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governance, ethics, evidence, policy, practice

Center for Informed Consent Integrity

Informed Consent: A Monthly Review

November 2024 :: Issue 71

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
SOCIAL SCIENCE RESEARCH

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.

SPOTLIGHT

This month we have chosen to spotlight the recently revised *Declaration of Helsinki* and have provided the World Medical Association press release which positions the revision and how it was achieved below. We invite readers to review the full declaration as consent related issues are interwoven throughout, and we make special note of paragraphs 25-32 which deal with free and informed consent.

Revised Declaration of Helsinki adopted by the global medical community, strengthening ethical standards in clinical research involving humans

Press Release

World Medical Association, 21 October 2024

The World Medical Association (WMA) has announced the adoption the 2024 Revision of the Declaration of Helsinki (DoH), the global reference for medical research involving human participants, at its General Assembly in Helsinki, Finland.

Newly inaugurated President of the WMA, Dr Ashok Philip said, “This landmark revision of the Declaration of Helsinki highlights the World Medical Association’s commitment to reinforcing the ethical principles that guide medical research involving human participants, to safeguard patient rights and to ensure the integrity of scientific studies.

“This was a mammoth revision process spanning 30 months, and the World Medical Association extends its heartfelt thanks to everyone who participated,” continued Dr Ashok Philip, President of the World Medical Association.

Under the leadership of Dr. Jack Resneck Jr., Chair of the WMA Declaration of Helsinki revision workgroup, the revision team concluded that some areas of the document had to be updated to ensure the Declaration's continued relevance. The 2024 revision of the Declaration of Helsinki provides for increased protection for vulnerable populations, improved transparency in clinical trials, and stronger commitments to fairness and equity in research.

"Previously, the Declaration of Helsinki addressed WMA members and constituents. The new version of the Declaration says that as physicians, it's part of our moral obligation to ensure that our patients and the participants in research are respected and treated with dignity," said Dr Jack Resneck Jr.

"The revised Declaration of Helsinki calls on everybody involved in the research enterprise now to uphold those principles, whether they are individuals or teams or organizations across the medical research activity," he continued.

Dr Resneck Jr. highlighted some new language in the sixth paragraph of the Declaration as important, saying, "To really address the theme of distributive and global justice, this change means that the Declaration of Helsinki calls on researchers to carefully consider how the benefits, the risks, the burdens of research are distributed."

The substantive changes to the Declaration of Helsinki can be categorised in two areas:

- **Participant-centered inclusion, respect and protection, including recognition of participant vulnerability, calls for community engagement, pursuit of global justice, obtaining informed consent, and use of participant-centered language.**
- **Research beneficence and value, including the pursuit of "individual and public health", upholding scientific rigor and integrity, and considered distribution of benefits, risks and burdens.**

More information

- See the Declaration of Helsinki 2024 full text here.
- See JAMA Viewpoint Revisions to the Declaration of Helsinki on Its 60th Anniversary A Modernized Set of Ethical Principles to Promote and Ensure Respect for Participants in a Rapidly Innovating Medical Research Ecosystem, by Dr Jack Resneck Jr.
- Listen to JAMA Author Interview with Dr Jack Resneck Jr. Declaration of Helsinki Addresses New Ethical Challenges.
- Jama published a number of relevant papers on the date the revision was approved, these papers are available here.
- See WMA Declaration of Helsinki 2024 interview with Dr Jack Resneck Jr.
- Read Background information on the Declaration of Helsinki here.

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BIOMEDICAL RESEARCH

Advance Consent for Participation in Acute Stroke Trials: A Focus Group Study with People with Lived Experience of Stroke

Brief Communication

Ubong Udoh, Rena Seeger, Emma Cummings, Brian Dewar, Stuart Nicholls, Mark Fedyk, Sophia Gocan, Victoria Shepherd, Dar Dowlatshahi, Michel Shamy

The Canadian Journal of Neurological Sciences, 15 October 2024

Abstract

Advance consent could address many of the limitations traditional consenting methods pose to participation in acute stroke trials. We conducted a series of five focus groups with people with lived experience of stroke. Using an inductive thematic approach, two themes were developed: factors in favour of, and against,

advance consent. Participants supported the idea of advance consent and highlighted trust, transparent communication and sufficient time as major factors that would positively affect their decision to provide advance consent. The results will be used to finalise a model of advance consent suitable for testing the feasibility in stroke prevention clinics.

Advance Consent for participation in Acute Stroke Trials (ACTION): protocol for a feasibility study

Ubong Udoh, Rena Seeger, Brian Dewar, Emma Cummings, Sophia Gocan, Stuart Nicholls, Mark Fedyk, Victoria Shepherd, Jeff Perry, Robert Fahed, Tim Ramsay, Jamie Brehaut, Michael D Hill, Alexandre Y Poppe, Bijoy K Menon, Richard H Swartz, Dar Dowlatshahi, Michel Shamy

Stroke and Vascular Neurology, 2 October 2024

Abstract

Introduction

Obtaining informed consent for research from patients in medical emergencies remains a challenge, particularly in acute stroke care as treatment must be administered quickly and patients often arrive in the hospital in a state of incapacitation. Adaptations to standard consenting approaches-such as the use of surrogate consent or deferral of consent-have significant limitations. This feasibility study aims to test a new consenting approach in acute stroke care that we call advance consent. Advance consent has the potential to render emergency trial enrolment faster, fairer and more transparent, leading to more generalisable results.

Methods and design

We will conduct a five-part study at The Ottawa Hospital, a quaternary care stroke centre: (1) administering questionnaires in the Ottawa Hospital Stroke Prevention Clinic that will examine patients' perspectives on research participation and advance consent; (2) inviting participants to consent in advance to any or both currently enrolling acute stroke trials; (3) tracking patient enrolment into these trials over 1 year; (4) administering a follow up questionnaire to participants at 1 year and (5) administering a questionnaire to participating hospital staff in order to interrogate their experiences with advance consent. Outcomes include but are not limited to eligibility rate, recruitment rate, withdrawal rate and the proportion of patients whose advance consent results in trial enrolment.

Conclusion

This study will test the feasibility of enrolling patients at risk of stroke into acute stroke trials using advance consent.

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ARTIFICIAL INTELLIGENCE

Comparing ChatGPT vs. Surgeon-Generated Informed Consent Documentation for Plastic Surgery Procedures

Ishan Patel, Anjali Om, Daniel Cuzzone, Gabriela Garcia Nores

Aesthetic Surgery Journal, 22 October 2024

Abstract

Background

Informed consent is a crucial requirement of a patient’s surgical care but can be a burdensome task. Artificial intelligence (AI) and machine learning language models may provide an alternative approach to writing detailed, readable consent forms in an efficient manner. No studies have assessed the accuracy and completeness of AI-generated consents for aesthetic plastic surgeries.

Objectives

This study aims to compare the length, reading level, accuracy, and completeness of informed consent forms that are AI chatbot (ChatGPT-4, OpenAI, San Francisco, CA)-generated versus plastic surgeon-generated for the most commonly performed aesthetic plastic surgeries.

Methods

This study is a cross-sectional design comparing informed consent forms created by the American Association of Plastic Surgeons (ASPS) with informed consent forms generated by ChatGPT-4 for the five most commonly performed plastic surgery procedures: liposuction, breast augmentation, abdominoplasty, breast lift, and blepharoplasty.

Results

The average word count of ChatGPT forms was lower than for the ASPS generated forms (1023 vs 2901, p=0.01). Average reading level for ChatGPT forms was also lower than ASPS forms (11.2 vs 12.5, p=0.02). There was no difference between accuracy and completeness scores for general descriptions of the surgery, risks, benefits, or alternatives. The mean overall impression score for ChatGPT consents was 2.33, whereas it was 2.23 for ASPS consent forms (p=0.18).

Conclusions

Our study demonstrates that informed consent forms generated by ChatGPT were significantly shorter and more readable than ASPS forms with no significant difference in completeness and accuracy.

Automated informed consent

Research article

Adam John Andreotta, Björn Lundgren

Big Data & Society, 18 October 2024

Open access

Abstract

Online privacy policies or terms and conditions ideally provide users with information about how their personal data are being used. The reality is that very few users read them: they are long, often hard to understand, and ubiquitous. The average internet user cannot realistically read and understand all aspects that apply to them and thus give informed consent to the companies who use their personal data. In this article, we provide a basic overview of a solution to the problem. We suggest that software could allow users to delegate the consent process and consent could thus be automated. The article investigates the practical feasibility of this idea. After suggesting that it is feasible, we develop some normative issues that we believe should be addressed before automated consent is implemented.

> *Editor's Note: We are concerned that the core argument being made in this article challenges the integrity of the informed consent process.*

Informed consent in the age of smart technologies

Jaana Leikas, Arja Halkoaho, Marinka Lanne

Finnish Journal of eHealth and eWelfare, 14 October 2024

Abstract

Technology is increasingly being brought into the home care of older people. Digitalization is seen as an enabler for efficient and resource-saving operations. In the use of technology, informed consent is considered an ethical practice and part of a responsible home care service system. The aim of this article is to describe the problem of informed consent in situations where emerging technologies, such as artificial intelligence (AI) and mass data, are used as part of welfare services and home care for older people. The article discusses principles and ways to better integrate informed consent as an ethical practice into a responsible home care service system.

A qualitative study was carried out to gather the views of experts in the field of elderly care and ethics. A content analysis of a semi-structured focus group was used to explore perceptions of the changing nature of

informed consent. According to our findings, the informed consent model requires updating. The key is to embrace the idea that consent is a living process designed to respect people's autonomous choices and protect them from risk. If the nature of the use of the data collected from individuals changes significantly in the future, the consent should also be updated to reflect this change. This aspect is important because new technologies will change the nature of the collection and use of the data. Mass data collection combines multiple databases so that the resulting data can be used even far from the original purpose or context in which it was collected. Therefore, consent should always be tailored to the context, allowing sufficient time for the person seeking and giving consent to clarify the content of the consent. This process highlights the importance of understanding the agency of the consent giver.

Using Large Language Models to Create Patient Centered Consent Forms

J. Beattie, S. Neufeld, D.X. Yang, C. Chukwuma, N.B. Desai, M. Dohopolski, S.B. Jiang

International Journal of Radiation Oncology, Biology, Physics, 1 October 2024

Abstract

Purpose/Objective(s)

Understanding informed consent forms, which outline the risks, costs, and procedures of clinical trials, presents a significant challenge for patients due to their complex language and length. Recognizing that such complexity can impede patient comprehension and decision-making, this study proposes the use of Large Language Models (LLMs) to distill these forms into concise, easy-to-understand cover pages. We hypothesize that we can significantly improve the readability of these forms using LLMs.

Materials/Methods

Five approved institutional clinical trial consent forms were assessed for their readability using SMOG and the Flesch-Kincaid Ease of Reading score using Python libraries. The documents were segmented and catalogued in a vector database to facilitate similarity searches. OpenAI's GPT-4 API was prompted to extract information about costs, payments, contact information, eligibility criteria, treatments, duration, and requirements based on relevant information retrieved from the vector database. Furthermore, each prompt included instructions to respond at a 7th to 8th-grade reading level. The answers were collected, and their readability evaluated using the aforementioned metrics. Finally, the SMOG and Flesch-Kincaid readability scores were compared using a Wilcoxon signed-rank test.

Results

The original informed consent forms exhibited an average SMOG score of 16.74 (± 0.86), corresponding to a graduate reading level, and an average Flesch-Kincaid score of 12.93 (± 0.70), corresponding to an undergraduate reading level. Conversely, the LLM-generated information sheets exhibited an average SMOG score of 11.25 (± 0.50), corresponding to a high school reading level, and an average Flesch-Kincaid score of 8.15 (± 0.68), corresponding to an 8-9th grade reading level, demonstrating a significant reduction in reading level ($p<0.05$ for both SMOG and Flesh-Kincaid scores). Some LLM-generated information sheets were successful in adhering to a 7th to 8th-grade reading level, as denoted by a Flesch-Kincaid score < 8.

Conclusion

Our approach successfully simplified clinical trial consent forms using LLMs, reducing reading levels and making information more accessible. This approach could significantly enhance the transparency and comprehensibility of the clinical trial consent process, fostering a more patient-centric approach. Feedback from patients on LLM-generated information sheets could provide invaluable insights into the practicality and usefulness of this approach.

Multi-Center Pilot Study to Assess Provider Experience with an Artificial Intelligence Multimedia Informed Consent Platform

Usman Latif, Timothy Deer, Sean Li

Neuromodulation: Technology at the Neural Interface, October 2024

Introduction
Informed consent is a keystone of medical care, involving a thorough discussion of the procedure, risks and benefits involved, and reasonable expectations for patients. 24% of malpractice suits in the field of spine surgery are attributable to insufficient informed consent. Numerous studies indicate that informed consent is frequently inadequate.
Multimedia aids have been shown to enhance patient comprehension and satisfaction. This study assessed experience at multiple centers with a platform that delivers multimedia videos and utilizes artificial intelligence to ensure patients view the entire video while maintaining attention before signing a digital consent. A permanent videographic record of the patient viewing the video is created for the purpose of reducing malpractice exposure.

> *Editor's Note: After assessing the observations and arguments made in this paper, we are reaching out to the corresponding authors for clarification.*

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TECHNOLOGY/OTHER MEDIATION

Understanding and processing informed consent during data-intensive health research in sub-Saharan Africa: challenges and opportunities from a multilingual perspective

Research article
Lillian Omutoko, George Rugare Chingarande, Marietjie Botes, Farayi Moyana, Shenuka Singh, Walter Jaoko, Esperança Sevene, Tiwonge K Mtande, Ama Kyerewaa Edwin, Limbanazo Matandika, Theresa Burgess, Keymanthri Moodley
Research Ethics, 26 September 2024
Open access
Abstract
Africa has a colonial past that renders it a linguistic melting pot, where language is not only important for communication but is inextricably related to cultural identity. In Africa, there are over 2000 languages that are still being used and spoken. Language diversity coupled with cultural diversity may affect the process of obtaining informed consent in data-intensive research. We explore some of the challenges and opportunities of multilingualism in handling informed consent in the context of data-intensive research. In multilingual contexts, as in most African countries, language is exceptionally central, and translation has potential cultural, social, historical, functional and scientific importance. However, it is recognised that terminological and translation activities may not always be cost-effective or feasible. We consider alternative mechanisms of harmonisation of data-related terminology and concepts in multilingual contexts, such as iconography, graphic elicitation and other multimedia formats of information sharing. The inclusion of visual or multimedia explanations in informed consent forms can improve comprehension, enhance information transfer and learning, reduce potential vulnerabilities associated with low literacy levels or the inability to interpret technical language associated with data-intensive research, build trust with participants and their communities, and promote autonomy of potential participants. We recognise that the inclusion of visual or multimedia content to facilitate information transfer is only one component of the informed consent process for data-intensive research. Research ethics committees (RECs) should be mindful of other key considerations and challenges of informed consent for data-intensive research in sub-Saharan Africa (SSA), and to explore whether these alternative forms of consent are ethical and effective in multilingual contexts.

Infrastructuring Readability: Framing and Overflowing in Writing Assistant Software for Biomedical Research Informed Consent Forms

Research article

Loïc Riom, Solène Gouilhers, Claudine Burton-Jeangros

Science, Technology, & Human Values, 8 October 2024

Open access

Abstract

This article analyzes the development process of a software solution designed to assist researchers in writing biomedical research–informed consent forms. Funded by a Swiss ethics committee, the purpose of the software is to enhance the readability of such documents to improve biomedical research participants' understanding of the information disclosed therein and to reduce the editing work of research ethics committees. Drawing on an embedded ethnographic research, we show how concerns that emerge in ethics reviews shape ethics committee IT infrastructure and how, in turn, this infrastructure contributes to redefining research ethics. We demonstrate that while the software reinforces the biomedical framing of research ethics, it also generates unexpected overflows. By forming new collectives, this infrastructuring process furthers expertise on informed consent forms while giving rise to new areas of inquiry and redefining the issue of readability in biomedical research. Thus, we provide insights into the complex entanglements between research ethic, computer programs, and writing practices. We conclude by reflecting on the role played by our research team during the software's development and outline proposals on how ethnographic methods can contribute to make research ethics review accountable.

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HEALTH DATA/DATA

Data professionals' attitudes on data privacy, sharing, and consent in healthcare and research

Research Article

Katya Kaplow,Max Downey, Darren Stewart, Allan B. Massie, Jennifer D. Motter, Lauren Taylor, John Massarelli, Taylor Matalon, Carolyn Sidoti, Macey L. Levan, Brendan Parent

Digital Health, 22 October 2024

Open Access

Abstract

Objective

Individuals who work on health data systems and services are uniquely positioned to understand the risks of health data collection and use. We designed and conducted a survey assessing the perceptions of those who work with health data around health data consent, sharing, and privacy practices in healthcare and clinical research.

Methods

A 43-item online survey was distributed via a market research firm to individuals (18+) who work with health data in the United States from March to April 2023. Descriptive statistics were calculated for all variables. Associations with demographic variables were assessed using Pearson's X2 tests and ordinal logistic regression.

Results

Most of our respondents (61.7%) reported that they would trust people to use their health data across various sectors, but more respondents trusted those working in academic medical research (86.5%) and healthcare offices (89.9%) compared to those working in industry (68.2%). Despite this reported trust, a strong majority believed that individuals should have complete control over their health data (97.3%), specific consent should be obtained for each use of their health data (92.0%), and that there should be higher standards of consent and privacy for health records data than other types of data (93.7%).

Conclusions
Based on our findings, we might infer that people who work with health data generally trust institutions across sectors to protect their health data. However, many would prefer to have complete control over who has access to their health data and how it is used. These insights should be explored further through qualitative studies.

Considerations for the Design of Informed Consent in Digital Health Research: Participant Perspectives

Research article
Brian J. McInnis, Ramona Pindus, Daniah Kareem, Camille Nebeker
Journal of Empirical Research on Human Research Ethics, 14 October 2024
Abstract
The research team, prospective participants, and written materials all influence the success of the informed consent process. As digital health research becomes more prevalent, new challenges for successful informed consent are introduced. This exploratory research utilized a human centered design process in which 19 people were enrolled to participate in one of four online focus-groups. Participants discussed their experiences with informed consent, preferences for receiving study information and ideas about alternative consent approaches. Data were analyzed using qualitative methods. Six major themes and sixteen sub-themes were identified that included study information that prospective participants would like to receive, preferences for accessing information and a desire to connect with research team members. Specific to digital health, participants expressed a need to understand how the technologies worked and how the volume of granular personal information would be collected, stored, and shared.

Trust and Inclusion in Digital Health: The Need to Transform Consent

Brief Communication
Celia Brightwell, Stefanie Brückner, Orit Halpern, Stephen Gilbert
Digital Society, October 2024
Open Access
Abstract
As health systems increasingly adopt digital solutions, such as remote monitoring and telemedicine, the use of health apps is becoming increasingly widespread. Meanwhile, data protection regulations and digital transformation initiatives are making the individual responsible for protecting their health data. In this brief communication, we focus on how the consent interface in a health app can impact trust and inclusion in digital health for privacy-sensitive people. As the consent interface determines how an individual's health data can be used in medical research, it represents a critical point between the citizen's right to informational self-determination and the potential public benefit of advances in medical science. We find that app developers' interests in controlling access to health data may influence the design of the consent interface and undermine an individual's ability to understand what they are consenting to. We describe how a standardized consent interface applied to health apps could foster a trusting relationship between individuals and the digital transformation of healthcare.

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BIOBANKING

Biobank consent under the GDPR: are potential sample donors informed about all lawful uses of biobank data?

Emmi Kaaya

Medicine, Health Care and Philosophy, 8 October 2024

Abstract

This paper analyses the information disclosures in two biobank consent documents used by biobanks operating under the General Data Protection Regulation (GDPR). The aim of the analysis is to investigate how these documents inform potential sample donors about possible future uses of biobank data. The findings suggest that the consent documents provide potentially misleading information regarding the range of possible future uses of biobank data. Based on these information disclosures, potential sample donors may reasonably believe that the data can only be used for a narrowly defined range of research purposes. However, the range of lawful uses of the data is much broader and less clearly defined. Consent provided based on misleading information is not morally transformative, even if it were legally valid. To facilitate morally transformative biobank consent, this paper provides two recommendations for information disclosure to potential sample donors regarding future uses of biobank data: first, potential sample donors should be informed about the legal scope of consent; and second, they should be informed about the full range of lawful uses of biobank data.

Biobanking, digital health and privacy: the choices of 1410 volunteers and neurological patients regarding limitations on use of data and biological samples, return of results and sharing

Emilia Giannella, Josep Miquel Bauça, Simona Gabriella Di Santo, Stefano Brunelli, Elisabetta Costa, Sergio Di Fonzo, Francesca Romana Fusco, Antonio Perre, Valerio Pisani, Giorgia Presicce, Francesca Spanedda, Giorgio Scivoletto, Rita Formisano, Maria Grazia Grasso, Stefano Paolucci, Domenico De Angelis, Giulia Sancesario

BMC Medical Ethics, 27 September 2024

Open access

Abstract

Background

The growing diffusion of artificial intelligence, data science and digital health has highlighted the role of collection of data and biological samples, thus raising legal and ethical concerns regarding its use and dissemination. Further, the expansion of biobanking, from the basic collection of frozen specimens to the virtual biobanks of specimens and associated data that exist today, has given a revolutionary potential on healthcare systems, particularly in the field of neurological diseases, due to the inaccessibility of central nervous system and the need of non-invasive investigation approaches. Informed Consent (IC) is considered mandatory in all research studies and specimen collections, and must specifically take into account the ethical respect to the individuals to whom the used biological material and data belong.

Methods

We evaluated the attitudes of patients with neurological diseases (NP) and healthy volunteers (HV) towards the donation of biological samples to a biobank for future research studies on neurological diseases, and limitations on the use of data, related to the requirements set by the General Data Protection Regulation (GDPR). The study involved a total of 1454 subjects, including 502 HVs and 952 NPs, recruited at Santa Lucia Foundation IRCCS, Rome, from 2020 to 2024.

Results

We found that (i) almost all subjects agreed with the participation in biobanking (ii) and authorization to genetic studies (HV = 99.1%; NP = 98.3%); Regarding the return of results, (iii) we found a statistically significant difference between NP and HV, the latter preferring not to be informed of potential results (HV = 43%; NP = 11.3%; $p < 0.0001$); (iv) a small number limited the sharing inside European Union (EU) (HV = 4.6%; NP = 6.6%), whereas patients were more likely to refuse transfer outside EU (HV = 7.4%;

NP = 10.7% p = 0.05); (v) nearly all patients agreed with the use of additional health data from EMR for research purposes (98.9%).

Conclusions

Consent for the donation of material for research purposes is crucial for biobanking and biomedical research studies that use biological material of human origin. Here, we have shown that choices regarding participation in a neurological biobank can be different between HVs and NPs, even if the benefit for research and scientific progress is recognized. NP have a strong interest in being informed of possible results but limit sharing of samples, highlighting a perception of greater individual or relative benefit, while HV prefer a wide dissemination and sharing of data but not to have the return of the results, favoring a possible benefit for society and knowledge. The results underline the need to carefully manage biological material and data collected in biobanks, in compliance with the GDPR and the specific requests of donors.

Public Perspectives on Consent for and Governance of Biobanking in Japan

Research Article

Masanori Oikawa, Yoshiyuki Takimoto

Journal of Empirical Research on Human Research Ethics, 27 September 2024

Abstract

Through strengthened biobank governance, broad consent has been widely accepted as a means to replace donors' discretion based on the information of individual research protocols. Trust and other ethical and social notions, such as reciprocity and solidarity, are key concepts that support biobank governance. The types of allowed broad consent are several; however, they remain unclear, and whether these ethical and social notions are associated with public attitudes toward the consent model is not fully understood. This quantitative study examined two hypotheses: narrower and limited broad consent are more accepted by the public, and acceptance rates for broad consent increase with established measures related to biobank governance. This analysis supported both hypotheses, implying that the limited type of broad consent should be considered an important option, and that a specific type of governance is critical in promoting trust, reciprocity, and solidarity between biobanks and the public.

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GENOMIC MEDICINE/GENE EDITING

On the exercise of the right to withdraw consent by human genetic resources providers

Qi Su, Jing Zhang, Ping Wang

Chinese Medical Ethics, 2024; 37(8) pp 896-902

Abstract

To fully respect the true meaning and self-determination of human genetic resources providers, the Regulation on the Administration of Human Genetic Resources gives the providers the right to withdraw unconditionally at any time, that is, the right to withdraw consent. "Withdraw unconditionally at any time" means that the providers have the right to withdraw their consent at any stage without any adverse consequences. To ensure that the right to withdraw the consent of human genetic resources providers can be realized under the rule of law, adequate information should be provided to ensure the provider's right to know, institutional management systems and withdrawal mechanisms should be established, and ethical reviews should be strengthened, which will ultimately produce legal effects, such as providers' termination of participation, the destruction or deletion of genetic resources and no further use.

Editor's note: This is a Chinese language publication from Xi'an Jiaotong University.

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YOUNG PERSONS

Comparing comprehension of consent document between adolescent girls and caregivers of adolescents in Siaya County, Kenya: implications for research with adolescents

Research article

Jacob Onyango, Gift-Noelle Wango, Nicky Okeyo, Lennah Oluoch, Harsha Thirumurthy, Millicent Omoya, Nancy Ounda, Dickens Omondi, Kawango Agot

Research Ethics, 16 October 2024

Open access

Abstract

Despite their vulnerability, adolescents are often excluded from health research due to ethical concerns about research with minors, especially in low-income regions like Sub-Saharan Africa. We enrolled adolescent girls aged 15–17 years and caregivers of girls of the same age. Using a 25-question Comprehension Score Sheet, we applied a quantitative approach to compare the comprehension of informed consent of 33 adolescent girls and 41 caregivers of adolescent girls aged 15–17 years. The assessments were audio-recorded and reviewed for quality check. The results showed that adolescent girls were significantly better than caregivers in comprehending informed consent information overall and specifically on study procedures, voluntarism and study purpose. This suggests that adolescents can understand informed consent information at the same level as or better than caregivers who are entrusted with providing permission for adolescents to participate in research.

Developing best practice guidance for educational psychologists gaining consent across the 0-25 age range

Althea Lyons, George Thomas, Sean Octigan, Joe Orme

Educational Psychology in Practice, 26 September 2024

Open access

Abstract

Consent is essential for legal and ethical psychological practice. EPs in the UK work with children and young people from ages 0 to 25, meaning that consent gaining practices must take account of the complexities of different professional guidelines, legislation, and case law depending on the age and competence of individual service users. This study used participatory action research to develop consent gaining guidance specific to EPs, considering issues related to children's rights, parental responsibility, Gillick competence, mental capacity, and data protection. Findings from a preliminary study were used by a stakeholder group of EPs to create draft guidance. The project was guided by a working party comprising a trainee educational psychologist, a main grade EP, a professional body representative and a solicitor specialising in education law. Implications for professional practice and future research are discussed.

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CAPACITY TO CONSENT

The Ethical Importance of Assent in Adults with Decisional Incapacity

Videocast

David Wendler

NIH Webinar, 17 October 2024

Description

Our speaker for this session is Dr. David Wendler, senior investigator, and head of the section on research ethics in the NIH Clinical Center Department of Bioethics.

Topics addressed:

- Ethical background about why it is important to consider whether obtaining assent/respecting dissent in adults who are unable to provide consent for research is appropriate
- When is obtaining assent appropriate vs. not?
- How would they conduct such an assent process
- The difference between assent and dissent

Capacity to consent: a scoping review of youth decision-making capacity for gender-affirming care

Systematic Review

Loren G. Marino, Katherine E. Boguszewski, Haley F. Stephens, Julia F. Taylor

BMC Medical Ethics, 8 October 2024

Open Access

Abstract

Background

Transgender and gender expansive (TGE) youth often seek a variety of gender-affirming healthcare services, including pubertal suppression and hormone therapy requiring that TGE youth and their parents participate in informed consent and decision making. While youth must demonstrate the ability to understand and appreciate treatment options, risks, benefits, and alternatives as well as make and express a treatment choice, standardized approaches to assess the capacity of TGE youth to consent or assent in clinical practice are not routinely used. This scoping review identified the currently available data regarding adolescent capacity to consent to gender-affirming medical treatments.

Methods

Articles relevant to assessing adolescent capacity for clinical decision-making were identified using OVID Medline, Web of Science, and PubMed. Articles were reviewed and thematically analyzed.

Results

Eight relevant articles were identified using three tools for measuring adolescent clinical decision-making capacity: Measure of Understanding, Measure of Competence, and MacArthur Competence Assessment Tool (MacCAT). These studies explored hypothetical treatment decisions, mental health treatment decisions, HIV treatment decisions, genetic testing decisions, and gender-affirming medical decisions. Only one study specifically examines the capacity of TGE youth to consent to medical treatments. Age was correlated with capacity in most, but not all studies. Other studies found cognitive measures (IQ, literacy, numeracy) may impact important aspects of capacity (understanding and reasoning).

Conclusions

For clinicians caring for TGE youth, tools such as the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) may prove useful, in conjunction with consideration of youth developmental abilities and utilization of shared decision-making practices. A standardized, collaborative approach to assessing TGE youth capacity would benefit TGE youth and their parents, and allow clinicians to more easily resolve ethical concerns.

> *Editor's Note: After assessing the observations and arguments made in this paper, we are reaching out to the corresponding author for clarification.*

Capacity, autonomy, and risk: reflecting on asymmetries in capacity to consent and capacity to refuse

Jonathan Pugh

Ethical Theory and Moral Practice, 2024

Abstract

There has been renewed interest in whether we should understand standards of decision-making capacity (DMC) to be risk relative. Critics of risk-relative standards often highlight a puzzling asymmetry that they imply; a patient may have the requisite DMC to consent to a treatment that is in their best interests, whilst lacking the requisite DMC to refuse that same treatment, given the much higher risk that this would entail. Whilst some have argued that this asymmetry suggests that risk-relative standards are nonsensical, in this paper I defend a 'quality of evidence' view of such standards. I begin by outlining DMC's purported gate-keeping role in medical ethics, and identifying three key normative claims that undergird this role. I then explain how two competing theories of risk-relative standards are incompatible with at least one of these claims. Drawing on Douglas' distinction between standards of 'true capacity' and standards invoked in the 'test' for capacity, I then outline my 'quality of evidence' view. I explain how the view is compatible with the aforementioned normative claims and outline the nature of the asymmetry it implies. I conclude by responding to the objection that there is no meaningful distinction between 'true capacity' and the 'test' for capacity.

> *Editor's note: The distinction between the standards of 'true capacity' referenced in this abstract refer to arguments made by Thomas Douglas in his article Pragmatic argument for an acceptance-refusal asymmetry in competence requirements.*

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CULTURAL/HERITAGE/RELIGIOUS/COUNTRY CONTEXT

Analysis of Attitudes Towards Opt-Out Organ Donation Consent: A Cross-Sectional Study Among Saudi Arabian Residents

Sami Alobaidi

Transplantation Proceedings, 24 October 2024

Abstract

Objective

The study aims to investigate public opinion on opt-out organ donation registration in Saudi Arabia, addressing a gap identified in existing research that reveals varied attitudes and intentions among the population, as indicated by studies in Qatar and Saudi Arabia.

Methods

This study employed a secondary analysis approach, utilizing data from a cross-sectional survey conducted online among 1397 residents of Saudi Arabia. The survey utilized a GoogleTM form questionnaire adapted from a previous study in Qatar. The questionnaire comprised three sections, gathering socio-demographic information, assessing general awareness about organ donation, and exploring participants' agreement with opt-out consent and beliefs related to organ donation using the Theory of Planned Behaviour (TPB) model.

Results

Among the participants, 44.4% supported opt-out consent, with 25.7% females and 39.1% Saudi citizens. Females and diploma/graduation-level education were significantly associated with opt-out support ($P < .001$, $P = .012$, respectively). 98.06% of opt-out supporters were familiar with organ donation. 93.05% agreed to promote organ donation, 98.38% believed registration saves lives, and 81.91% were willing if family had no objections. 86.75% were ready with more information, and 85.78% if informed about their religion's perspective. 92.25% believed living and posthumous donation positively impact life after death. Concerns

included inadequate care (33.44%) and bodily disfigurement (28.43%) postmortem. Majority felt healthy (45.56%) and appropriate in age for donation (57.67%). Among opt-out supporters, 20.84% expressed interest, 8.4% conveyed disinterest, while 36.34% remained undecided regarding organ donation registration.

Conclusion

The study reveals a considerable openness among Saudis toward adopting an opt-out organ donation system, suggesting a potential avenue for increased organ donation rates. While acknowledging cultural nuances, particularly familial influences, targeted interventions are vital to overcome specific barriers and ensure the successful implementation of an opt-out policy.

Implementation of Respect for Autonomy in Hospital Services Within the Indonesia National Health Insurance System

Desdiani Desdiani, Sri Mulatsih, Diah Ayu Puspandari

National Journey of Community Medicine, 1 October 2024

Abstract

The principle of patient autonomy forms the foundation of medical ethics. However, its exploration within the context of national health insurance systems in developing countries remains under-researched. This study aimed to evaluate respect for patient autonomy within Indonesia's National Health Insurance (NHI/JKN) system. The study using a qualitative research interview analyzed thematically. Conducted in Depok, West Java, the study involved in-depth semi-structured interviews with 18 participants, encompassing patients from first-level health facilities (FLHF), general practitioners at FLHF, specialist doctors, and management of referral hospital (RH) officers, and staff members of the JKN. The data were transcribed and analyzed using a thematic approach. The study revealed substantial underutilization of respecting patient autonomy within medical contexts under the JKN. Five themes emerged: challenges in the referral system, knowledge and information dissemination, decision-making and autonomy, quality of healthcare services, and systemic constraints and impact. These themes highlight the lack of patient awareness, restricted medical choices, the dominant role of paternalism (a system in which the government or a person in a position of authority makes decisions for other people) in healthcare decisions, and improper informed consent process. The findings suggest that the principles of beneficence and paternalism often overshadow respect for patient autonomy in the JKN system. This raises concerns about the ethical aspect of patient treatment, particularly the need for greater focus on patient autonomy and shared decision-making to align more closely with global medical ethics practices. This study contributes to understanding autonomy in national health insurance systems in developing countries. It highlights the need for systemic reforms to enhance healthcare efficiency and effectiveness while respecting patient autonomy.

Consent: The practice of the Nigerian Orthodontist

Sylvia Etim, Onyinye Dorothy Ume

International Dental Journal, October 2024

Open Access

Abstract

Aim or Purpose

The aim of the study was to survey the knowledge and practices of Nigerian Orthodontists regarding the obtainment of consent before administering procedures capable of modifying the facial profiles of patients.

Materials and Method

This was a 6-months cross-sectional study design involving Orthodontic practitioners in Nigeria. A 14-item questionnaire was administered to participants via google form, consisting of 2 sections. Section A elicited information on socio-demographic data, professional status, and institution of practice. Section B elicited information on the knowledge and practice of consent taking before Orthodontic procedures. Data collected

was analyzed using both descriptive and inferential statistics with significance set at P value > 0.05. Ethical approval was duly obtained from the Research and Ethics committee of University of Port Harcourt Teaching Hospital.

Results

There were 66 participants (Male-46; Female-20) with mean age 43.7 +/- 9.26 years. Those who had knowledge of informed consent (64, 97%), verbal consent (57, 86.4%), and implied consent (49, 74.2%), but in terms of practices, most obtained informed (52, 78.8%), next was expressed consent (27,40.9%) and least was surrogate consent (6,9.1%). Informed consent was obtained more for fixed appliance therapy and aligners (62, 94%) than removable appliances (49,74%).

Conclusion

Most Nigerian Orthodontic practitioners are aware of the importance of obtaining consent from their patients and they do obtain appropriate consent before carrying out Orthodontic procedures.

Enhancing Professional Awareness of Informed Consent : Safeguarding the Rights of Patients and Practitioners

Min Ji Kim

Journal of Korean Neurosurgical Society, 30 September 2024

Abstract

Informed consent is a crucial communication process between doctors and patients for obtaining patients' approval before initiating medical treatment. It is derived from the legal principles of medical contracts and requires doctors to explain the treatment process to patients. Surgeons should be aware of informed consent not only to avoid unnecessary litigation risks but also to provide patients with the right to self-determination. The aim of the study is to help surgeons in Korea understand the legal doctrine on informed consent for practical application. This article reviews the legal doctrine of IC according to 4W1H-why, who, what, when, and how-with judicial cases to communicate effectively with patients in clinical settings. Regardless of seniority or rank, doctors may provide competent patients with information to protect their rights to self-determination. Informed consent should be advanced for patients to consider, discuss with significant others, and determine whether or not to undergo medical treatment. At that stage, patients need to be informed of the necessity, risks, and so on. The most common method of informed consent is an oral explanation utilizing certain forms for documentation. However, the informed consent of patients can be exempted on certain occasions. Optimal informed consent, when implemented, leads to patient-centered care, which significantly improves patient satisfaction and outcomes. Ultimately, it not only protects doctors from litigation risks but also upholds patients' autonomy.

Researchers experience and views on participants' comprehension of informed consent in clinical trials in Malawi: a descriptive qualitative study

Research

Dorothy Maxwell Kazembe, Yimtubezinash Woldeamanuel, Solomon Mequanente Abay

BMC Medical Ethics, 27 September 2024

Open access

Abstract

Background

Informed consent is the cornerstone of research ethics. One of its goals is that participants enter research with an understanding of what their participation entails. This paper is a study on how researchers understand the informed consent process. Previous studies have looked at this topic from a research participant perspective. However, few studies focus on the perspectives of the researchers. Therefore, this is

an important paper that highlights an important issue (informed consent) from the perspective of those who administer it during research.

Methods

In-depth interviews were conducted with 18 researchers from 3 different research centers in Malawi working in clinical trials. The data was analyzed using open code utilizing the thematic approach to qualitative data.

Results

This study identified that researchers have good awareness of the role of informed consent, how important it is for participants to understand the given information and ways to adjust their practice accordingly when obtaining it in order to enhance participant understanding. According to the research staff, most participants do not really understand all the concepts of the study at the initial visit, they gain more understanding during subsequent visits. It was emphasized that the best method of facilitating informed consent is reading the informed consent to the participant, thus a face-to-face conversation. Long and complex informed consent was identified as one of the barriers to participant understanding of the informed consent. Shortening the informed consent form and having additional conversation with the participants was suggested as one way of improving participant comprehension.

Conclusion

Most of the participants understand much of the information during subsequent visits as you keep reminding them since informed consent is an ongoing process. Existing relationship or trust between a participant and a researcher, may influence participants' decision and misguide their understanding on the purpose of the study. Adequate time should be allocated to informed consent discussions. Shortening the informed consent forms and having additional conversations with potential participants may help improve their understanding.

Comparison of informed consent for breast cancer surgery in the UK and the Czech republic and patients' satisfaction with the process

Monika Rezacova

BMJ Surgery, Interventions, & Health Technologies, 27 September 2024

Abstract

Background

Informed consent is a concept accepted largely in the world, however its interpretation varies. Understanding the diagnosis and process of treatment should be a crucial part of doctor-patient relationship.

Methods

We have assessed 100 patients with a new breast cancer diagnosis (50 in each centre). We have compared the consent forms, risks mentioned to the patient and proposed surgery. A questionnaire was given to patients following the consent process to assess patients' satisfaction with information given and possibility of outcome change.

Results

In the UK, patients were given a surgical management plan with multiple potential risks listed on consent. Patients in Czech were given all possible surgical options without specific plan and only few complications. Patients in the UK were satisfied although some of them would appreciate fewer information on risks. Patients in Czech had trust in the doctor's decision however majority of them would appreciate the exact procedure proposed and more information regarding risks.

Conclusion

Although patients had very different experiences, the vast majority would like to hear the exact type of procedure that is being done and list of significant risks.

Practices of Informed Written Consent for Elective Urological Procedures at a Tertiary Care Hospital in Sudan

Mohammed Elsiddig, Mohammed Hassan

Cureus, 26 September 2024

Abstract

Objective

This study aimed to assess informed consent practices in elective urological surgeries at a tertiary care facility.

Materials and methods

A retrospective cross-sectional survey was carried out between March 1, 2023 and April 1, 2023, at the Department of Urology, Omdurman Military Hospital, Sudan. We included all patients who had undergone elective urological procedures under local, spinal, or general anesthesia. The medical records were accessed to analyze the consent forms' standards. A total of 42 consent forms were included and analyzed. We use the General Medical Council's (GMC) Guidance on Professional Standards and Ethics for Doctors: Decision Making and Consent, and the Royal College of Surgeons (RCS) of England's Consent: Supported Decision-Making as the standard for our study. The GMC and the RCS of England have provided comprehensive and standardized guidelines for obtaining informed written consent, including indications, benefits, risks involved, and alternatives in addition to demographics, patient details, responsible consultant, diagnosis, and title of the surgery, intended benefits, probable risks, type of anesthesia, consenting doctor's name, designation, and signature, and the patient's signature and name.

Results

A total of 42 consent forms were included. The diagnosis and the intended surgical procedure were mentioned in all consents. The potential benefits and risks were discussed in 36 (85.7%) and 18 (42.9%) cases, respectively. The type of anesthesia was discussed in 39 (92.9%) of cases. The likely result of not having the procedure and the alternative treatment: Recorded completion rates of 10 (23.8%) and 12 (28.6%), respectively. Patient demographics were completely documented in 41 (97.6%) forms. Senior doctors were only involved in 14 (33.3%) of the consents. Details of the consenting doctor, including name, title, and signature, were present in 30 cases (71.4%), and the date of signing the consent was documented in 38 cases (90.5%). The completeness of the consent form correlated with the level of the doctor obtaining it, with consultants achieving the highest completion rates (100%), followed by registrars (66.7%) and medical officers (35.7%).

Conclusion

The current practices of informed consent were found to be substandard. Handwritten consent forms do not adhere to the recommended guidelines for informed consent in elective urological procedures. It is preferable to utilize a pre-designed consent form, allowing for personalized additions based on the patient's specifics. Our recommendation is to organize an educational session for junior doctors to emphasize proper consent procedures, and deepen their knowledge of common urological elective procedures, and associated risks. This approach promotes adherence to best clinical practices and minimizes the risk of legal challenges.

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RIGHTS/LEGAL/LEGISLATIVE

Nova Scotia's Deemed Consent for Deceased Organ Donation: Family Member Perspectives and Experiences in the ICU Setting

Aimee J. Sarti, Stephanie Sutherland, Matthew J. Weiss, Alain Landry, Heather Hemming, Jade Dirk, Ken Lotherington, Stephen Beed

Transplantation Direct, November 2024

Abstract
Background
The purpose of this study was to explore the experience of family members of potential organ donors in the intensive care unit following the change to deemed consent legislation in Nova Scotia.
Methods
This was a qualitative study with semistructured, in-depth interviews with 17 family members who were asked to make an organ donation decision on behalf of patients admitted to the intensive care unit in Nova Scotia. We analyzed themes using a descriptive approach. Participants were recruited from the organ donation organization in Nova Scotia, Canada.
Results
Participant awareness and knowledge of the Human Organ and Tissue Donation Act legislation varied from individuals having no awareness and knowledge of the bill to those who had awareness and optimism that the legislation would be beneficial for increasing organ donation rates in the province. Other themes emerging from the interviews included (1) COVID context, (2) quality of healthcare professional care, (3) family support, and (4) barriers to donation (waiting, consent questionnaire, and patient transfers).
Conclusions
The Human Organ and Tissue Donation Act legislation included enhanced support, which was viewed positively by family members. There is a need for continued evaluation as most participants felt it was too early to see the tangible impacts of the newly implemented legislation.

Rethinking with Onora O'Neill the Kantian Concept of Autonomy in Biolaw

Book Chapter
María Jesús Vázquez Lobeiras
The Discourse of Biorights, 1 October 2024; Chapter 6 [Springer]
Abstract
The concept of autonomy plays a significant role in Bioethics as well as in Biolaw, the Kantian conception of autonomy being an unavoidable element in the debate. Some of the most relevant contributions in this discussion stem from Onora O'Neill's work. Prof. O'Neill promotes an anti-individualist interpretation of autonomy and, in order to increase its ethical efficiency, suggests reconsidering the meaning of autonomy as closely linked to trust. This chapter tries to show how intertwined information, autonomy and trust are at a time when medical technologies and care need to be interpreted and disclosed in order to be properly understood.
Introduction
…Informed consent and the ethical and legal principle of autonomy are closely linked, since the former is usually considered a genuine expression of the latter…Considering informed consent to be one of the main expressions of autonomy, although not the only one, in what follows we will analyse it from the perspective of Onora O'Neill. Kant's texts will be consulted once again in order to clarify what the eminent thinker of Königsberg understands by autonomy and to what extent his concept of application can be applied in the field of biolaw.

Unraveling a Political Technology: Free, Prior, and Informed Consent in Peruvian Oil and Mining Sectors

Research Article
Roger Merino
Journal of Politics in Latin America, 27 September 2024
Open Access
Abstract

The worldwide dissemination of the right to free, prior, and informed consent (FPIC) has fostered discussions about its significance for removing the social exclusion of indigenous peoples. Most studies address problems in the regulation and implementation of FPIC, but less attention is paid to how the strengths and weaknesses of indigenous organizations and their different political engagements influence FPIC processes and outcomes. Based on the analysis of consultation agreements in the mining and oil sectors in Peru (2011–2022) and the evaluation of two case studies, this article explains how FPIC might be a tool for indigenous politics and state governance.

Ethical, Psychological and Social Un/certainties in the Face of Deemed Consent for Organ Donation in England

Original Article

Laura L. Machin, Elizabeth Wrench, Jessie Cooper, Heather Dixon, Mark Wilkinson

Health Care Analysis, 24 September 2024

Open access

Abstract

Deemed consent legislation for deceased organ donation was introduced in England in 2020, and is considered a vital part of the new UK NHS Blood and Transplant's 10-year strategy to increase consent for organ donation. Despite the legislation containing safeguards to protect the public, the introduction of deemed consent creates ethical, psychological and social un/certainties for healthcare professionals in their practice. In this paper, we offer insights into healthcare professionals' perspectives on deemed consent, drawn from interview data with 24 healthcare professionals in an NHS Trust in England, prior to the introduction of the legislation. Whilst participants supported deemed consent in principle, they were concerned that it would present a threat to the nature of donation as a 'gift'; the notion of informed consent (or non-consent); and the autonomy of donors, their relatives, and their own roles as health professionals, posing dilemmas for practice. We argue that healthcare professionals present themselves as guardians of potential (non)donors and thus as having ethics and integrity in their own practice. We draw conclusions around the values and principles that matter to healthcare professionals when contemplating consent in deceased donation which will be useful for organ donation committees and ethics forums.

The requirement to obtain the consent of a legal guardian for the provision of reproductive health pharmacist services to minors under the pilot program

Marek Tomków, Radosław Balwierz, Opole University, Adam Majewski,Aleksandra Szopa

Polish Journal of Public Health, September 2024

Abstract

Emergency contraception in Poland is often referred to as the "morning-after pill". Its legal status has changed many times. In Poland, it has only been available on prescription since 2017. Attempts have been made to change the legal status in 2024. A draft amendment to the Pharmaceutical Act was then submitted to Parliament. However, the bill was vetoed by the President of the Republic of Poland. In response to the veto, the Minister of Health issued a decree on a pilot programme in the field of pharmacists' services related to reproductive health. In connection with this regulation, a question arose for pharmacists: whether it is necessary to obtain the consent of the legal guardian of minors who want to use the programme. Therefore, the aim of the work was a legal-comparative and dogmatic-legal analysis of legal acts in the field of reproductive health. A review of the data shows that while the pharmacist carries out the activities indicated in the pilot programme for pharmacist services about reproductive health, health services are provided to patients. Therefore, in the case of minor patients under 16 years of age, or who are over 16 but under 18 years of age, the consent of their legal representatives is required. It should also be noted that the term "pharmacist service" used in the title is not defined in any way in the law (unlike the term "pharmaceutical

service") and does not constitute a definition that would allow the statement to be made that it is another unlisted activity that exempts the pharmacist from the obligation to obtain the consent of the legal guardian. It should therefore be assumed that this consent is necessary to provide the service.

The Civil Law Aspects of Informed Consent to Medical Procedures

Gede Agus Kurniawan, Ade Chandra

SASI, September 2024

Abstract

Introduction

Informed consent is a communication process between healthcare providers and patients regarding the medical procedures to be performed. Its aim is to provide sufficient information so that patients can make informed decisions, and it is regulated by various laws and regulations in Indonesia.

Purpose of the Research

The purpose of this research is to analyze the legal position of informed consent from the perspective of Indonesian civil law and to examine the civil law implications that arise if there is a violation of the informed consent principle in medical procedures.

Method of Research

This research uses normative legal methods with legislative and conceptual approaches, analyzing primary, secondary, and tertiary legal materials through literature study, and applying descriptive qualitative analysis.

Results of Research

Research findings indicate that informed consent holds a strong legal position within the perspective of Indonesian civil law, being viewed as a manifestation of a therapeutic agreement that must meet the valid agreement requirements according to the Civil Code (KUHPerdata) and be supported by various regulations. Violations of the principles of informed consent can lead to significant civil legal implications, including claims for damages on the grounds of breach of contract or unlawful acts, cancellation of the therapeutic agreement, liability for breach of professional standards, and claims based on consumer protection law. These implications can involve healthcare professionals and healthcare institutions, with consequences that include payment of material and immaterial damages, the burden of proof in court, and impacts on reputation and medical practice.

> *Editor's note: SASI is a peer-reviewed journal published by the Faculty of Law, Universitas Pattimura, Indonesia.*

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MEDICAL/SURGICAL

Prevalence of pelvic examinations on anesthetized patients without informed consent

Rachel Cutting, Varsha Reddy, Sneha Polam, Nicole Neiman, David Manna

Journal of Osteopathic Medicine, 7 October 2024

Open Access

Abstract

Context

The pelvic examination is a fundamental tool for the evaluation and diagnosis of women's health conditions and an important skill for all medical students to learn as future physicians for the early detection of treatable conditions such as infection or cancer. Although the American College of Obstetricians and Gynecologists (ACOG) asserts that performing pelvic examinations under anesthesia for educational purposes should only occur if the patient provides explicit and informed consent, there still have been reports of medical students performing pelvic examinations on anesthetized patients across the country, and many

states are now starting to pass bills requiring informed patient consents to conduct pelvic examinations under anesthesia.

Objectives

The objectives of this study are to evaluate the prevalence of pelvic examinations performed by osteopathic medical students on anesthetized patients without consent while fulfilling their third-year OB-GYN clerkship requirements.

Methods

The survey was administered and distributed to all osteopathic medical schools in the country via the Student Osteopathic Medical Association's (SOMA's) chapter emails, outreach emails, and SOMA's social media accounts to collect data. Inclusion criteria included third- or fourth-year osteopathic medical students who completed their OB-GYN clerkship rotations when taking the survey. The exclusion criteria included any osteopathic medical student who had not completed their OB-GYN clerkship rotation. We utilized descriptive analysis to summarize the final data.

Results

We received 310 responses. The final number of responses was 291 after meeting the exclusion criteria. Most osteopathic medical students (94.2 %, n=274) considered the practice of performing pelvic examinations on anesthetized patients without their explicit consent unethical. Among the participants, 40.9 % (n=119) admitted to performing pelvic examinations on patients under anesthesia while on OB-GYN rotations, but most of them (57.1 %, n=68) did so without obtaining prior consent from the patients. Notably, the number of pelvic examinations performed by medical students on patients under anesthesia ranged widely from 1 to 25 with a median number of 10. Moreover, 58.9 % (n=70) indicated that they had not been properly educated to obtain specific consent before performing pelvic examinations under anesthesia. Many participants cited efficiency of practice, lack of policy awareness and personal education by medical students, and failure to refuse to perform pelvic examinations on anesthetized patients as trainees when asked by their seniors or preceptors.

Conclusions

This study demonstrates that although most osteopathic medical students consider performing pelvic examinations on anesthetized patients unethical, many still admit to practicing pelvic examinations on patients under anesthesia, while on OB-GYN rotations for efficiency of practice, lack of policy awareness and personal education, and being in unique positions in which grades are determined by seniors and preceptors for their willingness to do what is asked even if the practice does not align with their conviction. This study highlights the importance of ongoing research and implementation of policies at institutional and state levels that will procure the value of pelvic examinations while protecting and upholding the ethics of patients' rights and autonomy of medical students.

The Impact of Obtaining Explicit Informed Consent for Medical Student Participation in the Pelvic Exam Under Anesthesia: A Qualitative Interview Study

Research Article

Hannah C Milad, Katie Watson, Patrick F Eucalitto, Ricky Hill, Alithia Zamantakis, Marlise Jeanne Pierre Wright, Adaeze A Emeka, Susan Tsai, Susan Goldsmit, Magdy P Milad

International Journal on Obstetrics and Gynecology, 26 September 2024

Open Access

Abstract

The pelvic exam under anesthesia (EUA) is an essential step in gynecologic surgery. Attending, fellow, and/or resident physicians utilize exam findings for surgical planning. Afterwards, medical students often perform this exam for their own learning; the student exam provides no direct clinical benefit to patients. Historically, consent for trainee EUAs was embedded within the surgical consent form. At one urban academic medical center, a written consent form specifically for medical student participation in the pelvic EUA was introduced. Our study examines patient, physician, and operating room (OR) staff perceptions of this new,

explicit consent process between May 2021 and May 2023. Thirty-one (31) subjects including patients, OR staff, and physicians were interviewed and Northwestern University IRB approval was obtained. Our data suggest patients appreciated being asked to explicitly consent to or refuse the student pelvic EUA and having a dedicated consent form left them with a positive feeling about the hospital and their healthcare providers. OR staff and physicians agreed that the student pelvic EUA is necessary and almost all supported an explicit consent form. Physicians did not find the additional consent form burdensome and noted only a modest decline in learning opportunities. Patients and healthcare providers agreed that requiring explicit written consent for the student pelvic EUA respected patient autonomy, improved healthcare quality, and caused minimal disruption to medical education. Our data support the use of an explicit written consent form for student participation in the pelvic exam under anesthesia as standard practice.

Reevaluating Informed Consent: Integrating Shared Decision-Making into Spinal Surgery for Better Patient Outcomes

Jeffrey N. Wang, Mohamed A. Elhakeem, Matthew J. Mesimer, Paul G. Mastrokostas, Salman Ahmad, Tim Reed, Brandon Klein, Lucas E. Bartlett, Adam D. Bitterman, Andrew Megas

Global Spine Journal, 26 October 2024

Abstract

Study Design

Narrative review.

Objectives

The objectives of this study were to answer the following questions: (1) What is the quality of informed consent in spine surgery, including both neurosurgery and orthopaedic spine surgery? (2) What limitations impede the ability of surgeons to engage in effective shared decision-making (SDM) and obtain adequate informed consent? (3) What strategies and solutions may improve the quality of informed consent and SDM? (4) What factors decrease the incidence of litigation in spine surgery?

Methods

N/A.

Results

SDM is a collaborative process where patients are involved in their treatment choices through open communication about risks, alternatives, and postoperative expectations. Informed consent is a vital component of this process, ensuring that patients are fully informed and empowered to make decisions based on their values and preferences. This review highlights the current state of informed consent within the context of SDM in spine surgery and explores how enhancing this process can improve patient outcomes, reduce dissatisfaction, and decrease litigation. By emphasizing patient autonomy and improving the quality of risk communication, SDM fosters better physician-patient relationships and more positive clinical outcomes.

Conclusions

Orthopaedic surgery and neurosurgery are highly litigated specialties, with failure to obtain informed consent frequently cited in lawsuits. These legal challenges are costly and time-consuming for both physicians and patients. Integrating SDM into the informed consent process can help mitigate these issues, leading to improved patient satisfaction and fewer legal disputes.

Development and early Evaluation of a novel tool for assessment of individualised risk tolerance during surgical consent

Research Article

James Booker, Jack Penn, Nicola Newall, David Rowland, Siddharth Sinha, Hani J Marcus

British Journal of Neurosurgery, 17 October 2024

Abstract
Purpose
The legal interpretation of consent has transitioned over the last decade. Surgeons must identify what patients value to individualise surgical consent. This presents a considerable challenge during busy ward rounds or outpatient clinics. We aimed to develop and evaluate a novel risk tolerance tool to aid surgical consent.
Methods
This prospective, longitudinal cohort study evaluated the views of adult, elective surgical patients from a single centre. Attitudes to the existing surgical consent process were assessed (n = 48) and responses underwent thematic analysis. From these responses and a stakeholder focus group, a novel risk tolerance tool was developed. The risk tool was evaluated using questionnaires in 25 pre-operative patients. Post-operatively, the same cohort were followed-up with a telephone clinic 6–8 weeks after discharge.
Results
Overall patients were satisfied with the current consent process, but negative themes emerged including that it is generalised, impersonal, and time pressured. The developed risk tool contained six domains: death, pain, loss of physical function, loss of cognitive function, need for repeat medical interventions, and social disability. Loss of physical function (mean = 34.0, SD = 12.8) and loss of cognitive function (mean = 34.0, SD = 6.1) had lowest risk tolerance, and need for repeat medical interventions (mean = 18.8, SD = 10.9) had the highest risk tolerance. Thirteen (93%) patients had a positive experience of the consent process vs 85% of patients in pre-consent tool cohort.
Conclusions
The tool demonstrated good patient acceptability and patient reported experience. The tool gathered data that may enhance understanding of patient risk tolerance and personalise the surgical consent process.

Pain Management Consent Considerations

Book Chapter
Elizabeth Wilson, Kristopher Schroeder
Perioperative Pain Management, 16 October 2024 [Springer]
Abstract
Healthcare professionals must consider patients as collaborators in the process of healthcare decision making. In matters of perioperative pain management, it is important to consider and include patients in decisions that may be impacted by their personal history of pain management/analgesic administration, value system/thought process regarding pain management, and the relative impact of potential complications related to analgesic procedures and opioid analgesics. To make these decisions, healthcare professionals must consider the ability of patients to make decisions in the setting of pain and polypharmacy and if the use of adjunct/surrogate decision makers may be appropriate/beneficial. In addition, it is important to consider how information is conveyed and the degree of detail that is required to ensure that patients are equipped to make a decision that best aligns with their belief system and values. Finally, patient decisions must be respected, and they must know that they possess the autonomy to be ultimately responsible for the decisions that will impact their healthcare delivery.

Role of procedure-specific consent forms in clinical practice: a systematic review

Research Article
J Norvill, C Bent, JA Mawhinney, N Johnson
The Annals of The Royal College of Surgeons of England, 3 October 2024
Open access
Abstract
Introduction

Consent forms play an active role in the consent process with generic, handwritten consent forms (GCF) often the standard across the National Health Service. Increasingly, procedure-specific consent forms (PSCF) are being used as an alternative. However, concerns remain about whether they meet the standard for consent. We therefore conducted a systematic review with the objectives of investigating evidence for PSCF, study methodology and medicolegal criteria.

Methods

This systematic review was prospectively registered on PROSPERO (CRD42023392693) and conducted from 1 January 1990 to 17 March 2023 using the MEDLINE, Embase, CINAHL, CENTRAL and Emcare databases. A grey literature search was also performed. All studies evaluating PSCF in medical and surgical settings were included. Risk-of-bias analysis was performed using 'RoB 2' and 'ROBINS-I'. Meta-analysis was not possible because of the results' heterogeneity.

Findings

We identified 21 studies investigating PSCF with no systematic reviews and meta-analyses reported. Most studies were quality improvement projects (n = 10) followed by randomised studies (n = 5). No definitive legal guidance for PSCFs and no studies assessing their role in litigation post-procedural complications were identified. PSCFs were associated with improved documentation (70%–100%; n = 11) and legibility (100%; n = 2) compared with GCF. Randomised studies (n = 4) investigating patient understanding and recall for PSCF were inconclusive compared with GCF.

Conclusions

The heterogeneous evidence available merely demonstrates superior documentation of PSCF compared with GCF. Studies do not adequately investigate the impact on informed consent and fail to address the associated legal concerns. Further randomised studies with patient-centric outcomes and consideration for medicolegal criteria are needed.

A tool for optimising shared decision making and informed consent for surgical innovation: development and implementation of a core information set

Christin Hoffmann, Daisy Elliott, Cynthia Ochieng, Samuel Lawday, Abigail Vallance, Leila Rooshenas, Barry Main, Jane Blazeby, Pete Wheatstone, Angus McNair

BMJ Surgery, Interventions, & Health Technologies, 27 September 2024

Abstract

Introduction

There are significant challenges in achieving high-quality shared decision making (SDM) and informed consent for surgical innovation. Evidence shows that patients' information needs are insufficiently addressed. We co-developed a core information set (CIS) to provide baseline information for consultation discussions between clinicians and patients offered novel surgical procedures/devices.

Methods

This study adhered to guidance for CIS and core outcome set development (COS-STAD) to (i) generate a provisional CIS from data sources (44 stakeholder interviews, 34 consultations, 213 studies, 58 policies) applying thematic content analysis, (ii) refine/agree CIS with stakeholders (patients, surgeons, anaesthetists, lawyers, ethicists, medical directors, SDM experts, regulators) using nominal group technique, (iii) conduct UK public consultation, (iv) implement the CIS nationally.

Results

A provisional CIS contained 8 themes/28 subthemes. Some 25 stakeholders refined/agreed a final 7-theme CIS covering what is 'new' about the procedure, conflicts of interest, reasons for the innovation, treatment alternatives, unknowns, surgeons' expertise, and governance. Public consultation (N=136) endorsed all themes. Industry collaboration will implement the CIS in digital consent platforms across 38 institutions.

Conclusions

An evidence-based CIS has been co-developed with key stakeholders and is the recommended standard to optimise SDM and informed consent for surgical innovation.

Exploring consent for animal-derived products in surgery

Tega Ebeye, Chantal R. Valiquette, Natalia Ziolkowski

The American Journal of Surgery, 24 September 2024

Abstract

Informed consent is integral to the practice of ethical and patient-centered medicine. Barring specific life and limb emergencies where there is no capable decision maker to provide consent, surgeons typically rely on informed consent to decide on provision of surgical care. However, determining what constitutes informed consent – what risks are deemed material enough, how to appropriately weigh risks, benefits, and alternatives, as well as answering procedure-related questions – is ever evolving. An emerging area of discovery, with limited literature, has focused on how to obtain informed consent when animal-derived products (ADPs) are used. Here, ADPs include both human and animal-derived products used in surgery. As surgeons and surgical trainees, we have encountered different approaches to including ADPs in informed consent – from failure to discuss ADP use in general, to the blanket statement indicating the use of potential animal-derived products in surgery, to actually discussing and listing known ADPs like “nerve glue” and "AlloDerm" on the consent form – prompting our interest in this topic as it affects surgical practice and patient autonomy. However, while it has been argued that disclosing the use of ADPs is warranted under Beauchamp and Childress’ four principles of biomedical ethics, it remains unclear how detailed our discussions need to be to meet this ethical standard without creating undue burden, and potentially substandard care, for patients.

Co-Designing Body Donation Consent Processes

Conference Abstract [published in special journal edition]

Georgina C. Stephens

International Federation of Associations of Anatomists Congress 2024 - Kimdaejung Convention Centre, Gwangju, Korea, South

Published: Anatomy & Cell Biology, September 2024

Abstract

It is widely accepted that body donation programs should obtain informed consent from donors during life. Despite the existence of consent guidelines, consent form content varies considerably. Furthermore, consent forms are typically developed by anatomical and legal experts, and may not include details valued by donors or students. Co-design is a form of participatory action research which engages end users to understand phenomena and inform change. Co-design may therefore be ideal to develop consent processes that better incorporate values of donors, students and educators, alongside ethical and legal considerations. As a first step to developing consent processes for a proposed body donor program at an Australian university, this study aimed to bring together participants from these groups to co-design a consent process. Study participants included 7 prospective donors, 9 anatomy students and 6 anatomy educators. Data were collected through 4 focus groups involving at least one member of each participant group. During focus groups, the facilitator worked with participants to identify priorities relating to consent processes. Thematic analysis was used to develop draft consent principles encompassing perspectives across groups. Draft principles were sent to participants, and feedback on these collected through a survey. Four principles for body donation consent processes were established: 1. Consent processes should be informative, transparent and community-focused, 2. Consent processed should include personalised and flexible options, 3. Consent processes should be developed on legal and ethical foundations, and 4. Consent processes should be future-focused. Although some principles addressed aspects within existing consent guidelines (e.g. information adequacy), participants highlighted ways consent processes typical of body donor programs in Australia could be enhanced (e.g. personalised options including naming preferences after death). Participants also

expressed how co-design facilitated a deeper understanding of the value of body donation. Ongoing work will now focus on developing consent resources based on these principles.

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GENERAL/OTHER

A Turn Toward Caring Research: Iterative Consent, Reflexive Multilingual Methods, and Reciprocal Knowledge Production

Olivia Orosco

The Professional Geographer, 7 October 2024

Abstract

The discipline of geography continues to redress historically violent methods and move toward a more ethical and intentional research practice, one hopes. Derived from research with professional immigrant Latina caregivers during the first years of the COVID-19 pandemic (2021–2022), this article offers a reflective approach to the growing conversation of more intentional geographical methods. Learning from feminist and Indigenous methodologies as intertwining, this project takes reciprocity and accountability to and with the caregivers seriously. The research combines artistic portraiture and ethnographic methods to center caregivers as knowledge creators deserving of respect, attention, and artistic portrayal. Collaborative portraits, created by BIPOC artists, were part of the fifteen semistructured testimonio conversations and allowed the tangible centering of caregivers as people to be seen and heard. Learning from the caregivers themselves and through reflective work on methods, this article theorizes a process of iterative consent, multilingual methods, and reciprocal knowledge production and asks what a more ethical and accountable research partnership can and should look like.

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PRE-PRINT SERVERS

Online cognitive assessments in elderly cohorts - the British 1946 birth cohort case study

Ziyuan Cai, Valentina Giunchiglia, Rebecca Street, Martina Del Giovane, Kirsty Lu, Maria Popham, Andrew Wong, Heidi Murray-Smith, Marcus Richards, Sebastian Crutch, Peter J. Hellyer, Jonathan M Schott, Adam Hampshire

medRxiv, 12 October 2024

This article is a preprint and has not been peer-reviewed. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.

Abstract

Introduction

Online assessments are scalable and cost-effective for detecting cognitive changes, especially in elderly cohorts with limited mobility and higher vulnerability to neurological conditions. However, determining the uptake, adherence, and usability of these assessments in older adults, who may have less experience with mobile devices is crucial.

Methods

1,776 members (aged 77) of the MRC National Survey of Health and Development (NSHD) [UK] were invited to complete 13 online cognitive tasks. Adherence was measured through task compliance, while uptake (consent, attempt, completion) was linked to health and sociodemographic factors. Usability was evaluated through qualitative feedback.

Results
This study's consent (56.9%), attempt (80.5%), and completion (88.8%) rates are comparable to supervised NSHD sub-studies. Significant predictors of uptake included education, sex, handedness, cognitive scores, weight, smoking, alcohol consumption, and disease burden.
Discussion
With key recommendations followed, online cognitive assessments are feasible, with good adherence, and usability in older adults.

Patients' Perceptions and Understanding of Pre-operative Informed Consent in a Tertiary Care Setting- Dar-es-salaam

Research Article
Steven Michael, Willbroad Kyejo, Allyzain Ismail, Eric Aghan, Columba Mbekenga, Athar Ali
BMC Medical Ethics, 11 October 2024
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 medico-legal formality. This has led to increased malpractice, misunderstanding, anxiety, and overall postoperative dissatisfaction.
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.

Towards Personal Data Sharing Autonomy: A Task-driven Data Capsule Sharing System

Qiuyun Lyu, Yilong Zhou, Yizhi Ren, Zheng Wang, Yunchuan Guo
arXiv, August 2024
Abstract
Personal data custodian services enable data owners to share their data with data consumers in a convenient manner, anytime and anywhere. However, with data hosted in these services being beyond the control of the data owners, it raises significant concerns about privacy in personal data sharing. Many schemes have been proposed to realize fine-grained access control and privacy protection in data sharing. However, they fail to protect the rights of data owners to their data under the law, since their designs focus on the management of system administrators rather than enhancing the data owners' privacy. In this paper, we introduce a novel task-driven personal data sharing system based on the data capsule paradigm realizing

personal data sharing autonomy. It enables data owners in our system to fully control their data, and share it autonomously. Specifically, we present a tamper-resistant data capsule encapsulation method, where the data capsule is the minimal unit for independent and secure personal data storage and sharing. Additionally, to realize selective sharing and informed-consent based authorization, we propose a task-driven data sharing mechanism that is resistant to collusion and EDoS attacks. Furthermore, by updating parts of the data capsules, the permissions granted to data consumers can be immediately revoked. Finally, we conduct a security and performance analysis, proving that our scheme is correct, sound, and secure, as well as revealing more advantageous features in practicality, compared with the state-of-the-art schemes.

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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 calls for public consultation referencing consent identified.

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NEW NORMATIVE/REGULATORY GUIDANCE/ANALYSIS REFERENCING CONSENT

No new guidance or analysis 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.

Patient-Centered Informed Consent in Clinical Study of FDA-Regulated Medical Products

FDA Patient Engagement Advisory Committee Meeting
Webinar: October 30, 2024
Video recording: [7:13] https://www.youtube.com/live/Th3fkIpi3vc
AGENDA:

On October 30, 2024, the Committee discussed and made 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. FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting.

Background material and the link to the online teleconference and/or video conference meeting are available at https://www.fda.gov/AdvisoryCommittee....

Briefing Documents providing further information:

- Meeting Agenda
- Discussion Questions
- Executive Summary

# # # #

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