentation. This study supports developing standardized training and guidelines for the surrogate informed consent process that could be consistently applied by ethics review boards in reviewing consent processes for clinical care research.

Impact of Multilingual Informed Consent on Lung Transplant Recipients Participating in Explant Tissue Collection at the University of California, San Diego

S.S. Gaboyan, E. Golts, K. Afshar, J. Verheyden, J. Chin, C. Pathak, I.N. Advani, C.M. Lin, A. Meier, X. Sun, Z. Borok, L.E. Crotty Alexander

American Journal of Respiratory and Critical Care Medicine, May 2025

Abstract

Background

Traditional ischemic times for human lung tissue studies often range from hours to days, compromising transcriptomic data accuracy due to the rapid impact of hypoxia on gene transcription. In 2021 we established a pipeline at UC San Diego for the rapid collection of explanted lungs from the operating room (OR) at time of lung transplantation. Multilingual consent forms were adopted in 2024 to increase inclusivity and improve data accuracy across a diverse range of patient populations and disease states.

Methods

Institutional Review Board (IRB) approval was obtained and all subjects provided informed consent. Initially, only English consent forms were used. In early 2024, Arabic, Hebrew, and Spanish consent forms were added. Descriptive statistics and logistic regression were used to assess changes pre- and post-implementation of multilingual consent forms. Explant methodology: immediately after blood flow cross-clamping, explanted lung is handed to the research team in the OR, and multiple 1 cm^3 cubes from upper and lower lobes are harvested. Adjacent segments undergo fresh frozen storage, OCT cryo-embedding, and 4% paraformaldehyde fixation. Sample quality has been validated through single-cell RNA sequencing (scRNAseq) and immunofluorescent staining.

Results

Lung tissues has been collected from 103 lung explants representing various pathologies, including IPF, COVID-19-related fibrosis, COPD, and other interstitial lung diseases. Average ischemic time was 8 minutes (SD=3). Among participants, 39% were female with a mean age of 56 years (SD=12), 62% were non-Hispanic White, 27% Hispanic, and 27% other/mixed. In 35 months, 76 explants (74%) were collected using English consent forms. Following the introduction of multilingual forms, 27 explants (26%) were collected in 8 months, increasing the explant rate from 2.2 to 3.4 per month. Among patients using multilingual consent forms, 37% were female, 50% non-Hispanic White, 33% Hispanic, and 44% other/mixed. These patients were less likely to be White (OR: 0.03, 95% CI: 0.00-0.81) and more likely to require pre-transplant mechanical ventilation (OR: 15.0; 95% CI: 1.1-201.1) or high-flow O_2 (OR: 18.4; 95% CI: 3.2-105.0).

Conclusion

An extremely low-ischemic time bank of explanted lung tissues from a racially/ethnically, and gender-diverse population of lung transplant recipients has been achieved using an established procurement protocol and enhanced with the addition of multilingual informed consent forms. These tissues are well-suited for modern research applications and have already been successfully utilized for scRNAseq across various disease states. Expanding our multilingual consent forms to include Mandarin and Farsi will further diversify our sample population, enhancing future analyses.

New Emphasis: Medications and Informed Consent

Robert C. Accetta

Caring for the Ages, May 2025; 26(3) pp 12-13

Outline

Post-acute and long-term care providers are preparing with renewed vigilance for the revisions made to the Centers for Medicare & Medicaid Services State Operations Manual (SOM), Appendix PP, which become effective at the end of April 2025. I refer the reader to the advance copy, which has been available since November 2024 (https://www.cms.gov/files/document/qso-25-14-nh.pdf). Sections of the SOM, including the revised F605 tag, pertain to chemical restraints, psychotropic medications, resident rights, and consent for treatment, and F757 pertains to unnecessary drugs.

Renewed verbiage in the guidance emphasizes the concepts of residents' autonomy and freedom to accept or decline proposed interventions for their care, which aligns with the person-centered care planning directives. The guidance reaffirms the duty of facilities and prescribers:

- To provide behavioral or nonpharmacological interventions.
- To have conversations with the residents or their representative about the benefits and risks associated with any proposed treatment or alternative available options.
- To document consent to the agreed-upon plan.

As this pertains to medications, disclosure about the risks, benefits, and warnings (including boxed warnings for antipsychotics) and consent to the proposed initiation or increase of a medication regimen are now of utmost importance.

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PRE-PRINT SERVERS

Re-Consent Practices in Biobanks in Japan: Current Status and Stakeholder Perspectives

Research Article

Hiroko Terui-Kohbata, Hiyori Ueda, Masayuki Yoshida

Research Square, 13 May 2025

Abstract

Pediatric research in rare diseases relies on sharing biological specimens, clinical data, and analytical information among researchers. Re-consent is essential in longitudinal biobank (BB) research to ensure that pediatric participants remain informed and willing to continue. However, the issue of re-consent—obtaining consent once as participants reach adulthood—remains a significant ethical concern. This study examined the current practices of re-consent acquisition in Japanese BBs and explores stakeholder opinions regarding genomic data sharing. A survey of 41 BBs revealed that only 25% of those handling pediatric samples obtained re-consent, all via written informed consent. Although 71% of respondents recognized the necessity of re-consent, the methods used to obtain it varied. Stakeholders identified ethical and logistical challenges, including privacy concerns and administrative burden. Various re-consent methods were suggested, with preferences depending on feasibility and ethical considerations. The findings highlight the need for policy discussions to balance data-sharing benefits with participant rights and privacy protection in pediatric genomic research. Determining optimal re-consent methods requires continued stakeholder engagement, including research participants and the public.

Ethics and consent in randomized clinical trial integrity: A scoping systematic review

Authorea, 6 May 2025

Mohamad Alaa Elsuity, Furqan Ahmad Butt, Khalid Saeed Khan, Mohamed Fawzy, Manuel Martín-Díaz, Javier Perez Rojas, Patrick FW Chien, María Núñez-Núñez, Mosab M Rashwan, Aurora Bueno-Cavanillas

Abstract

Background

Research ethics committee approval and informed consent are fundamental to the integrity of randomized clinical trials (RCTs), the strongest possible evidence source for informing clinical decision-making.
Objectives
This scoping systematic review aimed to collate and synthesize available evidence on research ethics and consent aspects related to research integrity standards in RCTs. Prospective registration (https://osf.io/gxryb).
Search Strategy and selection criteria
We searched PubMed and Scopus databases from January 2018 to August 2023, using combinations of terms related to research ethics, approval, and informed consent. We included full academic articles relevant to the scope of the review without language restriction, including primary research articles, systematic reviews, scoping reviews, and narrative reviews.
Data collection and analysis
Two teams of four reviewers independently assessed the full text to select articles and extract data, performing the tasks independently and any disagreements were resolved through arbitration. A descriptive synthesis of the included articles main characteristics and findings were performed.
Results
69 articles were selected, covering RCT-related ethics and consent issues in 141 countries, including 89 (63%) low or middle-income ones. The extracted data fell into nine domains: general issues (30 articles; 43%), journals' instructions and policies (one article; 1.4%), research institutions and funders' policies (three articles; 4.3%), ethics committee regulations (five articles; 7.2%), ethics committee evaluation and approval (12 articles; 17%), informed consent and related procedures (six articles; 8.7%), monitoring of trials for compliance (three articles; 4.3%), post-publication concerns on ethics and consent (five articles; 7.2%), and recommendations for future research (four articles; 5.8%).
Conclusions
The key areas include standardization of ethics committee approval processes and enhancement of informed consent procedures. There were notable deficiencies in trial registration and reporting concerning ethics and consent. The observed variability in ethics and consent practices across RCTs globally needs to be addressed through an international expert consensus.

The ethics of simplification: Balancing patient autonomy, comprehension, and accuracy in AI-generated radiology reports

Research Article
Hong-Seon Lee, Seung-Hyun Song, Chaeri Park, Jeongrok Seo, Won Hwa Kim, Jaeil Kim, Sungjun Kim, Kyunghwa Han, Young Han Lee
Research Square, 2 May 2025
Abstract
Background
Large language models (LLMs) such as GPT-4 are increasingly used to simplify radiology reports and improve patient comprehension. However, excessive simplification may undermine informed consent and autonomy by compromising clinical accuracy. This study investigates the ethical implications of readability thresholds in AI-generated radiology reports, identifying the minimum reading level at which clinical accuracy is preserved.
Methods
We retrospectively analyzed 500 computed tomography and magnetic resonance imaging reports from a tertiary hospital. Each report was transformed into 17 versions (reading grade levels 1–17) using GPT-4 Turbo. Readability metrics and word counts were calculated for each version. Clinical accuracy was evaluated using radiologist assessments and PubMed-BERTScore. We identified the first grade level at which a statistically significant decline in accuracy occurred, determining the lowest level that preserved both accuracy and readability. We further assessed potential clinical consequences in reports simplified to the 7th-grade level.

Results
Readability scores showed strong correlation with prompted reading levels (r = 0.80–0.84). Accuracy remained stable across grades 13–11 but declined significantly below grade 11. At the 7th-grade level, 20% of reports contained inaccuracies with potential to alter patient management, primarily due to omission, incorrect conversion, or inappropriate generalization. The 11th-grade level emerged as the current lower bound for preserving accuracy in LLM-generated radiology reports.
Conclusions
Our findings highlight an ethical tension between improving readability and maintaining clinical accuracy. While 7th-grade readability remains an ethical ideal, current AI tools cannot reliably produce accurate reports below the 11th-grade level. Ethical implementation of AI-generated reporting should include layered communication strategies and model transparency to safeguard patient autonomy and comprehension.

Feasibility of a Study Within a Trial to evaluate a decision support intervention for families deciding about research on behalf of adults lacking capacity to consent (CONSULT SWAT)

Victoria Shepherd, Kim Smallman, Fiona Wood, Katie Gillies, Adam Martin, Maria Moore, Stacy Todd, Kerenza Hood

Research Square, 22 April 2025

Abstract
Background
Trials involving adults who lack capacity to consent can be challenging, partly due to the involvement of 'proxy' decision-makers. This is usually a family member, who advises the researchers about the person's wishes. Families can find decision making difficult and some experience a decisional burden. Following the development of a decision aid for family members making trial participation decisions, we are conducting a mixed-methods randomised Study Within a Trial (SWAT) to evaluate its (cost-)effectiveness. This paper reports the feasibility stage conducted in one host study to inform the delivery of the main SWAT.
Methods
Family members approached to act as a consultee for the host study were randomised 1:1 to receive the decision aid booklet alongside standard study information (intervention), or standard information plus a blank notebook (control), and asked to complete the CONCORD scale (Combined Scale for Proxy Informed Consent Decisions) questions about their experience and take part in a semi-structured interview. Acceptability of the SWAT was assessed through recruitment rates, data completeness, and qualitatively through interviews with family members and research staff. Interviews were analysed using a rapid qualitative approach.
Results
In total, 92 family members were randomised to the SWAT and 16 completed the CONCORD scale. Interviews were conducted with consultees (n=4), and host study staff (n=3) who also provided resource use data. Mean CONCORD scores were higher in the control group (94.5 on a 100-point scale) compared with the intervention group (87.5), indicating higher decision quality, Differences in time staff spent with consultees were small. Key themes identified included 1) setting up the SWAT and balancing priorities with the host study, 2) differences when recruiting consultees to a SWAT, 3) feasibility and acceptability of the SWAT, 4) challenges of measuring decision quality, 5) views and experiences of the decision support intervention.
Conclusion
The CONSULT SWAT is feasible, but changes to study processes are needed in advance of the main SWAT. The small number of trials involving participants lacking capacity limits opportunities for developing the evidence-base. Recruitment of host trials continues, with a focus on evaluating the intervention in a broad range of populations and settings.

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CURRENT CALLS FOR PUBLIC CONSULTATION

We will selectively include calls for public consultation from multilateral agencies, governments, INGOs and other sources where there is a clear intersection with consent/assent. This might be obvious from the title of the draft guidance, regulations, etc., but more often, it will be a thematic area or topic – if properly addressed at all. If you would like to explore participation with our working group developing submissions for these calls, please contact us [david.r.curry@ge2p2global.org].

No new content referencing consent identified.

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NEW NORMATIVE/REGULATORY GUIDANCE/ANALYSIS REFERENCING CONSENT

No new content referencing consent identified.

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SYMPOSIA/CONFERENCES/WEBINARS

We will selectively include information on major symposia and conferences which address issues, evidence, analysis or debates involving consent/assent. This listing will include [1] meetings already concluded but which are posting presentations/recordings, etc.; [2] future meetings which have posted registration/logistics information, and [3] meetings which have announced calls for abstracts/panels, etc.

No new content referencing consent identified.

# # # #

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