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governance, ethics, evidence, policy, practice

**Center for Informed Consent Integrity**

# *Informed Consent: A Monthly Review*

***October 2024 :: Issue 70***

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This digest aggregates and distills key content addressing informed consent 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.

In preparing this digest, we monitor a broad range of academic journals and utilize *Google Scholar* to identify articles referencing informed consent or assent. After careful consideration, a selection of these results appear in the digest. We also monitor other research, analysis, guidance and commentary beyond the academic literature globally, including calls for public consultation and symposia/conferences which address consent/assent in whole or in part. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

Overall, we have elected to be inclusive in our content selection, including articles that may be controversial and warrant closer scrutiny. This approach aligns with our goal of presenting a holistic landscape of informed consent literature as it is being published. We may include "Editor's Notes" or other notations to identify such content.

*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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We organize content in this digest using subject categories to help readers navigate to areas of interest. We expect that these categories will evolve over time. We lead each edition with a spotlight section highlighting content which the editorial team has assessed to be strategically important and well aligned to our thematic focus areas of governance, ethics, evidence, policy and practice. The full citation/abstract for each spotlight item appears just below the summary beginning that section. Active subject areas in this edition include:

No new content was identified for the following established categories:

COMPASSIONATE USE/EXPANDED ACCESS
COVID-19
HUMANITARIAN CONTEXT
RELATIONAL, CULTURALLY-CONDITIONED, DECOLONIZED CONSENT

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 cross tagged. We maintain a glossary, an inventory of assessment and other tools, as well as standards and guidance documents, also on the website.

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## SPOTLIGHT – Upcoming Meeting

The spotlight this month is shining on an important upcoming meeting at the US Food and Drug Administration. On October 30th the FDA Patient Advisory Committee will "provide recommendations on the informed consent process and the areas of focus of the informed consent" from a patient/trial participant view. The committee will also provide specific recommendations for how the informed consent process be undertaken given these considerations.

The meeting will be open to the public for both observation and participation. We see this as an opportunity to have a real impact in the informed consent policy making space and we invite you to consider participating. We have applied to give oral testimony and will submit written comments as below.

*Ways to participate*
Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee, or individuals may participate in virtual breakout scenario discussions

- Written submissions may be made on or before 3 October 2024 to letise.williams@fda.hhs.gov
- Sign up to participate in virtual breakout session on or before 16 October 2024
- Oral presentation requests should be submitted on or before 25 September 2024 *[deadline passed]*

### Patient Engagement Advisory Committee Meeting: Patient-Centered Informed Consent in Clinical Study of FDA-Regulated Medical Products

Food and Drug Administration

**30 October 2024 [Virtual], 10:00-17:00 EST**

*Summary*

The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Patient Engagement Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

*Agenda*

The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. On October 30, 2024, the Committee will discuss and make recommendations on "Patient-Centered Informed Consent in Clinical Study of FDA-Regulated Medical Products." The individuals who volunteer to participate in clinical research play an integral role in advancing scientific knowledge and supporting the development of potentially life-saving therapies for patients in need. Informed consent is a key element in clinical studies and can be one of a patient's first interactions with the clinical community. Too often, however, informed consent forms are lengthy and difficult for potential research participants to understand. FDA has worked to improve informed consent over the years, including several recent activities such as developing a draft guidance in identifying key information in informed consent.

The Committee will provide recommendations on the informed consent process and the areas of focus of the informed consent. The Committee will also provide recommendations on factors to consider when communicating informed consent to clinical study participants to increase the likelihood of participants understanding the key elements of research…

*For Further Information Contact: Letise Williams [Letise.Williams@fda.hhs.gov; 301-796-8398] or FDA Advisory Committee Information Line [1-800-741-8138 (301-443-0572 in the Washington, DC area)]*

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## BIOMEDICAL RESEARCH

### The Need for an Evolving Informed Consent Process in a Fetal Therapy Trial

*Case Commentaries*

Meredith A. Atkinson, Erika Ezumba, Jena L. Miller

**The American Journal of Bioethics, 16 September 2024**

*Excerpt*

… In the face of uncertainty about the longer-term burden of morbidity and mortality in surviving neonates, the study team had to consider what level of detail regarding neonatal outcomes observed in infants born to trial participants to share with potential participants during the study screening process, while the study continued active recruitment. In addition, they had to determine if and how such information should be modified over the course of the trial as additional neonates were born to trial participants, and an increasing amount of data on the clinical course and outcomes of the neonates became available. Given the high potential burden in neonatal survivors and their families, including the need for intensive caregiver-provided, at-home care for infants who survive to hospital discharge and a need for life-long renal replacement therapy, the consent discussion takes place over days and in collaboration with multiple specialists… More information is required to deeply characterize long-term outcomes among survivors and the psychosocial impact on the family, whether the amnioinfusion intervention is offered through a research protocol or as clinical care. This will require systematic collection of prospective data beyond the primary outcome defined in the RAFT trial, including observational data from institutions where the intervention is offered as clinical care.

## Ethical analysis of informed consent methods in longitudinal cohort studies: A Chinese perspective

Kun Li, Mingtao Huang, Xiaomei Zhai, Chen Wang

**Developing World Bioethics, 13 September 2024**

*Abstract*

In longitudinal cohort studies involving large populations over extended periods, informed consent entails numerous urgent challenges. This paper explores challenges regarding informed consent in long-term, large-scale longitudinal cohort studies based on the longitudinal and dynamic nature of such research. It analyzes and evaluates widely recognized broad consent and dynamic consent methods, highlighting limitations concerning their ability to adapt to evolving research objectives and participant perspectives. This paper discusses trust-based informed consent and emphasizes the needs to establish and maintain trust with research participants and to balance information disclosure with respect for participants' autonomy. Informed consent in long-term studies is an evolving process that must adapt to changing research environments. Based on participant trust, researchers should observe and assess potential research risks. Finally, the paper recommends enhancing institutional credibility, implementing reconsent procedures, and ensuring robust ethical oversight to safeguard participants' rights despite the complexity of modern biomedical research.

## Readability of informed consent documents and its impact on consent refusal rate

*Original Article*

Yash V. Kamath, Yashashri C. Shetty, Ishita C. Lanjewar, Ankita Kulkarni

**Perspectives in Clinical Research, 30 August 2024**

*Abstract*

*Introduction*

Informed consent documents (ICDs) are integral to a research project and must provide all required information to the participant. We undertook a 6-year retrospective cross-sectional analysis of ICDs to assess the same.

*Methods*

We accessed 300 ICDs from studies submitted to institutional ethics committee. Studies were selected using random proportional-to-size sampling across years and study types (thesis, pharma, government, investigator initiated [OA] studies). We used the Flesch–Kincaid Reading Ease Score (FRES), estimated reading time (ERT) and scored ICDs out of 13 points on the basis of the Indian Council of Medical Research (ICMR)-mandated headings (ICD Quality Score [IQS]). Information pertaining to the consent refusal rate (CRR) of each study was correlated with FRES, ERT, and other parameters. $P < 0.05$ was considered statistically significant.

*Results*

Two hundred and ninety-three ICDs had complete information. Median FRES was 48.3 (interquartile range [IQR] = 7), median ERT was 4.5 min (IQR = 1.3), the median expected duration of participation was 35 min (IQR = 40); compensation was provided by 23 projects and median compensation was Rs. 2500 (IQR = Rs. 4750). Mean IQS improved from 11.95 to 12.60 in 6 years (Kruskal–Wallis test, $P < 0.001$). FRES was weakly negatively correlated to the CRR ($r = -0.120$, $P = 0.039$), while the expected duration of participation was weakly positively correlated ($r = 0.144$, $P = 0.014$).

*Conclusion*

Pharma studies performed better and ICDs have improved in their readability and ICMR guidelines compliance.

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## SOCIAL SCIENCE RESEARCH

### Informed consent and coercion in recruitment advertisements for oocyte donors

*Research*

Ruby Lake, Isa Berzansky, Andrea Lanes, Serene Srouji, Elizabeth Ginsburg, Iris Insogna

**BMC Women's Health, 20 September 2024**

*Open Access*

*Abstract*

*Background*

As the use of donor eggs for in vitro treatment has increased, both medically affiliated and private donor egg agencies have turned to online advertisements to recruit donors. The American Society for Reproductive Medicine provides recommendations encouraging ethical recruitment of donors, however there is no formal regulation for the informed consent process for egg donor recruitment and compensation. Underrepresentation of risks and targeted financial incentives may pose a risk to the informed consent process.

*Methods*

Data from online advertisements for egg donors active between January 1 - August 31, 2020, were collected to analyze content related to risks, Covid-19 precautions, donor payment, and desired donor characteristics. Advertisements for egg donors on Google, Craigslist, and social media were analyzed. Primary outcomes included the mention of the risks of egg donation, including the risk of Covid-19 exposure, in donor egg advertisements. Secondary outcomes included language targeting specific donor characteristics and financial compensation.

*Res*ults

103 advertisements were included. 35.9% (37/103) of advertisements mentioned some risk of the egg donation process, and 18.5% (19/103) mentioned risks or precautions related to Covid-19 exposure. Of advertisements for private donor egg agencies, 40.7% (24/59) mentioned any risk, compared to 29.6% (13/44) of medically affiliated egg donation programs; the difference was not statistically significant (p-value = 0.24). Agencies targeting students and donors of a specific race were more likely to offer payments over $10,000 for an egg donation cycle. Among advertisements offering over $20,000 for donor compensation, 72.7% (8/11) recruited women under the age of 21.

*Conclusion*

Egg donor recruitment advertisements, for both medically affiliated programs and private agencies, were unlikely to mention risks including the risk of exposure to Covid-19. Non-medically affiliated private donor egg agencies were more likely to violate multiple American Society for Reproductive Medicine ethics guidelines, including offering higher than average compensation, and recruiting donors from young and vulnerable populations.

### Co-designing body donor program consent processes

Georgina C. Stephens

**Anatomical Sciences Education, July 2024**

*Abstract*

*Objective*

It is widely accepted that body donation programs should obtain informed consent from prospective donors during life. However, consent forms vary in detail, are typically developed by anatomical and legal experts, and may not include features valued by prospective donors. Concomitantly, anatomy students report concerns that prospective donors are not adequately informed about dissection procedures. To address

these issues, this study aimed to bring together prospective body donors, anatomy students, anatomy educators, and a governance expert to co- design a donor-centered consent process.
*Methods*
Utilizing participatory co- design, focus group discussions were used to explore participants' perspectives on informed donor consent. The facilitator worked with participants to identify priorities for inclusion in donor consent processes. Framework analysis is being used to analyze data, and priorities identified in each group will inform the development of a draft donor consent process, on which further participant feedback will be sought.
*Results*
Forty-one people expressed interest in study participation. Two focus groups (n = 11 participants) have been held, wherein prospective body donors emphasized their desire for their bodies to contribute to anatomical education, including dissection and representation in educational resources. Group members agreed consent forms should explicitly detail how donor bodies are utilized for learning and include personalized elements such as naming preferences. Further focus groups are planned for September and October 2023.
*Conclusion*
This ongoing study is expected to yield recommendations for community involvement in developing body donor program consent processes, and how community participation can enhance educational activities, such as preparing students for dissection.

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## ARTIFICIAL INTELLIGENCE

### Patient Autonomy in Medical Education: Navigating Ethical Challenges in the Age of Artificial Intelligence

*Review article*
Hui Lu, Ahmad Alhaskawi, Yanzhao Dong, Xiaodi Zou, Haiying Zhou, Sohaib Hasan Abdullah Ezzi, Vishnu Goutham Kota, Mohamed Hasan Abdulla Hasan Abdulla, Sahar Ahmed Abdalbary
**INQUIRY: The Journal of Health Care Organization, Provision, and Financing, 18 September 2024**
*Open access*
*Abstract*
The increasing integration of Artificial Intelligence (AI) in the medical domain signifies a transformative era in healthcare, with promises of improved diagnostics, treatment, and patient outcomes. However, this rapid technological progress brings a concomitant surge in ethical challenges permeating medical education. This paper explores the crucial role of medical educators in adapting to these changes, ensuring that ethical education remains a central and adaptable component of medical curricula. Medical educators must evolve alongside AI's advancements, becoming stewards of ethical consciousness in an era where algorithms and data-driven decision-making play pivotal roles in patient care. The traditional paradigm of medical education, rooted in foundational ethical principles, must adapt to incorporate the complex ethical considerations introduced by AI. This pedagogical approach fosters dynamic engagement, cultivating a profound ethical awareness among students. It empowers them to critically assess the ethical implications of AI applications in healthcare, including issues related to data privacy, informed consent, algorithmic biases, and technology-mediated patient care. Moreover, the interdisciplinary nature of AI's ethical challenges necessitates collaboration with fields such as computer science, data ethics, law, and social sciences to provide a holistic understanding of the ethical landscape.

## Patient Consent and The Right to Notice and Explanation of AI Systems Used in Health Care

*Target Article*

Meghan E. Hurley, Benjamin H. Lang, Kristin Marie Kostick-Quenet, Jared N. Smith, Jennifer Blumenthal-Barby

**The American Journal of Bioethics, 17 September 2024**

*Abstract*

Given the need for enforceable guardrails for artificial intelligence (AI) that protect the public and allow for innovation, the U.S. Government recently issued a Blueprint for an AI Bill of Rights which outlines five principles of safe AI design, use, and implementation. One in particular, the right to notice and explanation, requires accurately informing the public about the use of AI that impacts them in ways that are easy to understand. Yet, in the healthcare setting, it is unclear what goal the right to notice and explanation serves, and the moral importance of patient-level disclosure. We propose three normative functions of this right: (1) to notify patients about their care, (2) to educate patients and promote trust, and (3) to meet standards for informed consent. Additional clarity is needed to guide practices that respect the right to notice and explanation of AI in healthcare while providing meaningful benefits to patients.

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## HEALTH DATA/DATA

## Rethinking Informed Consent in the Big Data Age

*Book*

Adam J. Andreotta

**Routledge, 23 December 2024**

*Abstract*

In the “big data age”, providing informed consent online has never been more challenging. Countless companies collect and share our personal data through devices, apps, and websites, fuelling a growing data economy and the emergence of surveillance capitalism. Few of us have the time to read the associated privacy policies and terms and conditions, and thus are often unaware of how our personal data are being used. This is a problem, as in the last few years, large tech companies have abused our personal data. As privacy self-management, through the mechanism of providing online consent, has become increasingly difficult, some have argued that surveillance capitalism, and the data economy more broadly, need to be overthrown.

This book presents a different perspective. It departs from the concept of revolutionary change to focus on pragmatic, incremental solutions tailored to everyday contexts. It scrutinizes how consent is currently sought and provided online and offers suggestions about how online consent practices can be improved upon. These include: the possibility of subjecting consent-gathering practices to ethics committees for review; the creation of visual-based consent agreements and privacy policies, to help with transparency and engagement; the development of software to protect privacy; and the idea of automated consent functionalities that allow users to bypass the task of reading vast amounts of online consent agreements. The author suggests that these “small-scale” changes to online consent-obtaining procedures, could, if successfully implemented, provide us with a way of self-managing our privacy in a way that avoids a revolutionary dismantling of the data economy. In the process, readers are encouraged to rethink the very purpose of providing inform consent online.

Rethinking Informed Consent in the Big Data Age will appeal to researchers in normative ethics, applied ethics, philosophy of law, and the philosophy of AI. It will also be of interest to business scholars, communication researchers, students, and those in industry.

## Opportunities and challenges of a dynamic consent-based application: personalized options for personal health data sharing and utilization

*Research*

Ah Ra Lee, Dongjun Koo, Il Kon Kim, Eunjoo Lee, Sooyoung Yoo, Ho-Young Lee

**BMC Medical Ethics, 31 August 2024**

*Open Access*

*Abstract*

*Background*

The principles of dynamic consent are based on the idea of safeguarding the autonomy of individuals by providing them with personalized options to choose from regarding the sharing and utilization of personal health data. To facilitate the widespread introduction of dynamic consent concepts in practice, individuals must perceive these procedures as useful and easy to use. This study examines the user experience of a dynamic consent-based application, in particular focusing on personalized options, and explores whether this approach may be useful in terms of ensuring the autonomy of data subjects in personal health data usage.

*Methods*

This study investigated the user experience of MyHealthHub, a dynamic consent-based application, among adults aged 18 years or older living in South Korea. Eight tasks exploring the primary aspects of dynamic consent principles–including providing consent, monitoring consent history, and managing personalized options were provided to participants. Feedback on the experiences of testing MyHealthHub was gathered via multiple-choice and open-ended questionnaire items.

*Results*

A total of 30 participants provided dynamic consent through the MyHealthHub application. Most participants successfully completed all the provided tasks without assistance and regarded the personalized options favourably. Concerns about the security and reliability of the digital-based consent system were raised, in contrast to positive responses elicited in other aspects, such as perceived usefulness and ease of use.

*Conclusions*

Dynamic consent is an ethically advantageous approach for the sharing and utilization of personal health data. Personalized options have the potential to serve as pragmatic safeguards for the autonomy of individuals in the sharing and utilization of personal health data. Incorporating the principles of dynamic consent into real-world scenarios requires remaining issues, such as the need for powerful authentication mechanisms that bolster privacy and security, to be addressed. This would enhance the trustworthiness of dynamic consent-based applications while preserving their ethical advantages.

## Data Altruism, Personal Health Data and the Consent Challenge in Scientific Research: A Difficult Interplay between EU Acts

Gauthier Chassang, Lisa Feriol

**European Data Protection Law Review, 2024**

*Abstract*

The article explores the challenges in implementing data altruism, focusing on personal health data altruism for scientific research purposes. The analysis highlights conceptual gaps and lack of clarity of the Data Governance Act (DGA) provisions and their unclear interplay with the General Data Protection Regulation (GDPR). Ethical considerations regarding the relationship between altruism and solidarity-based systems are discussed, along with legal issues surrounding the scope of data altruism and consent requirements in different scenarios of personal health data altruism for scientific research. The discussion extends to existing opt-out practices in scientific research and their recognition, pointing out potential drawbacks of an overly restrictive emphasis on consent in the context of data altruism. The conclusion highlights the conceptual and ethical shortcomings of data altruism, advocates for the development of an integrative approach to altruism within the regulatory sphere and within health data-sharing organisations for encouraging collaboration and

recognition of contributors to not-for-profit research in the public interest. Ultimately, the article supports the development of new approaches to participation in research through dynamic opt-out mechanisms in health systems and emphasises the need for clearer regulatory guidance to unlock the full potential of health data altruism.

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## BIOBANKING

### Addressing the ethical challenges to informed consent for brain tissue donation

Amitabha Palmer
**Medicine & Ethics, 10 September 2024**
*Abstract*
The tremendous medical promise of human organoids has led large research institutions and national agencies to create brain tissue banks. In response, regulatory agencies have created regulations that guide consent processes for collecting tissue samples from donors. These regulations are, in part, intended to ensure that donors' samples are not used in ways that conflict with their moral values, beliefs, and goals. While these regulations frequently serve this purpose well, we argue that they are insufficient in the case of brain tissue donation because of unique ethical concerns that arise from technologies and applications that use brain tissue samples. After considering the inadequacies, we suggest how consent policies can be improved. We focus on US policy specifically because some Caribbean and Latin American countries reference US regulatory frameworks in developing their own.

### Ethical, legal, and social implications in research biobanking: A checklist for navigating complexity

*Original Article*
Olga Tzortzatou-Nanopoulou, Kaya Akyüz, Melanie Goisauf, Łukasz Kozera, Signe Mežinska, Michaela Th. Mayrhofer, Santa Slokenberga, Jane Reichel, Talishiea Croxton, Alexandra Ziaka, Marina Makri
**Developing World Bioethics, 10 July 2023**
*Open Access*
*Abstract*
Biobanks' activity is based not only on securing the technology of collecting and storing human biospecimen, but also on preparing formal documentation that will enable its safe use for scientific research. In that context, the issue of informed consent, the reporting of incidental findings and the use of Transfer Agreements remain a vast challenge. This paper aims to offer first–hand tangible solutions on those issues in the context of collaborative and transnational biobanking research. It presents a four-step checklist aiming to facilitate researchers on their compliance with applicable legal and ethical guidelines, when designing their studies, when recruiting participants, when handling samples and data, and when communicating research results and incidental findings. Although the paper reflects the outcomes of the H2020 B3Africa project and examines the transfers from and to the EU as a case study, it presents a global checklist that can be used beyond the EU.

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## GENOMIC MEDICINE/GENE EDITING

## Implications of genetic testing and informed consent before and after genetic testing in individuals with cancer

Priyanka Kumar, David J Benjamin, Sourat Darabi, Goetz Kloecker, Arash Rezazadeh Kalebasty
**World Journal of Clinical Oncology, 24 August 2024; 15(8) pp 975-981**
*Abstract*
Recent advancements in next generation sequencing have allowed for genetic information to become more readily available in the clinical setting for those affected by cancer and by treating clinicians. Given the lack of access to geneticists, medical oncologists and other treating physicians have begun ordering and interpreting genetic tests for individuals with cancer through the process of "mainstreaming". While this process has allowed for quicker access to genetic tests, the process of "mainstreaming" has also brought several challenges including the dissemination of variants of unknown significance results, ordering of appropriate tests, and accurate interpretation of genetic results with appropriate follow-up testing and interventions. In this editorial, we seek to explore the process of informed consent of individuals before obtaining genetic testing and offer potential solutions to optimize the informed consent process including categorization of results as well as a layered consent model.

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## YOUNG PERSONS

## Adolescent Self-Consent for the HPV Vaccine and the Effects on Vaccine Rates

*Health Policy*
Alexa D. Thompson, Regena Spratling
**Journal of Pediatric Health Care, 22 September 2024**
*Abstract*
The adolescent development age is the period between 10 and 19 years when a child becomes a young adult and learns to make important health decisions independently. Adolescents consenting to receive a vaccine without parental or legal guardian consent is adolescent self-consent. Adolescent self-consent for the human papillomavirus (HPV) vaccine is a health policy issue that could increase vaccine uptake rates. Adolescent self-consent for the vaccine may increase adolescents' autonomy with their healthcare decisions. Pediatric advanced practice nurses and other healthcare providers should advocate for adolescents and encourage parents to allow adolescents to be more active regarding the HPV vaccine.

## Research Ethics of Involving Adolescents in Health Research Studies: Perspectives From Australia

Neha Faruqui, Angus Dawson, Katharine Steinbeck, Elizabeth Fine, Julie Mooney-Somers
**Journal of Adolescent Health, September 2024**
*Open Access*
*Abstract*
*Purpose*
Adolescent participation in health research studies is critical yet complex given the lack of clarity around issues such as consent. This study aimed to understand how those conducting research in Australia navigate research ethics in health research involving adolescents, through qualitative interviews.
*Methods*
Purposive sampling was used to recruit 23 researchers involved in adolescent health research using semi-structured in-depth interviews. Interviews were conducted via Zoom and audio-recorded after obtaining informed consent. Thematic analysis was used to construct themes and data were organised using NVivo.
*Results*

Two contrasting positions emerged from the data: (1) framing of adolescents as inherently vulnerable, their participation in research understood in terms of risk and protection and (2) adolescent engagement in research is understood in terms of empowerment, emphasising their capacity to make decisions about research participation. We traced these positions through three key themes, particularly in relation to the role of ethics committees: (1) competing positions as a result of inferior or superior knowledge about adolescent lives, (2) competing positions resulting in a risk averse or an empowerment approach, and (3) reflections on processes of obtaining consent which involves gatekeeping and tokenism.

*Discussion*

Our study highlights the contentious topic of navigating ethics committee requirements for the needs of adolescents. Majority of participants felt the current research ethics establishment is not favourable for researchers or adolescents themselves. While it is imperative that perceptions of ethics committees also be studied in the future, our study provides preliminary understanding of how experiences and perceptions shape how researchers interact with the research ethics establishment.

### Consent in Pediatric Critical Care Trials: Duty or Burden?

*Editorial*

Mark J. Peters, Kate Plant

**Pediatric Critical Care Medicine, September 2024**

*Excerpt*

Clinical practice is highly variable. Some of our colleagues use more maintenance fluids than we would choose for our patients. Or we might continue antibiotics beyond when they would stop them. We suspect any reader could think of similar examples in their own teams.

We currently accept this variability as commonplace in a complex setting such as a PICU. After all, there are tens, if not hundreds, of minor management decisions for each patient each day (1). If there were no differences between clinicians, our job could be replicated by robots or at least protocolized. There is a reasonable argument that this variability brings an additional level of safety. Practice regresses toward a mean such that over the duration of an admission any more extreme requests by one clinician will tend to be moderated by the colleague who takes over on the following shift.

Although we share our decision-making and plans with parents and patients where appropriate, we do not typically seek consent for these small variations in practice between staff…

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## CAPACITY TO CONSENT

### Assessment of decision-making autonomy in chronic pain patients: a pilot study

*Research*

Marguerite d'Ussel, Emmanuelle Sacco, Nathan Moreau, Julien Nizard, Guillaume Durand

**BMC Medical Ethics, 18 September 2024**

*Open Access*

*Abstract*

*Background*

Patient decision-making autonomy refers to the patients' ability to freely exert their own choices and make their own decisions, given sufficient resources and information to do so. In pain medicine, it is accepted that appropriate beneficial management aims to propose an individualized treatment plan shared with the patients, as agents, to help them live as autonomously as possible with their pain. However, are patients in chronic pain centers sufficiently autonomous to participate in the therapeutic decisions that concern them? As this question still remains unanswered, a pilot study was set up to that aim.

*Methods*
Over a 2-month period, first-time patients within a tertiary multidisciplinary pain center underwent a systematic evaluation of their autonomy using the MacArthur Competence Assessment Tool for Treatment (MacCAT-T), considered the benchmark tool for measuring a patient's ability to consent to treatment. Demographic data and pain characteristics of the patients were collected and their respective attending pain physicians were asked to clinically assess their patients' degree of autonomy. Another physician, who had not participated in the initial patient evaluation, subsequently administered the MacCAT-T questionnaire to the same patients.
*Results*
Twenty-seven patients were included during the study period (21 women and 6 men), with an average age of 50 years. The average duration of pain was 8 years. Based on their clinical experience, the 4 different pain physicians in charge of these patients considered that out of 25 assessed patients, 22 of them (89%) had full decision-making capacity, with no deficit in autonomy. According to the MacCAT-T results, only 13 of these 25 patients (48%) had no deficit, while 7 (26%) had a major deficit in autonomy. The only patient characteristic that appeared to be related to autonomy was pain type, specifically nociplastic pain. The average time taken to complete the test was 20 min, and patients were very satisfied with the interview.
*Conclusion*
Results from the present pilot study suggest that patients suffering from chronic pain do not appear to be entirely autonomous in their decision to consent to the proposed treatment plan according to the MacCAT-T questionnaire, and physicians seem to find it difficult to properly assess this competence in a clinical setting. Further studies with larger samples are needed to better evaluate this concept to improve the complex management of these patients.

## Consent to voluntary antipsychotic drug treatment-Is it free and informed?

Refael Yonatan-Leus, Nili Karako-Eyal
**Psychiatric Rehabilitation Journal, 16 September 2024**
*Abstract*
*Objective*
The present research investigates the dynamics of consent in the context of antipsychotic drug therapy, with a particular emphasis on the essential attributes that constitute free and informed consent within medical treatment scenarios.
*Method*
Twenty individuals treated with antipsychotic drugs with consent underwent semistructured interviews.
*Results*
The following major themes were identified: (a) lack or total absence of information regarding the treatment, emphasizing side effects, risks, chances of success, and treatment alternatives. (b) A subjective experience of the lack of free choice that was sometimes also accompanied by the conditioning of psychiatric rehabilitation services or receiving treatment in an open ward by taking antipsychotic medication.
*Conclusions and implications for practice*
The research findings may indicate a problem in obtaining informed consent for antipsychotic treatment that should be addressed. The themes highlight the need to examine the interface between rehabilitation services and psychiatric treatment from the legal and ethical perspective of the autonomy of individuals receiving care.

## Enhancing Assent and Treatment Outcomes: A Case Study on Responding to Aversive Ambient Auditory Stimuli for an Autistic Adult

*Original Article*
Faris R. Kronfli, J. Stephanie Gonzalez, Malchijah T. Williams, Timothy R. Vollmer

**Journal of Developmental and Physical Disabilities, 3 September 2024**

*Abstract*

We explored assent procedures to promote assent and treatment effectiveness for an autistic adult. The objective, at the request of the participant, was to evaluate an innovative approach to (a) identify aversive auditory stimuli and (b) teach Steven, a 19-year-old male, appropriate responses in the presence of these stimuli without directly exposing him to the stimuli. The results suggest that the procedures effectively identified auditory stimuli for assessment and taught the participant to avoid the aversive stimuli appropriately (that is, in ways that were not dangerous). Through the implementation of this novel approach, assent and treatment effectiveness were enhanced for the autistic individual.

## Communication Strategies in Negotiating Autonomy and Consent for Persons with Dementia (PWD)

Josephine Misaro, Jimoh J. Braimoh, Josephine Akuamoah Boateng

**International Journal of Enhanced Research in Medicines & Dental Care (IJERMDC), August 2024**

*Open Access*

*Abstract*

*Objectives*

The aim of this study is to explore the communication strategies deployed by administrators and staff in Assisted Living communities in negotiating sexual autonomy. Furthermore, the study investigates outcomes and effectiveness of such strategies in maintaining independence and freedom for Persons With Dementia (PWD)'s sexual and intimacy desires.

*Method*

This research relies on thematic qualitative design using interviews for collecting data. Semi-structured interviews with administrators and staff from 7 assisted living communities were analyzed based on how PWDs are communicated with and the outcomes.

*Results*

The findings revealed that some communication strategies, namely, Watchful Oversight/Oversurveillance, Redirecting, and Reporting ensure safety but often compromise residents' autonomy and well-being. Formal policies on sexual rights and comprehensive staff training could foster a more supportive and inclusive environment.

*Discussion*

This research is important because it emphasizes the unique communication strategies that support the autonomy and dignity of PWD. It was evident from the findings that while the communication strategies of Oversight/Oversurveillance, Redirecting, and Reporting ensure safety and compliance, they often compromise residents' autonomy and well-being. Balancing these strategies with empathy, formal policies on sexual rights, and comprehensive staff training is crucial for a supportive and respectful environment in AL communities.

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## CULTURAL/HERITAGE/RELIGIOUS/COUNTRY CONTEXT

## Application of Standard Informed Consent Procedure Amongst Practicing Anesthetists in Tertiary Care Hospitals of Karachi

Asif Hassan, Mahendar Wanwari, Adeel ur Rehman, Tarique Aziz, Kashif Naeem, Fahad

**Journal of Health and Rehabilitation Research, 4 August 2024**

*Abstract*

*Background*
Informed consent is a critical component of anesthesia practice, ensuring patient autonomy and safety. However, variability in the application of consent procedures among anesthetists may impact patient understanding and care quality.
*Objective*
To evaluate the application of standard informed consent procedures among practicing anesthetists in tertiary care hospitals in Karachi.
*Methods*
A cross-sectional study was conducted from February 15, 2021, to August 14, 2021, across five tertiary care hospitals in Karachi. A total of 112 anesthetists, including consultants and residents with at least two years of experience, were recruited through consecutive sampling. Data were collected using a custom-made 16-item questionnaire. Responses were scored from 0 to 64, with scores ≥32 considered acceptable. Data were analyzed using SPSS version 25, employing descriptive statistics and Chi-square tests for comparisons.
*Results*
The mean age of participants was 34.04 ± 8.15 years, with 5.43 ± 5.9 years of experience. Compliance with consent standards was 99.11%, with 111 out of 112 participants scoring ≥32. No significant differences were observed across age, gender, or qualification ($p > 0.05$).
*Conclusion*
Anesthetists in Karachi showed high adherence to informed consent standards, though enhancements in risk disclosure are recommended to further improve patient care.

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## RIGHTS/LEGAL/LEGISLATIVE

### Potential donor family behaviours, experiences and decisions following implementation of the Organ Donation (Deemed Consent) Act 2019 in England: A qualitative study

*Research Article*
Leah McLaughlin, Nicholas Mays, Mustafa Al-Haboubi, Lorraine Williams, Jennifer Bostock, Paul Boadu, Jane Noyes
**Intensive and Critical Care Nursing, February 2025**
*Open Access*
*Abstract*
*Background*
In May 2020, England implemented “deemed consent” legislation, to make it easier for individuals to donate their organs and convey their decision when alive. Families are supposed to support the decision but can still override it if they disagree. We aimed to learn more about this changed role when families were approached about organ donation.
*Methods*
A qualitative study using semi-structured interviews with families, feedback from nurses, comparisons with audit data, and public involvement. We used framework analysis with a health systems perspective and utilitarian theory to explore if the law worked.
*Findings*
103 participants were interviewed representing 83 potential donation cases. In 31/83 (37%) cases donation was fully supported, in 41/83 (49%) cases families supported retrieval of some organs, tissues and procedures, and in 11/83 (13%) cases families declined completely. Themes explaining why the law was not (yet) working included: Understanding and agreeing the family’s role, confusion about deemed consent, not supporting the deceased expressed decisions, organ donation as too much of a harm, the different experiences of donation pathways, transition from end-of-life to organ donation discussions, experiences of

'consent', paperwork and processes. Families frequently questioned if their relative wanted to have a surgery rather than supporting the person who died to save lives.

*Conclusion*

Families use the unique experience of their relative dying in intensive care to create alternate narratives whereby the outcome satisfies their own utility and not necessarily those of the potential donor. New public ongoing media campaigns crafted to be more supportive of organ donation as a benefit to transplant recipients could help families overcome the many difficulties they encounter at the bedside.

*Implications For Clinical Practice*

The soft opt-out policy has not empowered nurses to help families at their most vulnerable to increase their support for and consent to deceased organ donation.

## Pitfalls of the green transition: Towards a genuine understanding of the right to free, prior and informed consent of the Indigenous peoples

Yuko Osakada

**Polar Science, 6 September 2024**

*Abstract*

This article examines the changes required to make the green transition more inclusive and sustainable from an international human rights perspective. Indigenous peoples have been challenging the ways in which this transition is taking place, using the phrase "green colonialism." Although, in many countries, it has become common to consult Indigenous peoples to reach an agreement before licensing the establishment of green energy facilities, previous studies that dealt with the Sámi's struggle against the green transition have revealed that asymmetric power relationship between Indigenous peoples, sovereign states and business enterprises contributed to disguised dialogues and/or agreements among them. Therefore, this article concludes that a genuine transition from the obligation to consult Indigenous peoples to their right to free, prior, and informed consent (FPIC) is crucial when establishing green energy facilities that might affect them. In doing so, this article emphasizes that the meaning of the right to FPIC for Indigenous peoples should be understood correctly from an international human rights perspective. In particular, it argues that the right to FPIC should be ensured not only before the project affecting Indigenous peoples is licensed, but also at all stages of implementing the project with participatory monitoring.

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## TECHNOLOGY/OTHER MEDIATION

## Electronic Surgical Consent Delivery Via Patient Portal to Improve Perioperative Efficiency

*Original Investigation*

Karen Trang, Hannah C. Decker, Andrew Gonzalez, Logan Pierce, Amy M. Shui, Genevieve B. Melton-Meaux, Elizabeth C. Wick

**JAMA Surgery, 11 September 2024**

*Abstract*

*Importance*

Many health systems use electronic consent (eConsent) for surgery, but few have used surgical consent functionality in the patient portal (PP). Incorporating the PP into the consent process could potentially improve efficiency by letting patients independently review and sign their eConsent before the day of surgery.

*Objective*

To evaluate the association of eConsent delivery via the PP with operational efficiency and patient engagement.

*Design, Setting, and Participants*
This mixed-methods study consisted of a retrospective quantitative analysis (February 8 to August 8, 2023) and a qualitative analysis of semistructured patient interviews (December 1, 2023, to January 31, 2024) of adult surgical patients in a health system that implemented surgical eConsent. Statistical analysis was performed between September 1, 2023, and June 6, 2024.
*Main Outcomes and Measures*
Patient demographics, efficiency metrics (first-start case delays), and PP access logs were analyzed from electronic health records. Qualitative outcomes included thematic analysis from semistructured patient interviews.
*Results*
In the PP-eligible cohort of 7672 unique patients, 8478 surgical eConsents were generated (median [IQR] age, 58 [43-70] years; 4611 [54.4%] women), of which 5318 (62.7%) were signed on hospital iPads and 3160 (37.3%) through the PP. For all adult patients who signed an eConsent using the PP, patients waited a median (IQR) of 105 (17-528) minutes to view their eConsent after it was electronically pushed to their PP. eConsents signed on the same day of surgery were associated with more first-start delays (odds ratio, 1.59; 95% CI, 1.37-1.83; P < .001). Themes that emerged from patient interviews included having a favorable experience with the PP, openness to eConsent, skimming the consent form, and the importance of the discussion with the surgeon.
*Conclusions and Relevance*
These findings suggest that eConsent incorporating PP functionality may reduce surgical delays and staff burden by allowing patients to review and sign before the day of surgery. Most patients spent minimal time engaging with their consent form, emphasizing the importance of surgeon-patient trust and an informed consent discussion. Additional studies are needed to understand patient perceptions of eConsent, PP, and barriers to increased uptake.

## Systematic Review and Meta-Analysis of Interactive multimedia Interventions used in the Informed Consent Process

Joshua Michael Clements, Jake Simon Clements, Mike Clarke, Stephen Kirk
**British Journal of Surgery, 9 September 2024**
*Abstract*
*Aim*
The use of digital technology to improve the informed consent process has increased over the past decade. A wide range of multimedia modalities are now available. This review aimed to assess the impact of interactive multimedia interventions on the informed consent process.
*Methods*
This was a subgroup analysis of a larger systematic review and meta-analysis conducted in accordance with a predefined protocol registered on PROSPERO (CRD42023380406). Five databases were searched using pre-defined search criterion in December 2022 for randomised trials of interactive multimedia interventions designed to improve the informed consent process. Adults >18 years undergoing invasive interventions with the capacity to consent were included. The Cochrane Risk of Bias (RoB) tool was used to assess study quality. Standardised mean difference for continuous variables and risk ratios for dichotomous variables were used to assess effect. Meta-analyses were performed in RevMan5.
*Results*
21 studies (22 interventions arms) with 2090 participants were included. All studies involved patients undergoing informed consent in an elective hospital setting for various surgical, cardiological and radiological procedures. Statistically significant improvement in immediate (SMD 0.40, 95% CI 0.18 to 0.62, I2=55%) and short-term knowledge (SMD 0.47, 95% CI 0.16 to 0.79, I2=45%) were demonstrated. No statistically significant differences were found for long term knowledge, generalised anxiety, satisfaction with the consent process or length of consultation.

*Conclusions*
Interactive multimedia interventions improve immediate and short-term knowledge in patients undergoing invasive interventions and could be considered as an adjunct to enhance patient knowledge during the informed consent process.

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

*Research Article*
Marije aan het Rot, Ineke Wessel
**Journal of Empirical Research on Human Research Ethics, 28 August 2024**
*Open Access*
*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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## MEDICAL/SURGICAL

## Global considerations for informed consent with shared decision-making in the digital age

*Education*
Edward Robert St John, Connor James Stewart Moore, Raghu Ram Pillarisetti, Erica Sarah Spatz
**BMJ Evidence-Based Medicine, 20 September 2024**
*Background*
Shared decision-making (SDM) is increasingly recognised as fundamental to patient-centred care and enabling patients to make voluntary, informed decisions about their health. SDM is the process whereby patients and clinicians come together to share their expertise. The patient acts as an expert of themselves, understanding their own preferences and their attitudes to risk. The clinician is an expert on the medical knowledge and scientific evidence. Together, treatment options should be explored, arriving at a treatment decision that is right for the patient and supported by the clinician. When dealing with invasive or high-risk procedures (eg, operations, chemotherapy, radiotherapy, immunotherapy), once the treatment decision has been made, the conversation turns to informed consent. This is the process of communicating and agreeing to the potential risks and benefits of the procedure, while acknowledging that there are alternative treatment options that have not been chosen. Though informed consent should be the culmination of SDM, alone it does not encapsulate the entire process. There is a distinction between decision-making and consent and this should ideally be accompanied by a period for reflection. Despite advances in SDM, the subsequent informed consent process has remained stagnant, often failing to meet ethical or legal standards of supporting meaningful patient autonomy.

## Multidisciplinary Team Discussions and the Inclusion of Individualized Patient Factors May Improve Informed Consent in Sports Medicine

John Grossi, Lexi Garber, Brandon Klein, Luke Bartlett, Adam Bitterman, Randy Cohn, Nicholas Sgaglione

**Arthroscopy, Sports Medicine, and Rehabilitation, 20 September 2024**

*Open Access*

*Abstract*

Informed consent allows for the maintenance of patient autonomy and is essential in establishing trusting relationships between physicians and their patients. This process involves thorough discussion of the risks and alternatives, as well as the short- and long-term outcomes, of proposed treatment options. Inadequacies with informed consent can lead to inferior patient outcomes and may be subject to severe legal consequences. Individualized discussions are warranted to address the questions of these patients, whether it be the high-level athlete or the weekend warrior. This review highlights factors, identifies barriers, and proposes potential solutions to improve informed consent within orthopaedic sports medicine.

## Developing a computer based standardised consent form for laparoscopic cholecystectomy

Charles Carey, Stuart James, Gemma Richardson, Shameen Jaunoo

**British Journal of Surgery, 9 September 2024**

*Abstract*

*Aims*

Laparoscopic cholecystectomy is a common general surgical procedure with approximately 65,000 procedures performed per year. The consent process is imperative as serious life changing and life-threatening risks must be discussed with the patient before surgery. At our trust [East Sussex Healthcare NHS Trust], this is currently performed with a generic consent proforma which is filled in during each consent process. We aimed to streamline this process for clinicians and ensure all risks were discussed. Further, we aimed to ensure the process was more medico-legally sound with increased legibility by removing the handwritten aspect and ensure concordance with GMC and RCS informed consent guidance.

*Methods*

We produced a standard computerised consent form for laparoscopic cholecystectomy. This included a diagram to aid patient explanation and sections where all the key risks of the procedure could be checked off once discussed.

*Results*

The consent form has proven popular with clinicians and has streamlined the consent process. It has ensured legibility of the consent form for all involved and is therefore preferable from a medico-legal perspective. It also ensures consistency for all patients undergoing the same consent process.

*Conclusions*

Standardising the consent process using this procedure specific form has helped clinicians cover all the necessary areas with patients before surgery and should be considered for other common operations. Producing the consent form has also been an excellent educational opportunity for trainees, who can now consider all risks associated with laparoscopic cholecystectomy using a single document.

## Informed Consent Practices for Publication of Patient Images in Dermatology Journals

Toluwani Taiwo, Bianca Obiakor, Sarah McClung, Kanade Shinkai

**Journal of the American Academy of Dermatology, September 2024**

*Abstract*

Clinical images play a crucial role in dermatology for patient care and education. The lack of standardized informed consent for publishing images in dermatology journals creates ambiguity for both patients and authors. This cross-sectional study examined informed consent practices in the top 50 dermatology journals

based on the 2022 Clarivate Journal Impact Factor ranking. We reviewed journal websites and patient consent forms during June 28 to July 24, 2023 using an author-created checklist compiled from available best practices for image publication. Approximately 90% of journals specified image consent requirements, though there was notable variability in criteria related to image modification, safeguards for anonymity (e.g., eyebars, cropping, blurring), and the definition of identifiable features. Examples of identifiable features (e.g., tattoos, birthmarks, jewelry) were provided in 14% of journals. Despite the prevalence of social media presence among journals (70%), only 6% acknowledged potential risks associated with image dissemination on these platforms. While around 52% of journals presented journal or publisher-specific consent forms, inclusion of essential components, guided by International Committee of Medical Journal Editors guidelines, varied. Notably, 77% of these forms explicitly addressed how images could be disseminated beyond print publication, with 39% detailing patients' ability to revoke consent, and 19% considering the possibility of patients benefiting financially from publication. Our assessment revealed inconsistencies in image consent practices across journals and their associated consent forms for patients. These findings highlight important opportunities for improvement, including uniform consent guidelines and standardized definitions of identifiable features to protect patient privacy in medical image publication.

## Surgical Options for Breast Cancer and Consent Guidelines for Indigenous Women

*Book Chapter*

Jennifer Erdrich, Felina Cordova-Marks, Amanda Bruegl

**Indigenous and Tribal Peoples and Cancer, 31 August 2024 [Springer]**

*Open Access*

*Key Points*

- Women diagnosed with breast cancer and preparing for surgery can choose between breast-conserving therapy (BCT) and mastectomy. Breast cancer survival for BCT and mastectomy are equivalent.
- Surgical patterns show that American Indian/Alaska Native (AI/AN) women in the United States have more mastectomy and less breast-conserving therapy for early-stage breast cancer compared to non-Hispanic White (NHW) women.
- For all women, regardless of race, informed consent for lumpectomy vs. mastectomy is a complex, time-intensive process entailing comprehensive counseling. Additional historical and cultural considerations must inform consent guidelines for Indigenous women preparing for breast cancer surgery.
- We propose innovative solutions to overcome the challenges that limit Indigenous women’s access to their preferred surgical choice.

*Abstract*

Breast-conserving therapy (BCT) consists of lumpectomy followed by radiation. A lumpectomy removes the tumor and surrounding rim of normal breast tissue, leaving most of the breast volume and shape intact. A mastectomy removes the entirety of the breast tissue. Randomized trials with long-term follow-up demonstrate that, regardless of the stage of disease, survival is equivalent for both treatment options. While the risk of recurrence with lumpectomy alone is higher, modern multidisciplinary care combining lumpectomy with radiation and various forms of systemic therapy achieves a similar low risk of recurrence, allowing clinicians to offer BCT or mastectomy as equally safe standard care options. This establishes a surgical choice that is highly personal and should be individualized to consider multiple unique factors, including age, family history, hereditary gene mutations, size of the tumor relative to total breast volume, ability to complete multimodality breast care and surveillance, future plans regarding fertility and lactation, and overall best outcome for the individual’s body-image, lifestyle, and peace of mind.

BCT consistently shows decreased surgical complications, decreased pain, faster recovery, more favorable cosmetics, and better-preserved sexuality and body image. This is not to say that it is the best choice for every woman. BCT is contraindicated for women with inflammatory breast cancer. For some, mastectomy is preferred for personal reasons, even with a full understanding of equivalent survival following BCT. Provided

the patient is well-informed and has worked with her clinical team to ensure her decisions are safe, she should be supported in her surgical choice.

## Ethical Issues and Consent in Oral and Maxillofacial Surgery

*Book Chapter*
Ahmad Nazari
**Handbook of Oral and Maxillofacial Surgery and Implantology, 13 April 2024 [Springer]**
*Abstract*
Oral and maxillofacial surgery, encompassing a wide range of procedures from corrective jaw surgery to facial trauma repair, sits at a complex intersection of aesthetics, functionality, and patient well-being. This specialty, therefore, faces unique ethical challenges, particularly in the realm of patient consent. Obtaining informed consent is not merely a legal formality but a fundamental ethical principle that honors patient autonomy and ensures shared decision-making. Surgeons must navigate these waters with care, ensuring patients understand the potential risks, benefits, and alternatives of proposed treatments. This chapter delves into the ethical nuances of consent in oral and maxillofacial surgery, exploring how surgeons can foster an environment of trust and transparency. It highlights the importance of clear communication, patient education, and the ethical considerations necessary to guide both routine and complex surgical decisions.

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## GENERAL/OTHER

## A rapid review of the benefits and challenges of dynamic consent

*Review Article*
Winnie Lay, Loretta Gasparini, William Siero, Elizabeth K Hughes
**Research Ethics, 9 September 2024**
*Open Access*
*Abstract*
Dynamic consent is increasingly recommended for longitudinal and biobanking research; however, the value of investing in such systems is unclear. We undertook a rapid review of the benefits and challenges of implementing dynamic consent by searching five databases (Ovid Medline, Ovid Embase, Scopus, Web of Science, Cumulative Index to Nursing and Allied Health Literature – CINAHL) for articles published up to May 2023 that report on participants' or researchers' experience of dynamic consent. From 1611 papers screened, 12 met inclusion criteria. Guided by thematic analysis with an inductive approach, we synthesised 31 benefits and 8 challenges. Benefits included: enhanced participant experience through improved consent management and tailoring; greater participant engagement and retention through increased autonomy, trust and communication; reduced costs and burden and increased accessibility and inclusivity. Participants and researchers also valued additional features that dynamic consent platforms facilitate such as two-way communication and return of research updates. The main challenges included the digital divide and consent fatigue. The papers gave recommendations to mitigate these challenges, for example by supplementing with other communication tools and allowing a broad consent approach, respectively. Overall, dynamic consent was described as a valuable consent approach with many benefits and some surmountable challenges. Most included literature was qualitative, so further research is needed to quantify the impact of dynamic consent on recruitment, retention, and participant experience. Further long-term investigations are necessary to explore whether participants want to and do change their consent over time, as well as the impact of dynamic consent on participant privacy.

## Quantifiable Bodies: The Influence of Biometric Technologies in Patient Consent

Morgan Banville, Elena Kalodner-Martin

**Surveillance & Society, 7 September 2024**

*Abstract*

While research has been done to identify the potential implications of biometric technology on marginalized populations' privacy and autonomy, this paper contributes to existing research by examining these technologies in healthcare settings. Drawing from insights across surveillance studies, rhetoric of health and medicine, and technical communication, we identify how one leading healthcare institution in New York City has employed rhetorics of efficiency, effectiveness, safety, and security regarding its biometric technology system. This employment of biometric technologies often contributes to patients' marginalization and dismissal. As we explore, interrogating the language used by the healthcare institution to describe biometrics opens opportunities for us—surveillance studies scholars, patients, allies, students, and more—to ensure that innovations within the healthcare system promote equity, agency, and improved outcomes for all.

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## PRE-PRINT SERVERS

## The research relationship: participant perspectives on consent in biobanking

*Research Article*

Rachel Thompson, Kate Lyle, Gabrielle Samuel, Jo Holliday, Fenella Starkey, Susan Wallace, Anneke Lucassen

**BMC Medical Ethics, 26 August 2024**

*Abstract*

*Background*

This paper examines the ethical challenges associated with the governance of large-scale biobanks. As the collection and interrogation of population-scale data is increasingly positioned as the route to new understandings of health and disease, these large-scale biobanks that rely on health research governance are becoming essential elements of research infrastructure. However, their longitudinal nature presents growing challenges for governance. Typically, health research governance uses a one-off consent model where participants agree to specific activities, but evolving technologies make it difficult to anticipate future research applications at the time of consent. Using a recent case study from UK Biobank, we demonstrate how trying to reconcile new research activities with old consent forms risks overlooking critical ethical issues —particularly how the proposed activity aligns with participants' understanding and expectation of biobank research.

*Methods*

We report on our qualitative research with UK Biobank participants, conducting focus groups using individual and group exercises to explore their views on consent and research applications. We conducted thematic analysis of focus group transcripts applying both an inductive and deductive approach to coding, which was done using NVIVO qualitative data analysis software.

*Results*

Our findings show that participants locate responsibility for research decisions with the biobank, rather than seeking control through their consent. They perceive their consent not as a one-off agreement but as the 'opening act' for an enduring research relationship with the biobank.

*Conclusions*

Prioritising the ongoing research relationship and the practices that sustain it, rather than relying solely on consent procedures, can better support ethical research over time.

## The First General Consent Implementation in Swiss Traditional Chinese Medicine Practices. A Prospective One-Year Study

Xiaying Wang, Xiaoying Lv, Bingjun Chen, Saroj Pradhan, Ralf Bauder, Yiming Li, Michael Furian

**medRxiv, 20 August 2024**

*Abstract*

*Summary*

*Background*

Traditional Chinese Medicine (TCM) encompasses a wide range of treatments focused on diagnosing and managing illnesses, with increasing adoption in Western countries. TCM is often applied in isolated practices, therefore, rigorous research and real-world data collection remain challenging. The implementation of the General Consent (GC) facilitates this research, therefore, the aim was to investigate the acceptance rate of the GC during the first year of its implementation in TCM practices.

*Methods*

This prospective cohort study was conducted from 1st January to 31st December 2023 in five TCM practices located in Bad Zurzach, Baden, Lenzburg, Wil, and Zug in Switzerland. GC, together with other registration forms, were sent to patients prior to their appointments, collected during their first visit, and recorded by clinic secretaries. Logistic regression analysis was performed to investigate demographic factors influencing GC acceptance, considering variables such as age, sex, and practice location.

*Results*

The study recorded 1,095 patients who sought TCM treatments in 2023, of which 73.6% returned a valid GC document. Overall, the GC acceptance rate was 611/1,095 (55.8%); of those returning the GC, the acceptance rate was 611/806 (75.8%). The median[IQR] age of patients was 52[37,64] years and female patients were twice as likely to seek TCM treatments compared to male patients. Logistic regression analysis, odds ratio (95%CI), revealed no difference in GC acceptance rate with older age: 1.015 (0.996 to 1.034), p=0.115; female sex: 1.847 (0.588 to 5.804), p=0.294 and age*female sex: 0.983 (0.962 to 1.004), p=0.119. Significant differences in GC acceptance rates were observed across the five TCM practices.

*Conclusion*

The GC implementation in TCM practices was feasible, and the GC was well accepted by patients, independent of sex and age. The observed practice-related differences in GC acceptance require further investigation. More TCM practices should implement the GC to enable practice-based TCM research.

## Self-Sovereign Identity for Consented and Content-Based Access to Medical Records using Blockchain

Marie Tcholakian, Karolina Gorna, Maryline Laurent, Hella Kaffel Ben Ayed, Montassar Naghmouchi

**arXiv, 31 July 2024**

*Abstract*

Electronic Health Records (EHRs) and Medical Data are classified as personal data in every privacy law, meaning that any related service that includes processing such data must come with full security, confidentiality, privacy and accountability. Solutions for health data management, as in storing it, sharing and processing it, are emerging quickly and were significantly boosted by the Covid-19 pandemic that created a need to move things online. EHRs makes a crucial part of digital identity data, and the same digital identity trends -- as in self sovereign identity powered by decentralized ledger technologies like Blockchain, are being researched or implemented in contexts managing digital interactions between health facilities, patients and health professionals. In this paper, we propose a blockchain-based solution enabling secure exchange of EHRs between different parties powered by a self-sovereign identity (SSI) wallet and decentralized identifiers. We also make use of a consortium IPFS network for off-chain storage and attribute-based encryption (ABE) to ensure data confidentiality and integrity. Through our solution, we grant users full control over their medical data, and enable them to securely share it in total confidentiality over secure

communication channels between user wallets using encryption. We also use DIDs for better user privacy and limit any possible correlations or identification by using pairwise DIDs. Overall, combining this set of technologies guarantees secure exchange of EHRs, secure storage and management along with by-design features inherited from the technological stack.

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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].

*See Spotlight [page 2]*

### Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle

*Draft Guidance*

**FDA Roundup: September 6, 2024**

…Today, the FDA issued a draft guidance "Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle". This guidance, when finalized, is intended to provide recommendations on how patient preference information might be collected and shared with the FDA and potentially be considered in FDA decision-making processes. It also provides recommendations on designing patient preference studies that may provide reliable scientific evidence. On Oct. 15, 2024, the FDA will host a webinar for industry and other parties interested in learning more about the draft guidance. Please submit comments under docket number FDA-2015-D-1580 at www.regulations.gov by Dec. 5, 2024, to ensure the FDA considers comments before it begins work on the final version of the guidance…

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## NEW NORMATIVE/REGULATORY GUIDANCE/ANALYSIS REFERENCING CONSENT

### Guidance for best practices for clinical trials

**WHO, 25 September 2024**

*Overview [excerpted from WHO announcement and guidance executive summary]*

The World Health Organization (WHO) today released guidance to improve the design, conduct and oversight of clinical trials in countries of all income levels. This guidance aims to support stronger country-led research and development (R&D) ecosystems to advance health science so that new, safe and effective health interventions can be made more accessible and affordable globally for people everywhere, faster.

The guidance was developed in response to World Health Assembly resolution WHA 75.8 in an extensive and inclusive process, involving nearly 3000 stakeholders from various sectors across 48 countries. The guidance covers trials for any health intervention, including, but not limited to pharmaceutical medicines; vaccines; diagnostics; nutritional measures; cognitive, behavioural and psychological interventions; preventive care; digital and public health approaches; and traditional or herbal measures.

This document aims to complement other guidance in order to support implementation of universal ethical and scientific standards in the context of clinical trials, with a focus on under-represented populations; it

does not represent a legal standard and does not supersede any existing guidance. In particular, this guidance shares many common concepts and principles with guidance produced by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) *(5)*, especially the ICH E8(R1) General Considerations for Clinical Studies guideline *(6)*, *(*the draft ICH E6(R3) Good Clinical Practice guideline *(7)*, and the ICH E9 statistical principles guideline *(8)* and its associated addendum *(9)*. In addition, it shares attributes with two further recent guidance documents that were highlighted through WHO's public consultation process in 2022: those of the Council for International Organizations of Medical Sciences (CIOMS) on clinical research in resource-limited settings *(10)* and the Good Clinical Trials Collaborative (GCTC) *(11)*.

Both the CIOMS and GCTC guidance have served as sources, with adaptations as needed, for this document. Additional sources highlighted through the consultation include the World Medical Association's (WMA) Declaration of Helsinki *(12)* on medical research involving human subjects, the WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks *(13)* and CIOMS' International Ethical Guidelines on Health-related Research involving Humans (2016) *(14)*.

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## SYMPOSIA/CONFERENCES

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 symposia/conferences identified.*

# # # #



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