ge²p² global foundation
governance, ethics, evidence, policy, practice

Center for Informed Consent Integrity

Informed Consent: A Monthly Review

January 2024 :: Issue 61

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 search articles broadly capturing informed consent and 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 journal 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.

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 articles which the editorial team has assessed to be strategically important and well aligned to our thematic focus areas of governance, ethics, 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
FREE PRIOR INFORMED CONSENT (FPIC)
HUMANITARIAN CONTEXT

Please note that while we strive to identify the primary subject area for the categorization of the monthly digest 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 ARTICLES

This month our spotlight section focuses on the practical development of approaches to obtain assent from persons who may not be able to provide full informed consent. Assent is of particular interest to the GE2P2 Global Foundation and we welcome any thoughts or engagement our readers may want to share.

In the *Psychology in the Schools* research article **Review of participatory research assent procedures in school psychology**, Flowers et al. point out that '[t]ransparency in research is vital for advancing science and safeguarding research participants' and provide the following recommendations for practitioners:

- Given the findings that only a small percentage of reviewed articles provided a detailed account of how assent was obtained from children and adolescent participants, it is crucial for practitioners in school psychology research to prioritize and transparently document their assent procedures.
- While the current review did not identify novel methods for obtaining assent in school psychology research, practitioners should consider looking to related fields for potentially innovative approaches. Engaging participants in a way that enhances their understanding and buy-in can lead to more accurate and valid research outcomes.
- Researchers and practitioners in school psychology should advocate for clear reporting standards regarding assent procedures in publications. Providing detailed information about the assent process should be seen as essential to ethical research, and authors and journal editors should consider the value of including this information in their manuscripts.

In Maureen Dykinga's University of Arizona *PhD Dissertation* **Promoting Health Literacy by Operationalizing a Developmental Approach to Assent**, the author finds that in the University of Arizona context, there is a 'need for operationalized resources that already contain simplified language for PIs to use when assenting youth'. Dykinga notes this research is important for 'deepening our understanding of the effect age has on interventions and the course of diseases [as this] is dependent upon youth-specific data'.

Review of participatory research assent procedures in school psychology

Research Article

Jaime Flowers, Daniel McCleary, Jillian Dawes, Hunter Marzolf

Psychology in the Schools, 5 December 2023

Abstract

In the realm of psychology and related fields, like school psychology, obtaining informed consent from clients or participants who are 18 years old or older is mandatory for researchers. However, if the individuals are below 18 years old or under a conservatorship, their assent is crucial even if their parent or legal guardian has provided formal consent. Despite the widespread recognition of the importance of assent during research, there is a lack of research and guidelines on how to obtain it effectively. To bridge this gap, we conducted a review and created a summary of research published in school psychology journals on gaining assent during research studies. The articles were categorized based on the experimental design, population, and level of assent described. Our findings offer a comprehensive overview of the current state of research on gaining assent in school psychology, which will enhance transparency in research methods.

Promoting Health Literacy by Operationalizing a Developmental Approach to Assent

PhD Dissertation

Maureen Dykinga

PhD Thesis, 2023 [University of Arizona]

Open Access

Abstract

Background

Since 1991, The Common Rule has provided regulation to protect humans participating in biomedical or social research. Despite clear protocols to obtain informed consent from adults, there is limited information on how to incorporate developmental factors such as simplified language, formative assessment, and feedback into youth assent practices. Adolescence, an important period for developing behaviors that impact health throughout the lifespan, is also a time when developmental capabilities vary greatly among peers of the same chronological age. Meaningfully engaging youth in research begins with an assent that integrates developmental factors and promotes the health literacy of youth. Operationalizing this approach narrows the gap between regulation and research practices.

Methods

To quantify the language complexity of two assent templates, 3 trained speech-language pathologists used Language Sample Analysis; the results were compared. To assess the usefulness of incorporating development into assent, a developmental approach to assent was designed. This approach was implemented with a randomized sample of 50 youth participating in the Children And Teens Study (CATS). A data capture system was utilized to present simplified assent language in segments and ask 6 questions assessing comprehension. For individuals with incorrect answers, feedback was provided, and the same question was presented a second time. To incorporate youth priorities, values, and strengths into assent resources, demographics, educational experiences, exposure to racism, and resiliency data were analyzed. To evaluate the feasibility of shifting institutional assent practices, semi-structured interviews were conducted, assessing the importance of assent, understanding of a developmental approach, its acceptability, the practicality of requiring it, and the resources needed for Principal Investigators (PIs), to be successful. To design a toolkit of operational resources, the knowledge from implementing a developmental approach, analyzing youth data, and conducting the feasibility study was applied.

Results

The simplified assent conveyed the same number of key study details as the more complex assent. 100% of the 6 questions were answered accurately by participants. The cross-section of the youth represented a diverse mix of demographics with 72% reporting comorbidities that impact language, learning, mental, and

chronic health. Ninety-eight percent indicated an awareness of racism while 16% had encountered it directly. Youth valued education/knowledge and prioritized flexibility, agency, and autonomy. They demonstrated strengths such as cooperation, connection, and belonging. PIs indicated that assent was important and incorporating a developmental approach was acceptable. They did not believe it would be practical to require this approach. Key barriers were identified as securing buy-in from researchers, addressing time constraints, and gaining institutional support. Resources that strengthen capacity, provide examples, and allow for flexibility, were identified as a need by researchers. A toolkit of resources that reflected youth awareness, priorities, values, and strengths while meeting researcher requests was developed and made available in the resources section of the University of Arizona (UArizona) Institutional Review Board (IRB) website.

Conclusion

The results suggest that integrating a developmental approach was useful in communicating key study elements and reinforced the necessity for inclusive assent practices that align with youth awareness. Incorporating developmental factors into assent empowers youth to exercise health literacy. Providing operational assent resources that reflect the values of diverse youth communities and strengthen the capacity of PIs is the first of many strategies to meaningfully engage youth in research.

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BIOMEDICAL RESEARCH

Testing and Practical Implementation of a User-Friendly Personalized and Long-Term Electronic Informed Consent Prototype in Clinical Research: Mixed Methods Study

Evelien De Sutter, David Geerts, Koen Yskout, Stef Verreydt, Pascal Borry, Liese Barbier, Isabelle Huys

Journal of Medical Internet Research, 19 December 2023

Abstract

Background

Over the years, there has been increasing interest in electronic informed consent (eIC) in clinical research. The user-friendliness of an eIC application and its acceptance by stakeholders plays a central role in achieving successful implementation.

Objective

This study aims to identify insights for the design and implementation of a user-friendly, personalized, and long-term eIC application based on a usability study with (potential) research participants and semistructured interviews with stakeholders on the practical integration of such an application into their daily practice.

Methods

An eIC prototype was evaluated and refined through usability testing among Belgian citizens and iterative redesign. On the basis of a digital literacy questionnaire, a heterogeneous sample of participants was established. Participants needed to complete a series of usability tasks related to personalization and long-term interaction with the research team while using the “think aloud” technique. In addition, usability tests involved completing the System Usability Scale questionnaire and taking part in a semistructured feedback interview. Furthermore, semistructured interviews were conducted with ethics committee members, health care professionals, and pharmaceutical industry representatives active in Belgium and involved in clinical research. Thematic analysis was undertaken using the NVivo software (Lumivero).

Results

In total, 3 iterations of usability tests were conducted with 10 participants each. Each cycle involved some participants who reported having low digital skills. The System Usability Scale scores related to the tasks on personalization and long-term interaction increased after each iteration and reached 69.5 (SD 8.35) and 71.3 (SD 16.1) out of 100, respectively, which represents above-average usability. Semistructured interviews conducted with health care professionals (n=4), ethics committee members (n=8), and pharmaceutical

industry representatives (n=5) identified the need for an eIC system that can be easily set up. For example, a library could be established enabling stakeholders to easily provide background information about a clinical study, presented in the second layer of the interface. In contrast, some functionalities, such as informing participants about new studies through an eIC system, were not considered useful by stakeholders.
Conclusions
This study provides insights for the implementation of a user-friendly personalized and long-term eIC application. The study findings showed that usability testing is key to assessing and increasing the user-friendliness of an eIC application. Although this eIC system has the potential to be usable by a wide audience, participants with low digital literacy may not be able to use it successfully, highlighting the need for additional support for participants or other alternatives to an eIC system. In addition, key lessons emerging from the interviews included ensuring that the application is easy to implement in practice and is interoperable with other established systems.

Opportunities to Advance Equity Through Informed Consent Discussions

Invited Commentary
Puja J. Umaretiya, Emily E. Johnston
JAMA Network Open, 11 December 2023; 6(12)
Excerpt
As pediatric oncologists, we often ask parents to do the unthinkable: grapple with a child's new cancer diagnosis and participate in a clinical trial informed consent discussion within hours to days of each other. Informed consent is essential to our practice because access to clinical trials is the standard of care in pediatric oncology. These discussions are both emotionally charged and medically complex, adding challenges to effective communication. Nearly 2 decades ago, Kodish and colleagues first examined this process in a cohort of parents consenting to therapeutic trials for children with newly diagnosed acute leukemia and found that only one-third of parents understood the concept of randomization and that non–English-speaking families were less likely than English-speaking families to understand key aspects of informed consent. Since then, our trials and informed consent discussions have become more complex. Aristizabal et al found that these gaps in our informed consent process persist, particularly for historically marginalized groups exposed to adverse social determinants of health…

> *Editor's Note: The text of the commentary does not reference assent or the involvement of pediatric patient in consent processes.*

Challenges regarding informed consent in recruitment to clinical research: a qualitative study of clinical research nurses' experiences

Research
Trails, 11 December 2023; 24(801)
Tove Godskesen, Joar Björk, Niklas Juth
Open Access
Abstract
Background
Clinical research nurses (CRNs) have first-hand experience with ethical challenges and play a crucial role in upholding ethical conduct and adherence to the principles of informed consent in clinical research. This study explores the ethical challenges encountered by CRNs in the process of obtaining informed consent for clinical research.
Methods
A qualitative exploratory design. Semistructured interviews (n = 14) were conducted with diverse CRNs in Sweden. These CRNs covered a wide range of research fields, including pharmaceutical and academic studies,

interventions, and observational research, spanning different trial phases, patient categories, and medical conditions. The interviews were analysed using inductive qualitative content analysis.

Results

The analysis identified three main categories: (i) threats to voluntariness, (ii) measures to safeguard voluntariness, and (iii) questionable exclusion of certain groups. CRNs face challenges due to time constraints, rushed decisions, information overload, and excessive reliance on physicians' recommendations. Overestimating therapeutic benefits in stages of advanced illness emerged as a risk to voluntariness. CRNs outlined proactive solutions, such as allowing ample decision-making time and offering support, especially for terminally ill patients. Concerns were also voiced about excluding certain demographics, such as those with language barriers or cognitive impairments.

Conclusions

In conclusion, upholding ethical research standards requires recognising various factors affecting patient voluntariness. Researchers and CRNs should prioritise refining the informed consent process, overcoming participation challenges, and aligning scientific rigour with personalised care. Additionally, a concerted effort is vital to meet the diverse needs of patient populations, including equitable inclusion of individuals with language barriers or cognitive limitations in clinical studies. These findings have significant implications for enhancing the ethics of clinical research and advancing person-centred care.

Parental Perceptions of Informed Consent in a Study of Tracheal Intubations in Neonatal Intensive Care

Original Research Article

Susanne Tippmann, Janine Schaefer, Christine Arnold, Julia Winter, Norbert W. Paul, Eva Mildenberger, André Kidszun

Frontiers in Pediatrics, 2023

Abstract

Obtaining informed consent in neonatal emergency research is challenging. The aim of this study was to assess parental perceptions of informed consent following participation in a clinical trial in neonatal emergency care. This was a supplementary analysis of a randomised controlled trial comparing video and direct laryngoscopy for neonatal endotracheal intubation in the delivery room and neonatal intensive care unit. After obtaining informed consent for the clinical trial, parents were asked to answer a series of self-administered questions about their perceptions of clinical trial participation and the consent process. Informed consent had been given either before birth, after birth but before inclusion in the trial, or after inclusion in the trial. We received responses from 33 mothers and 27 fathers (n = 60) of the 63 preterm and term infants who participated in the study. Fifty-three (89.8%, n = 59) parents agreed that infants should participate in clinical trials, and 51 (85%, n = 60) parents agreed that parents should be asked for informed consent. Fifty-three (89.8%, n = 59) parents felt that their infant's participation in this particular trial would be beneficial. Fifty-two (86.7%, n = 60) parents felt that the informed consent process was satisfactory. One parent (100%, n=1) approached before birth, 23 parents (82.1%, n=28) approached after birth but before enrolment and 26 (83.9%, n=31) parents approached after enrolment were satisfied with the timing of the consent process. Eight (13.3%, n = 60) parents felt.

Comparative analysis of multiple models of electronic informed consent in clinical research

Xu Zuo, Yue Li, Yingshuo Huang

Chinese Journal of Medical Science Research Management, 2023; (4) pp 194-199

Objective

To provide decision-making support for electronic informed consent selection and promotion in clinical research, and lay a possible theoretical foundation for better protection of subjects' rights and interests, as well as promotion of clinical research quality and efficiency.

Methods
This paper summarized the relevant laws and regulations of electronic informed consent, analyzed the advantages and challenges of the application of electronic informed consent in clinical research, sorted out several common electronic informed consent modes in domestic clinical research, explored their operational processes and applications, and discussed their advantages and limitations.
Results
At present, three electronic informed consent modes were mainly used in domestic clinical studies. Each had their own advantages and limitations in terms of convenience of operation, data security, privacy protection of subjects, cost input, popularization degree and so on.
Conclusions
Electronic informed consent needs continuing improvement of relevant laws and regulations and the joint efforts of all stakeholders engaged in clinical research. The sponsor and the researcher should take full consideration of the cost, safety, security, feasibility, and ofters, and make the selection according to the actual needs of the research.

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SOCIAL SCIENCE RESEARCH

Social Determinants of Health and Informed Consent Comprehension for Pediatric Cancer Clinical Trials

Original Investigation
Paula Aristizabal, Shilpa Nataraj, Arissa K. Ma, Nikhil V. Kumar, Bianca P. Perdomo, Maria Elena Martinez, Jesse Nodora, Lin Liu, Euyhyun Lee, Courtney D. Thornburg
JAMA Network Open, 11 December 2023; 6(12)
Abstract
Importance
Ensuring valid informed consent (IC) prior to enrollment in clinical trials is a fundamental ethical right.
Objective
To assess whether social determinants of health (SDOH) and related sociocontextual factors are associated with parental IC comprehension in therapeutic childhood cancer clinical trials.
Design, Setting, and Participants
This cross-sectional study prospectively enrolled 223 parents of children with newly diagnosed cancer at Rady Children's Hospital San Diego, a large quaternary academic center in California, from October 1, 2014, to March 31, 2021. Linear mixed effects models were used to assess whether IC comprehension overall and by domain (purpose, procedures, and randomization; risks and benefits; alternatives; and voluntariness) were associated with SDOH and sociocontextual factors. Data were analyzed from January 1, 2022, to July 31, 2023.
Exposures
Informed consent for a therapeutic childhood cancer clinical trial.
Main Outcomes and Measures
The primary outcome of interest was IC comprehension and its associations with SDOH (marital status, language, educational attainment, employment, insurance type, socioeconomic status, and health literacy) and sociocontextual factors (ethnicity, satisfaction with informed consent, and cancer type).
Results
Of 223 parents, 172 (77.1%) were aged 18 to 44 years, 111 (49.8%) were Hispanic, 152 (68.2%) were women, and 163 (73.1%) were married. In terms of race, 2 (0.9%) were American Indian or Alaska Native, 22 (9.9%) were Asian or Pacific Islander, 8 (3.6%) were Black, 149 (66.8%) were White, and 42 (18.8%) were more than 1 race. In multivariable linear mixed-effects analyses, limited vs adequate health literacy was associated with

lower comprehension of informed consent overall (mean [SD], 68.28 [11.81] vs 79.24 [11.77]; β estimate, −9.02 [95% CI, −12.0 to −6.07]; P < .001) and with lower comprehension of the purpose, procedures, and randomization (mean [SD], 65.00 [12.64] vs 76.14 [11.53]; β estimate, −7.87 [95% CI, −10.9 to −4.85]; P < .001); risks and benefits (mean [SD], 62.84 [20.24] vs 73.14 [20.86]; β estimate, −10.1 [95% CI, −15.6 to −4.59]; P < .001); alternatives (mean [SD], 54.27 [43.18] vs 82.98 [34.24]; β estimate, −14.3 [95% CI, −26.1 to −2.62]; P .02); and voluntariness (mean [SD], 76.52 [24.33] vs 95.39 [13.89]; β estimate, −9.14 [95% CI, −14.9 to −3.44]; P = .002) domains. Use of Spanish vs English language for medical communication was associated with lower comprehension overall (mean [SD], 66.45 [12.32] vs 77.25 [12.18]; β estimate, −5.30 [95% CI, −9.27 to −1.34]; P = .01) and with lower comprehension of the purpose, procedures, and randomization (mean [SD], 63.33 [11.98] vs 74.07 [12.52]; β estimate, −4.33 [95% CI, −8.43 to −0.23]; P = .04) and voluntariness (mean [SD], 70.83 [24.02] vs 92.54 [17.27]; β estimate, −9.69 [95% CI, −16.8 to −2.56]; P = .009) domains.

Conclusions and Relevance

In this cross-sectional study including parents of children with newly diagnosed cancer who provided IC for their child's participation in a therapeutic clinical trial, limited health literacy and use of Spanish language for medical communication were associated with lower comprehension of IC. These findings suggest that, in this setting, parents with limited health literacy or those who use Spanish language for medical communication may not fully comprehend IC and therefore may not make truly informed decisions. These findings support the investigation of interventions, across pediatric disciplines, tailored to the participant's language and health literacy level to improve IC comprehension, particularly in racial and ethnic minority populations.

Editor's Note: The text of the article does not reference assent or the involvement of pediatric patient in consent processes.

Boundaries of Parental Consent: The Example of Hypospadias Surgery

Katrina Roen, Rogena Sterling

Social Sciences, 8 December 2023; 12(12)

Abstract

Human rights organisations raise concerns about medical interventions on children with intersex variations, particularly when these interventions impinge on the child's bodily autonomy and are without a sound biomedical basis. Psychosocial literature and legal literature have made very different contributions to thinking about the healthcare of people with intersex variations, but both literatures pay attention to the process of informing patients about elective interventions and the workings of consent. The present paper addresses the absence of dialogue across medical, legal, and psychosocial literatures on the surgical treatment of children with intersex variations. The analysis presented in this paper focusses on the assumptions underpinning the practice of allowing parents to consent on behalf of their children to elective surgery in the instance of hypospadias. In this paper, we (i) introduce consent from a medico-legal perspective, (ii) analyse selected documents (including medical, psychosocial, and human rights documents) in relation to the concept of parental consent on behalf of a child, and (iii) reconsider the current practice of inviting parents to give consent for elective genital surgery on infants. What emerges from our analysis is a picture of long-term relationships and interactions over time within which the consent process is located. The focus is not whether consent is granted, but whether free and informed consent is granted. This picture allows us to expand the understanding of "informed consent," highlighting the importance of producing ethical interactions between health professionals and patients with the view that these relationships last for years. Understanding consent as a process, considering information as dynamic, partial, and negotiated, and understanding the doctor–patient interaction as relational might enable us to imagine the kind of informed consent process that genuinely works for everyone concerned. Our examination of selected legal, medical, and psychosocial texts raises doubt about whether current hospital practice meets the requirement of informed parental consent on behalf of children undergoing hypospadias surgery.

Editor's Note: The text of the article does not reference assent or the involvement of pediatric patient in consent processes.

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GENOMIC MEDICINE/GENE EDITING

Informed Consent In Genetic Research

Ljupco Chakar, Aleksandar Stankov, Goran Pavlovski, Natasha Bitoljanu, Viktorija Belakaposka Srpanova, Ana Ivcheva, Rosica Siamkouri, Zlatko Jakjovski

Journal of Morphological Sciences, 27 December 2023

Abstract

Recognizing the ethical, legal, and social implications (ELSI) of genetic testing becomes crucial for physicians in the face of complex medical issues, as they are increasingly expected to counsel their patients regarding the medical, psychological, and social responses arising from genetic information. Genetic medicine, with its extreme complexity and the potential repercussions on an individual's life, raises important questions in the ethical, deontological, and legal realms of medicine, playing a primary role in personalized medicine. The aim of this paper is to underscore the significance of informed consent and to provide insights into the ethical procedures associated with genetic testing.

Editor's note: The Journal of Morphological Sciences is a publication of the Brazilian Society of Anatomy and the Panamerican Association of Anatomists.

Ethical considerations for genetic research in low-income countries: perceptions of informed consent, data sharing, and expectations in Nicaragua

Iris S. Delgado, Abigail Outterson, Vaishnavi Ramesh, Alda Gabriela Amador Sanchez, Alfonso César Boza, Damaris Lopez-Pilarte, Juan José Amador Velázquez, David J. Friedman, Daniel R. Brooks, Madeleine K. Scammell, Catharine Wang

European Journal of Human Genetics, 5 December 2023

Open Access

Abstract

Genetic research presents numerous ethical, legal, and social implications (ELSI), particularly when the research involves collaborations between investigators in high and low-income countries. Some ELSI issues are universal, and others are specific to context and culture. This study investigates perceptions of genetic research in Nicaragua, Central America, where local and U.S. based researchers have collaborated for over a decade. A total of 43 residents from northwestern Nicaragua, a region with high mortality rates attributed to chronic kidney disease of non-traditional causes (CKDnt), were interviewed, including research participants in ongoing studies (n = 36), health professionals (n = 3), labor leaders (n = 2), and family members of research participants (n = 2). Questions focused on informed consent, data-sharing, and post-study expectations. Audio recordings of interviews conducted in Spanish were transcribed and translated into English. English transcripts were coded and analyzed using NVivo 12 software. The lack of familiarity with terms in the consent form presented a barrier to participant comprehension of key elements of the genetic research study, raising concerns about the validity of informed consent. Research participants often viewed their participation as access to health care. Health professionals emphasized the importance of long-term partnerships between foreign-based researchers and local health institutions. Leaders and family members recommended that they be informed of research studies and allowed the opportunity to consent, as they felt

the benefits and risks of research also apply to them. Our findings identified genetic research practices to be improved upon in order to be more responsive to the contextual realities of collaborators living in low-resource settings.

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BIOBANKING

GDPR Requirements for Biobanking Activities Across Europe

Book
Editors: Valentina Colcelli, Roberto Cippitani, Christoph Brochhausen-Delius, Rainer Arnold
2023 [Springer]
About this book
The book deals with the effective operation of the rules related to biomedical research and pays attention to the activities of the national legislatures of the 27 Member States in the field of scientific research. This multilevel system has an impact on biobanking activity. The book answers questions realized by operators on the main biobanks around the EU in the field of GDPR. The authors and editors used the questions born from brainstorming among members of the Association European, Middle East & Africa for Biopreservation and Biobanking (ESBB) to offer to the operators in biobanking activity and researchers quickly answer to their daily questions, but with authors highest quality. Further the book provides a comprehensive review of the rapidly expanding field of biobanking. It provides researchers and scholars working on biobanking and bio-sharing and more in general in the university hospitals and clinical trial consortiums, and companies, biomedical researchers, but also jurists and the professionals (in particular judges, lawyers, officers) an instrument rigorous but easy to use of the GDPR in the case of biobanking activities. The book identifies a methodological path to tackle the legal or ethical problem on a specific scientific-technological to verify existing solutions and give ideas for future applications. The importance of the legal solution influences the implementation of the development of the biobanking activity service itself.

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HEALTH DATA/DATA

How to Design Consent for Health Data Research? An Analysis of Arguments of Solidarity

Original Article
Svenja Wiertz
Public Health Ethics, 12 December 2023
Excerpt
…Informed consent has been set down as a core ethical requirement for medical research in the Declaration of Helsinki and the Nuremberg Code but was traditionally understood to apply to research with direct involvement of patients. As research without direct involvement of patients—based solely on collected data or biospecimen—becomes more relevant and prevalent, another set of normative requirements, also operating under the name of consent, comes into play: Gefenas et al. have employed the terms of ‘interventional consent’ and ‘informational consent’ to mark this difference. Informational consent, governed in the European Union today mainly under the General Data Protection Regulation (GDPR) sets the legal standards for processing personal data…

In safe hands: child health data storage, linkage and consent for use

Cervantée E K Wild, Ngauru T Rawiri, Ken Taiapa, Yvonne C Anderson

Health Promotion International, 6 December 2023; 38(6)

Abstract

While there is potential for societal benefit from linkage and integration of large datasets, there are gaps in our understanding of the implications for children and young people, and limited inclusion of their views within this discourse. We aimed to understand the views and expectations of children, young people and their parents/caregivers in Aotearoa New Zealand regarding child health data storage, linkage and consent for use. This qualitative study included 24 Māori and non-Māori children, young people and their families across five focus groups, recruited from a community-based health service. A mixed Māori and non-Māori research team facilitated participant recruitment and data collection. Child, adolescent and parent/caregiver groups were held separately. Sessions were audio-recorded and the verbatim transcripts were analysed thematically. We identified three themes: (i) I am more than a number: seeing patients as people; (ii) In safe hands: data as power; and (iii) What are your intentions with my data? Consent as an active relationship. A key challenge was the reductive and stigmatizing potential of data integration for minoritised groups. Hypothetical discussions of data sharing and linkage were contingent on trust between the participant and the health professional, with negotiated data ownership. Consent was conceived as an active relationship needing renewal and renegotiation as children reached adulthood. Current consent processes for ongoing use of child data require further deliberation. Without a strong ethical and child rights-based approach to issues of child health data management, consent and linkage, we risk exacerbating health inequities and experiences of breach of trust.

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CAPACITY TO CONSENT

A systematic review exploring challenges of informed consent processes in antipsychotic prescribing

Review Article

Jemima Thompson, Lisa M. Grünwald

Psychosis, 19 December 2023

Abstract

Introduction

Informed consent is the process whereby individuals make decisions about their medical care. Information provision, presumption of capability and absence of coercion are three fundamental assumptions required to provide informed consent. Informed consent may be complex to achieve in the context of antipsychotic prescribing. This systematic review aimed to explore challenges relating to informed consent processes in antipsychotic prescribing in the UK.

Method

This was a systematic review of the literature relating to informed consent in antipsychotic prescribing in community settings. Data were analysed using Framework analysis.

Results

Twenty-eight articles were included. Information provision has been perceived as lacking for a long time. Capacity has often not been assumed and loss of capacity has sometimes been viewed as permanent. Power imbalances associated with prescriber status and legal framework surrounding the Mental Health Act can blur lines between coercion and persuasion.

Discussion

Challenges relating to process of informed consent in antipsychotic prescribing have persisted throughout the last few decades. People prescribed antipsychotics need to be made aware of their effects in line with current research. Further research is required to develop models for best practices for informed consent.

Equitable and accessible informed healthcare consent process for people with intellectual disability: a systematic literature review

Systematic Review

Manjekah Dunn, Iva Strnadová, Jackie Leach Scully, Jennifer Hansen, Julie Loblinzk, Skie Sarfaraz, Chloe Molnar, Elizabeth Emma Palmer

BMJ Quality & Safety, 9 December 2023

Abstract

Objective

To identify factors acting as barriers or enablers to the process of healthcare consent for people with intellectual disability and to understand how to make this process equitable and accessible.

Data sources

Databases: Embase, MEDLINE, PsychINFO, PubMed, SCOPUS, Web of Science and CINAHL. Additional articles were obtained from an ancestral search and hand-searching three journals.

Eligibility criteria

Peer-reviewed original research about the consent process for healthcare interventions, published after 1990, involving adult participants with intellectual disability.

Synthesis of results

Inductive thematic analysis was used to identify factors affecting informed consent. The findings were reviewed by co-researchers with intellectual disability to ensure they reflected lived experiences, and an easy read summary was created.

Results

Twenty-three studies were included (1999 to 2020), with a mix of qualitative (n=14), quantitative (n=6) and mixed-methods (n=3) studies. Participant numbers ranged from 9 to 604 people (median 21) and included people with intellectual disability, health professionals, carers and support people, and others working with people with intellectual disability. Six themes were identified: (1) health professionals' attitudes and lack of education, (2) inadequate accessible health information, (3) involvement of support people, (4) systemic constraints, (5) person-centred informed consent and (6) effective communication between health professionals and patients. Themes were barriers (themes 1, 2 and 4), enablers (themes 5 and 6) or both (theme 3).

Conclusions

Multiple reasons contribute to poor consent practices for people with intellectual disability in current health systems. Recommendations include addressing health professionals' attitudes and lack of education in informed consent with clinician training, the co-production of accessible information resources and further inclusive research into informed consent for people with intellectual disability.

A survey of informed consent in patients with dementia in the US and Japan

Iijima Yoshihiko

Nagoya Journal of Medical Science, 31 October 2023;

Open Access

Abstract

This study aimed to confirm the reality of family-focused medical treatment of dementia in Japan and the US. It conducted a questionnaire survey on informed consent from patients with dementia among neurologists and psychiatrists in four prefectures in the Tokai Region (Aichi, Gifu, Mie, and Shizuoka) and dementia specialists in the US. Of the responses, 120 (39.7% response rate) and 20 (5.9% response rate) were

obtained, respectively. In obtaining informed consent from patients with dementia, 75 Japanese specialists (62.5%) and 16 US specialists (80.0%) regularly assessed patients' decision-making abilities. The majority of specialists in both Japan and the US used the Mini–Mental State Examination and Hierarchic Dementia Scale-Revised, which are widely used for cognitive function assessment. In the survey, 27 Japanese specialists (22.5%) and 10 US specialists (50.0%) had different considerations when obtaining informed consent for participation in research, compared to their medical practice. The majority of Japanese and US specialists obtained informed consent from both the patient and their family.

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YOUNG PERSONS

‘But, what is a researcher?’ Developing a novel ethics resource to support informed consent with young children

Julia Truscott, Laura Benton

Children's Geographies, 12 December 2023

Abstract

Young children are generally unfamiliar with the notion of research, which can generate ethical discomfort when seeking their consent to participate in it. Taking informed consent with young children as a focus, in this viewpoint article we reflect on what it means for young children (aged approximately 3–8 years) to be ‘informed’ in the context of research participation. We then share the process of developing an interdisciplinary, innovative ethics video resource to enhance children’s understanding of research, the researcher role and children’s participation in research. To ensure the resource was understandable and engaging for young children, we drew on existing research literature and other supplementary resources as well as creative storytelling and consultation with children and parents. The animated video, which is freely available online, builds from young children’s own experiences and questions with the aim of better supporting their understandings and upholding their rights through the informed consent process.

Evaluating the Decisional Capacity for Informed Consent of Transition age Children to Adolescence in Human Subject Research

Research Article

Kamran Salayev, Ulviyya Aslanova, Kerim Munir

Journal of Empirical Research on Human Research Ethics, 10 December 2023

Abstract

This study aimed to evaluate children's capacity for informed consent. We translated into Azerbaijani language and adapted the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC). We enrolled four healthy groups: children aged 11, 12, and 13 years and adults. We provided the participants with information about the simulated research proposal and a related informed consent form. Subsequently, they were administered the UBACC. The mean total UBACC scores were 11.9 (11-year-olds), 12.7 (12-year-olds), 14.0 (13-year-olds), and 16.0 (adults). The gradual increase in the mean UBACC scores with age suggests the continuous maturation of the capacity to comprehend the informed consent process. There was no specific cutoff age to decide whether the children were competent enough to provide informed consent.

American LGBTIQ+ youth using waived or parent/guardian informed consent: investigating social support and life satisfaction

Research Article

Sarah Kiperman, Emily Srisarajivakul, Carrie E. Lorig, Carla Kevern

Journal of LGBT Youth, 4 December 2023

Abstract

Minimal research in the United States has investigated how LGBTIQ+ youth who use waived consent– an ethical research method that facilitates inclusion for minors when informed consent poses a barrier– differ from LGBTIQ+ youth who can acquire consent from their parent(s)/guardian(s). The current study surveyed N = 313 American LGBTIQ+ youth, where n = 173 used waived consent and n = 92 used parent consent to participate. Researchers explored how these youth compared regarding their life satisfaction and support experiences across parents/guardians, teachers, close friends, classmates, and people at school. Differences were also investigated using MANOVAs and t-tests among n = 149 cisgender and n = 164 gender diverse (e.g., transgender, genderqueer, gender-nonconforming) LGBTIQ+ youth. While overall life satisfaction was similar among youth with waived and parent consent as well as among youth identifying as cisgender and gender diverse, youth who used parent consent perceived having greater support from their parents/guardians, people at school, and classmates compared to youth who used waived consent. Gender diverse youth reported significantly lower levels of support from parents, classmates, and people at school compared to their cisgender peers. Implications for research and practice are discussed.

Involvement and Autonomy of Minors in Medical Settings: Perceptions of Children Undergoing Surgery and Parents

Francisco J. Rodríguez-Domínguez, Teresa Osuna-García, Alberto Guillén, María D. Pérez-Cárceles, Eduardo Osuna

Children, 24 November 2023; 10(12)

Open Access

Abstract

Informed consent presupposes competence and represents a formal decision by an informed person who has the legal capacity to accept medical action or participate in research. Our aim was to analyze the perceptions of minors and their parents about the age at which they consider that a minor is competent for making health decisions. A descriptive observational study was carried out in 302 minors between 12 and 17 years of age undergoing elective surgery, and 302 parents (range 30 to 62 years). Two semistructured questionnaires were designed, one for the minors and the other, for the parents. A total of 20.1% of minors and 31.1% of parents believe that patients should not make decisions related to their health until they are 18 years old. A total of 74.9% of the minors surveyed consider that from 16 years of age, the minor is empowered to make decisions. In parents, this percentage is 60%. In the pediatric setting, each case and situation must be examined individually to determine if the minor meets the condition of maturity to decide. The ideal is to promote the minor's participation in decision-making, giving them the opportunity to participate in the process in a manner appropriate to their capacity.

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TECHNOLOGY/OTHER MEDIATION

Digital consent in gynecology: an evaluation of patient experience

Laura Burney Ellis, Jennifer Barcroft, Edward St John, Dafydd Loughran, Maria Kyrgiou, David Phelps

Archives of Gynecology and Obstetrics, 8 December 2023

Open Access
Abstract
Introduction
The surgical consent process is a crucial discussion between patient and surgeon, which is predominantly documented utilizing hand-written forms. The exchange of individualized information allows the patient to make a truly informed decision. Digital consent (also known as electronic consent or e-consent) has been shown to improve accuracy of information provided without increasing the time taken to consent patients. We aimed to evaluate patient experience and effectiveness of digital consent in a gynecology department in a tertiary London Teaching Hospital.
Methods
A questionnaire was designed and completed by 100 patients undergoing gynecological surgery: 50 consented using paper and 50 consented digitally. The questionnaire included 8 statements, with five possible answers to select, ranging from strongly agree to strongly disagree, on a standard five-point Likert Scale. Patients were all female and categorized into age groups (deciles) and asked whether consent was taken digitally or on paper. Data were collected between January and July 2021.
Results
Most responses were positive with 87% (694/800) of responses to the questions being either strongly agree or agree. Patients who were consented using paper selected 'strongly agree' 43.5% (174/400) of the time in comparison to 64.8% (259/400) of the time when they were consented digitally. The majority, 86% (43/50), of digitally consented patients received a copy of the consent form in comparison to 18% (9/50) of those consented using paper. On average, the patients consented digitally were older than their paper-consented counterparts (49–58 and 59–68 respectively). The mean scores for the questions relating to the ease of reading the form, ease of understanding the form, understanding of the potential complications, and overall satisfaction were higher in those digitally consented ($p < 0.05$).
Discussion
Overall, patients were satisfied with both methods of consent. However, individuals who were consented digitally reported higher levels of satisfaction throughout the consent process, compared to paper consent. These data suggest that digital consent is an acceptable alternative to paper consent for patients and facilitates adherence to national consent guidance, which stipulates patients should be given the information they request.

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ARTIFICIAL INTELLIGENCE

Generating Informed Consent Documents Related to Blepharoplasty Using ChatGPT

Original Investigation
Makoto Shiraishi, Yoko Tomioka, Ami Miyakuni, Yuta Moriwaki, Rui Yang, Jun Oba, Mutsumi Okazaki
Ophthalmic Plastic and Reconstructive Surgery, 19 December 2023
Abstract
Purpose
This study aimed to demonstrate the performance of the popular artificial intelligence (AI) language model, Chat Generative Pre-trained Transformer (ChatGPT) (OpenAI, San Francisco, CA, U.S.A.), in generating the informed consent (IC) document of blepharoplasty.
Methods
A total of 2 prompts were provided to ChatGPT to generate IC documents. Four board-certified plastic surgeons and 4 nonmedical staff members evaluated the AI-generated IC documents and the original IC

document currently used in the clinical setting. They assessed these documents in terms of accuracy, informativeness, and accessibility.

Results

Among board-certified plastic surgeons, the initial AI-generated IC document scored significantly lower than the original IC document in accuracy ($p < 0.001$), informativeness ($p = 0.005$), and accessibility ($p = 0.021$), while the revised AI-generated IC document scored lower compared with the original document in accuracy ($p = 0.03$) and accessibility ($p = 0.021$). Among nonmedical staff members, no statistical significance of 2 AI-generated IC documents was observed compared with the original document in terms of accuracy, informativeness, and accessibility.

Conclusions

Our results showed that current ChatGPT cannot be used as a distinct patient education resource. However, it has the potential to make better IC documents when improving the professional terminology. This AI technology will eventually transform ophthalmic plastic surgery healthcare systematics by enhancing patient education and decision-making via IC documents.

Comparison of artificial intelligence-assisted informed consent obtained before coronary angiography with the conventional method: Medical competence and ethical assessment

Fatih Aydin, Özge Turgay Yildirim, Ayse Huseyinoglu Aydin, Bektas Murat, Cem Hakan Basaran

Digital Health, 30 November 2023

Abstract

Objective

At the time of informed consent (IC) for coronary angiography (CAG), patients' knowledge of the process is inadequate. Time constraints and a lack of personalization of consent are the primary causes of inadequate information. This procedure can be enhanced by obtaining IC using a chatbot powered by artificial intelligence (AI).

Methods

In the study, patients who will undergo CAG for the first time were randomly divided into two groups, and IC was given to one group using the conventional method and the other group using an AI-supported chatbot, chatGPT3. They were then evaluated with two distinct questionnaires measuring their satisfaction and capacity to understand CAG risks.

Results

While the satisfaction questionnaire was equal between the two groups ($p = 0.581$), the correct understanding of CAG risk questionnaire was found to be significantly higher in the AI group (<0.001).

Conclusions

AI can be trained to support clinicians in giving IC before CAG. In this way, the workload of healthcare professionals can be reduced while providing a better IC.

Informed consent for artificial intelligence in emergency medicine: A practical guide

Kenneth V. Iserson

The American Journal of Emergency Medicine, 25 November 2023

Abstract

As artificial intelligence (AI) expands its presence in healthcare, particularly within emergency medicine (EM), there is growing urgency to explore the ethical and practical considerations surrounding its adoption.

AI holds the potential to revolutionize how emergency physicians (EPs) make clinical decisions, but AI's complexity often surpasses EPs' capacity to provide patients with informed consent regarding its use. This article underscores the crucial need to address the ethical pitfalls of AI in EM. Patient autonomy necessitates that EPs engage in conversations with patients about whether to use AI in their evaluation and treatment. As

clinical AI integration expands, this discussion should become an integral part of the informed consent process, aligning with ethical and legal requirements.

The rapid availability of AI programs, fueled by vast electronic health record (EHR) datasets, has led to increased pressure on hospitals and clinicians to embrace clinical AI without comprehensive system evaluation. However, the evolving landscape of AI technology outpaces our ability to anticipate its impact on medical practice and patient care. The central question arises: Are EPs equipped with the necessary knowledge to offer well-informed consent regarding clinical AI? Collaborative efforts between EPs, bioethicists, AI researchers, and healthcare administrators are essential for the development and implementation of optimal AI practices in EM.

To facilitate informed consent about AI, EPs should understand at least five key areas: (1) how AI systems operate; (2) whether AI systems are understandable and trustworthy; (3) the limitations of and errors AI systems make; (4) how disagreements between the EP and AI are resolved; (5) whether the patient's personally identifiable information (PII) and the AI computer systems will be secure; (4) if the AI system functions reliably (has been validated); and (5) if the AI program exhibits bias. This article addresses each of these critical issues, aiming to empower EPs with the knowledge required to navigate the intersection of AI and informed consent in EM.

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CULTURAL/COUNTRY CONTEXT

Informed Consent in Human Subjects Research: A Comparison of International and Saudi Arabian Guidelines

May M. Al-Madaney, Roberto Andorno, Margrit Fässler
Journal of Clinical Research & Bioethics, 11 December 2023
Open Access
Abstract
Objective
Informed Consent (IC) is an essential requirement for the conduct of medical research involving human subjects. Since the Nuremberg Code was adopted in the aftermath of the Second World War, various international guidelines have specified the conditions for a valid IC for medical research. Among the most relevant guidelines are the World Medical Association's Declaration of Helsinki, the guidelines of the Council of International Organization of Medical Sciences (CIOMS), and the Good Clinical Practice Guidelines of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH-GCP). This paper aims to compare the above-mentioned international guidelines with Saudi Arabia's Law of Ethics of Research on Living Creatures regarding the requirements for IC. The comparison also includes some relevant regional and domestic laws. The objective of the study is to determine whether the compared regulations coincide regarding the requirements for a valid IC or whether they show significant differences, and to what extent such requirements are also present in Saudi Arabia's regulations.
Methods
We conducted a content comparative analysis of the above-mentioned guidelines regarding five elements of IC: Disclosure, comprehension, voluntariness, competence, and form of consent. These five topics were subdivided into 44 subtopics. Then we compared and critically analyzed their similarities and differences.
Results
The similarities and differences observed in the seven guidelines are summarized under the five components of IC mentioned above and regarding 44 selected subtopics.
Conclusion
The analysis of the above-mentioned guidelines shows that while the most basic components of IC are present in all the compared documents, there are some differences between them. Specifically, the study

found that the Saudi Arabian regulations include 26 of the 44 subtopics considered and that most of the elements that are missing relate to the disclosure of information to participants.

Table 2: Comparison of informed consent elements from different ethical guidelines.

IC Components	Informed consent elements	DoH	CIOMS	GCP	CHRB	CFR	HRA	The Implementing Regulations
	The fact that this is scientific research	+	+	+	+	+	+	+
	Aims of the study	+	+	+	+	+	+	+
	Possible benefits and risks of the study intervention	+	+	+	+	+	+	+
	Trial–related injury treatment and/or compensation	+	+	+	+	+	+	+
	Right of the participant to withdraw the consent at any time without receiving any drawbacks	+	+	+	+	+	+	+
	Record confidentiality for identifying information	+	+	+	+	+	+	+
	Research participation invitation	–	+	–	+	+	–	+
	Research title	–	+	–	–	–	–	+
	Methods of the study, e.g., randomization	–	+	+	–	–	–	–
	Duties and functions of the participants connected to the study, including follow–up appointments	+	+	+	–	–	–	+
	Possible discomfort or burden	+	+	+	+	+	+	–
	Alternative interventions that are available outside the research and their benefits and risks	–	+	+	–	+	–	+
	Different interventions of the study arms	–	+	+	–	–	–	–
	Trial participation payment as prorated (if any)	–	+	+	–	–	–	–
	The chance to receive a placebo intervention or no intervention	–	–	–	–	–	–	–
	Blinding of the participant or the physician	–	+	–	–	–	–	–
Disclosure to								

Editor's note: Figure from p. 4 of article summarizing informed consent elements from various ethical guidelines.

An Audit of Preoperative Informed Consent in Surgical Patients at a Tertiary Care Hospital in Lahore, Pakistan

Muhammad Umer Shafique, Muhammad Salman Saleem, Maryam Saghir, Mohammad Saad Javaid, Mohammad Saad, Ahmad Sadiq, Hafiz U. Shibli, Muhammad Ahmad Khalid, Farhan Saleem

Cureus, 7 December 2023; 15(12)

Open Access

Abstract

Informed consent plays a crucial role in modern clinical practice, representing a fundamental aspect of patient rights and medical ethics. The purpose of informed consent is to ensure that patients fully comprehend the procedures to which they are providing consent and the recognition that the surgeon is not guilty of battery. Moreover, clinicians safeguard themselves against potential repercussions by documenting the risks adequately conveyed to patients before performing surgery. Therefore, the significance of informed consent cannot be overstated. This survey encompassed patients from various surgical departments who underwent surgery in April 2023 at a tertiary care hospital. For the survey participants above the age of 18 were selected undergoing either emergency or elective surgical procedures. The survey employed a structured questionnaire for interviews, assessing whether patients had given informed consent before surgery. The questionnaire also inquired whether patients received information about the diagnosis, proposed surgical procedure, associated risks, and any available alternative treatment options. Furthermore, patients were asked about the proposed anesthesia type and whether the associated risks were communicated to them before the surgery.

A random selection of 50 patients was done for this study, and the process of block randomization was used with the help of a computer app to reduce bias and allow the representation of the various surgical subspecialties present in the tertiary care hospital. No evidence of consent being taken was present in two patients(4%) or the document on which the consent was signed was not present in the file. Only 48% of the patients acknowledged that they fully understood the provided information. While 60% of the patients were informed about the type of anesthesia proposed, a mere 8% were provided information regarding anesthesia risks. None of the patients in the emergency setting signed the consent form themselves, regardless of their capability to do so. Conversely, only 24% of the patients in the elective setting signed the consent form themselves. The study revealed that the quality of informed consent signing in this tertiary care hospital is below average. Healthcare professionals, including doctors and staff, need education regarding the importance of informed consent and the patient's right to comprehend any procedure or intervention to which they are subjected. A shift in the paradigm of decision-making about a patient's health needs to emphasize that the patient is the most critical entity in these decisions.

The main aim of the study is twofold, primarily we want to analyze the existing method of taking informed consent by comparison with the guidelines and check whether the current practice of informed consent achieves its goal of involving the patients in their treatment. Secondarily, we want to discuss the effect that patient-doctor communication might have on the delivery of the above-mentioned information.

Towards objectivity in ethical assessment: legibility as part of informed consent form comprehension

Emma Verástegui, Ricardo Páez, Oscar Arrieta

Gaceta Médica de México, 2023; 159(5) pp 426-431

Abstract

Background

The experience on informed consent form (ICF) readability at the Research Ethics Committee of the National Institute of Cancerology of Mexico (INCan) is described.

Objective

To evaluate the readability of a randomly-selected sample of ICFs submitted for review between March 1, 2022 and March 31, 2023. The number of pages, the time the reader takes to read the text and the level of education necessary to understand it were determined.

Results

More than half the ICFs from internal investigations were shown to be somewhat or very difficult to read; the level of education required to understand them was up to 9.9 years, and the reading time was short. The ICF texts from international multicenter investigations were aimed at an average education level of 5.5 years and had normal readability. Most ICFs from external trials require a reading time of more than 60 minutes per ICF.

Conclusion

It is necessary to have tools that provide objectivity to the evaluation of ICFs under investigation by ethics committees, which should be indicators of their comprehension, such as readability of the documents.

Editor's note: Gaceta Médica de México is the official scientific dissemination of the National Academy of Medicine of Mexico.

Opinions and practices of midwives working in the delivery rooms on informed consent in vaginal deliveries

Pervin Sahiner, Nevin Utkualp

African Journal of Reproductive Health 2023; 27(11) pp 18-25

Abstract

Obtaining informed consent from women for vaginal birth both safeguards their autonomy and establishes a legal foundation for midwives. This study aimed to determine the opinions and practices of midwives on obtaining valid informed consent for vaginal deliveries. This descriptive study was conducted between November 2021 and December 2022 in two different cities of Turkey, Bursa and Kocaeli. Data were analyzed with Chi-square test. In the study all midwives who had not received ethics training had a common perception that informed consent merely involved obtaining a signature and was a standard practice for vaginal birth (p=0.002). In the study, 92.9% of the midwives reported that they found it necessary to obtain informed consent in vaginal deliveries, 97.6% reported that they provided verbal information. However, information provided by midwives for valid informed consent was mostly not comprehensive (range 44.4%-80.2%). Most midwives (80.2%) focused on highlighting the benefits of vaginal birth for mothers, with comparatively less emphasis on communicating information regarding the potential risks and complications associated with vaginal birth for newborns. The high percentage of midwives who considered it necessary to obtain informed consent in vaginal deliveries in our study suggests that these midwives are well aware of the significance of informed consent.

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RIGHTS/LEGAL/LEGISLATIVE

Consent practices in midwifery: A survey of UK midwives

Rachel Elf, Jacqueline Nicholls, Yanyan Ni, James Harris, Anne Lanceley

Midwifery, February 2024

Abstract

Objective

To explore midwives' knowledge and understanding of the law and practice of consent in the post-Montgomery world.

Design

Cross-sectional online survey. Descriptive statistical analysis of midwives' survey responses.

Settings

Social media: Instagram, Facebook and Twitter. Survey distribution was via the UCL Opinio survey platform.

Participants

A total of 402 midwives, surveyed over a four month period between 2nd March and 2nd July 2021.

Measurements

Knowledge of legal consent, 'sureness' of meeting current legal requirements and competence to gain consent.

Findings

91% of participants acknowledged correctly that consent must be voluntary. 91% reported that women must be informed of all the risks associated with their care, although 26% reported that women should be informed of some of the risks associated with their care. Most participants were 'sure' that their discussions of consent meet current legal requirements (91%). 21% rated their competence to gain consent as 'excellent', 71% rated themselves as 'very good', whilst 1% rated their competence as 'poor'. Deficiencies in fundamental knowledge of consent were noted in some participants rating themselves highest in 'sureness' of meeting legal requirements and competence to consent.

Key conclusions

Fundamental gaps in midwives' knowledge of legal consent were identified. Participants demonstrated uncertainty regarding the extent of risk disclosure and discussion of alternative care options. Participants generally rated themselves highly in their consenting practices, despite lacking in basic knowledge of legal consent, revealing a discrepancy between midwives' self-perceptions and their actual knowledge.

Implications for practice

The overconfidence displayed by some participants is concerning for clinical midwifery practice. Professional education and guidance for midwives on legal consent in keeping with Montgomery is urgently required to ensure that midwives are legally compliant in their consenting practices.

The Role of Informed Consent as Legal Protection for Doctors in Conducting Medical Procedures

Dian Fitriana

Sinergi International Journal of Law, 31 November 2023

Abstract

The field of Health Law recognizes Therapeutic transactions as an agreement between a doctor and a patient, granting authority to the doctor to provide healthcare services to the patient based on their expertise and skills. Therapeutic transactions take the form of informed consent or approval of medical procedures before they are carried out. Informed consent involves the doctor explaining to the patient the condition of their illness and the medical procedures intended to address it, in the doctor's efforts to achieve recovery. Research findings indicate that informed consent plays a crucial role in the relationship between doctors and patients, serving as written evidence of the agreement between the doctor and the patient before medical procedures are undertaken. Informed consent can serve as the basis for proving whether a patient accepts or refuses a medical procedure, providing protection to the doctor. Legal protection for doctors is obtained as long as they carry out procedures in accordance with professional standards and operational procedures. For doctors, informed consent provides a sense of security when performing medical procedures on patients and can be used as a means of self-defense against potential claims or lawsuits from patients or their families if the medical procedure results in unintended consequences. Legal measures that doctors can take in the event of an undesired outcome related to medical procedures include attempting mediation with the patient first. If mediation fails or lacks good faith, the resolution may proceed through the legal system.

Editor's note: The Sinergi International Journal of Law is an Indonesian publication by Yayasan Sinergi Kawula Muda.

Informed Consent and Related Civil Liability in Chinese Law: Focusing on Article 1219 of the Chinese Civil Code

Bai Yuanyuan

International Law Review, November 2023

Abstract

As an important guideline in Chinese medical legal system and a basic professional norm in the clinical practice, the patient informed consent is critical for enhancement of the level of Chinese medical civilization and establishment of a harmonious doctor-patient relationship. Thus, there are some revisions on the provision about the patient informed consent in the new Chinese civil code issued in 2019. In this paper the background, content and impact on medical and judicial practice of these revisions of the provisions are addressed. Article 1219 of the Chinese Civil Code about the informed consent basically follows the legal structure of Article 55 in original Chinese Tort Liability. The modifications and improvement have been made on the medical disclosure duty in three aspects: raising the standard of inform duty, enrichment of the forms of patient consent and the supplement of legal basis for "substituted consent". The modifications of provisions about informed consent in the CCC reflect the improvement of the legislator's understanding on patient informed consent, and are also the inevitable results of the requirements of patient informed consent in practice. Moreover, this paper analyzes the civil liability system related to informed consent. In addition, some problems in judicial practice, for example, the inconsistency of the judgment standards of the duty of medical staff to inform, the unclear definition of damage on the patients, and the incomplete analysis of causal connection, have been pointed out. This paper also discusses the special rule about burden of proof in the informed consent claim, and examines why judges tend to heavily rely on medical expertise during the trial of such cases. Finally, the causes of the above problems as well as the corresponding solutions are analyzed.

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MEDICAL/SURGICAL

Patients' Information before invasive coronary procedures, when signing a written consent is challenging!

R. Kallel, O. Haddar, Y. Mallek, W. Abbes, H. Denguir, H. Barhoumi, H. Ben Ahmed
Archives of Cardiovascular Diseases, January 2024

Abstract

Introduction

Despite the progress in Invasive coronary procedures, patients' anxiety is still of concern. This anxiety may compromise adherence to the exam and the signature of the written consent. This latter is a relatively emergent culture to the Tunisian patient. We noticed a discordance in patients attitude expressing oral consent and reticent to sign a written one.

Objective

We investigated the role of standardized oral information in reducing anxiety of patients before invasive coronary procedures, improving knowledge and signing written consent rate.

Method

We conducted an experimental randomized, prospective study including patients scheduled for coronary artery procedures over 4 weeks. The intervention consisted in a standardized oral information. We compared the level of anxiety, the level of knowledge and the rate of written consent's signature, before and after the intervention. Information was conducted by either a doctor or a nurse according to coin tossing randomization. Anxiety was measured with Visual analogical scale (VAS), and the State Anxiety Inventory (STAI-S). Knowledge was assessed via 10 yes or No questions about coronary artery procedure (utility, access route, X rays, Contrast solution injection, stent implantation, possible outcomes). Were excluded, patients with emergent procedures and patients that refused to participate.

Results

We included 39 patients, males in 89.7% of cases, mean age was 64.5 ± 7.8 ans. Clinical presentation was a stabilized acute coronary artery syndrome in 92.3% of cases. Patients were illiterates in 23.1%, with low instructive level in 46.2% of cases. In their history, patients were asked to sign a written consent in only 2.6% of cases. Level of anxiety evaluated via VAS was significantly improved (2.91/10 before, 2.47/10 after, $p = 0.041$). there was no significant difference according to STAI-S score (44.44 before, 44.85 after, $p = 0.39$). Level of information get better (2.94/10 before, 7.71/10 after, $p < 0.0001$). The rate of written consent 'signature improved significantly from 41% to 76% ($p < 0.004$). There was no difference between nurse and doctor in proceeding to oral information and asking for signing the written consent (73.9% with nurse versus 86.6% with doctor, $p = 0.44$)

Conclusion

Oral standardized information helped to improve level of knowledge of patients ongoing non emergent invasive coronary procedures, to reduce anxiety and to get a better adherence to exam attested by the signature of the written consent. Other types of information, especially with audio-visual support, may be more efficient and need to be tested.

Parturients feel capable of giving informed consent for epidural analgesia: A qualitative and quantitative analysis

Oliver Bastian Christoffersen, Ann Merete Møller, Laerke Vinberg Moestrup, Kim Wildgaard
Scandinavian Society of Anaesthesiology and Intensive Care Medicine, 27 December 2023

Abstract
Introduction
The patient's right to autonomy confirmed by informed consent is a cornerstone in modern medicine. Epidural analgesia is increasingly popular in obstetric analgesia, but physicians disagree whether labour pain impairs parturient decision-making. We investigated the fraction of parturients feeling capable of giving informed consent including their knowledge of risks.
Methods
Bedside survey postpartum women at the Herlev Hospital, Denmark. The inclusion criteria were recipient of epidural analgesia during labour. A power calculation based on the recognition of genuine and false side effects required the inclusion of 50 participants.
Results
Forty out of fifty (80%) of the participants felt they could make a judicious consent during labour and 46 out of 50 (92%) felt they knew enough about epidural analgesia to give consent to the procedure again if necessary. Participants spontaneously reported a median of two risks associated with epidural analgesia. Additionally, when prompted with a cued list of true and false risks from epidural analgesia, the participants reported on average 5.1 genuine risks compared with 0.4 made-up risks. The difference (4.7) suggests the included women could discern genuine risks from made-up risks.
Discussion
The majority of participants reported the capacity to give informed consent. Our quantitative results show the participants could clearly distinguish genuine risks of epidural labour analgesia from made-up risks. Our qualitative data likewise suggest that participants understood the information and consequently their informed consent was genuine. Accordingly, parturients are able to give informed consent. This is supported by parturients' ability to identify risks from epidural labour analgesia.

Should Obtaining Informed Consent Be Considered an Entrustable Professional Activity? Insights From Whether and How Attendings Entrust Surgical Trainees

Research Report
Erin M. White, Andrew C. Esposito, Peter S. Yoo
Academic Medicine, 19 December 2023
Abstract
Purpose
Because residents are frequently delegated the task of obtaining consent early in their training, the American Association of Medical Colleges describes “obtaining informed consent” as a core entrustable professional activity (EPA) for medical school graduates. However, prior studies demonstrated that residents frequently perform this task without receiving formal instruction or assessment of competency. This study sought to understand how attending physicians decide to delegate obtaining informed consent for surgical procedures to trainees.
Method
The authors conducted a survey of attending surgeons at a university-based health care system of 6 affiliated teaching hospitals (October–December 2020) to collect data about current entrustment practices and attendings’ knowledge, experience, and attitudes surrounding the informed consent process. Summary statistics and bivariate analyses were applied.
Results
Eighty-five attending surgeons participated (response rate, 49.4%) from diverse specialties, practice types, and years in practice. Fifty-eight of 85 (68.2%) stated they “never” granted responsibility for the consent conversation to a trainee and 74/81 (91.4%) reported they typically repeated their own consent conversation whenever a trainee already obtained consent. The most common reasons they retained responsibility for consent were ethical duty (69/82, 84.1%) and the patient relationship (65/82, 79.3%), while less than half (40/82, 48.8%) described concerns about trainee competency. Reflecting on hypothetical clinical scenarios,

increased resident competency did not correspond with increased entrustment (P = 0.27 – 0.62). Nearly all respondents (83/85, 97.7%) believed residents should receive formal training, however, only 41/85 (48.2%) felt additional training and assessment of residents might change their current entrustment practices.
Conclusions
Attendings view informed consent as an ethical and professional obligation that typically cannot be entrusted to trainees. This practice is discordant with previous literature studying residents' perspectives. Furthermore, resident competency does not play a predominant role in this decision, calling into question whether informed consent can be considered an EPA.

Informed Written Consent for Emergency and Elective General Surgery at a Model 4 Hospital: A Closed-Loop Audit

Ke En Oh, Nikhil Vasandani, Afiq Anwar, Babak Meshkat
Cureus, 27 November 2023; 15(11)
Abstract
Introduction
The objective of this investigation was to conduct an audit of the consent form standards signed by patients before elective or emergency general surgery at our institution. The investigation involved a comparison of these standards with those outlined in the "HSE National Consent Policy 2022" established by the Health Service Executive (HSE) and the Royal College of Surgeons in Ireland (RCSI). In the event of discrepancies, we intended to complete the audit loop by educating general surgeons on the essential standards for obtaining written consent in both elective and emergency general surgical procedures.
Methods
To assess the quality of patient consent, a pre-interventional phase was conducted over one week. Information was gathered exclusively through electronic medical record systems. Subsequent to the data analysis, an in-person educational session was conducted to enlighten non-consultant hospital doctors (NCHDs) in surgery about the significance of informed written consent and the criteria for lawful consent according to local guidelines established by the HSE and the RCSI. Three months following the intervention, a follow-up cycle was carried out to evaluate whether there were any improvements in the standards of consent.
Results
In the initial phase, prior to intervention, a total of 95 consent forms were collected. The patient's name, date of birth (DOB), and hospital board number (BN) were accurately recorded in all consent forms. However, only 66% (n=63) were accurately documented without the use of abbreviations or acronyms. Following the intervention, 145 consent forms were gathered. All appropriately indicated the patient's name, DOB, and BN. However, 84% (n=122) of consent forms were correctly labeled without the use of abbreviations or acronyms (p=0.0017).
Conclusion
This closed-loop review illustrates that the quality of consent can be notably enhanced through a straightforward educational intervention led by NCHDs in general surgery. Such interventions can be instructive, leading to improved consent form documentation. This, in turn, enhances patient safety and helps prevent potential medico-legal repercussions for both healthcare providers and institutions.

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GENERAL/OTHER

Foundations of Preemptive Compassion: A Behavioral Concept Analysis of Compulsion, Consent, and Assent

Anna M. Linnehan, Awab Abdel-Jalil, Sheila Klick, Jonathan Amey, Richele Yeich, Kyle Hetzel

Behavior Analysis in Practice, 15 December 2023

Abstract

The recent changes to the Behavior Analysis Certification Board *Ethics Code for Behavior Analysts* along with the calls to action for compassionate care have highlighted the need for a reevaluation of behavior research and clinical programs. We propose a behavior analytic definition of compassion where the relieving or prevention of distress is the reinforcer for the professional. One way of minimizing distress may be to require that assent be provided by a participant in an intervention. The definition of assent typically includes reference to willingness to participate in an intervention or activity. We provide a framework that goes beyond simple willingness to participate and distinguishes between apparent/implicit coercion and genuine assent by considering the alternatives described as degrees of freedom available to the participant. We distinguish between compulsion/explicit coercion, consent, and assent. Additionally, we will differentiate genuine consent and assent from apparent consent and assent in the design of compassionate behavioral programs.

> *Editor's Note: [Excerpts from Ethics Code]*
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> 2.11 Obtaining Informed Consent
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> Behavior analysts are responsible for knowing about and complying with all conditions under which they are required to obtain informed consent from clients, stakeholders, and research participants (e.g., before initial implementation of assessments or behavior-change interventions, when making substantial changes to interventions, when exchanging or releasing confidential information or records). They are responsible for explaining, obtaining, reobtaining, and documenting required informed consent. They are responsible for obtaining assent from clients when applicable
>
> 6.04 Informed Consent in Research (see 1.04, 2.08, 2.11)
>
> Behavior analysts are responsible for obtaining informed consent (and assent when relevant) from potential research participants under the conditions required by the research review committee. When behavior analysts become aware that data obtained from past or current clients, stakeholders, supervisees, and/or trainees during typical service delivery might be disseminated to the scientific community, they obtain informed consent for use of the data before dissemination, specify that services will not be impacted by providing or withholding consent, and make available the right to withdraw consent at any time without penalty.

Identifying facilitators of and barriers to the adoption of dynamic consent in digital health ecosystems: a scoping review

Research

Ah Ra Lee, Dongjun Koo, Il Kon Kim, Eunjoo Lee, Hyun Ho Kim, Sooyoung Yoo, Jeong-Hyun Kim, Eun Kyung Choi, Ho-Young Lee

BMC Medical Ethics, 1 December 2023; 24(107)

Open Access

Abstract

Background

Conventional consent practices face ethical challenges in continuously evolving digital health environments due to their static, one-time nature. Dynamic consent offers a promising solution, providing adaptability and flexibility to address these ethical concerns. However, due to the immaturity of the concept and accompanying technology, dynamic consent has not yet been widely used in practice. This study aims to identify the facilitators of and barriers to adopting dynamic consent in real-world scenarios.

Methods

This scoping review, conducted in December 2022, adhered to the PRISMA Extension for Scoping Reviews guidelines, focusing on dynamic consent within the health domain. A comprehensive search across Web of Science, PubMed, and Scopus yielded 22 selected articles based on predefined inclusion and exclusion criteria.

Results

The facilitators for the adoption of dynamic consent in digital health ecosystems were the provision of multiple consent modalities, personalized alternatives, continuous communication, and the dissemination of up-to-date information. Nevertheless, several barriers, such as consent fatigue, the digital divide, complexities in system implementation, and privacy and security concerns, needed to be addressed. This study also investigated current technological advancements and suggested considerations for further research aimed at resolving the remaining challenges surrounding dynamic consent.

Conclusions

Dynamic consent emerges as an ethically advantageous method for digital health ecosystems, driven by its adaptability and support for continuous, two-way communication between data subjects and consumers. Ethical implementation in real-world settings requires the development of a robust technical framework capable of accommodating the diverse needs of stakeholders, thereby ensuring ethical integrity and data privacy in the evolving digital health landscape.

Study of Informed Consent Rules in Face Recognition

Linxi Yang

Journal of Humanities, Arts and Social Science, 27 November 2023

Abstract

The advent of the era of big data is an irreversible trend. With the development of network technology, personal information has become closely integrated with various social fields, encompassing technologies for information capture, transmission, and storage. Daily applications, access to places, and face recognition technology play an indispensable role in various aspects. However, while enjoying the convenience brought by information technology, the protection of personal information also faces inevitable challenges. Informed consent rules are studied to address the issues that arise in the information society, such as the lack of sufficient information for individuals, unreasonable consent practices, and unclear handling of personal information dynamics. In order to address these shortcomings, the notification method in informed consent rules needs to be improved to effectively protect personal information. This will allow for better protection of personal information security while still utilizing the convenience provided by facial recognition technology in a reasonable manner.

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UPCOMING 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].

Master Protocols for Drug and Biological Product Development; Draft Guidance for Industry; Availability

Food and Drug Administration, HHS.

Scheduled Pub. Date: 12/22/2023 FR Document: 2023-28210 PDF: https://downloads.regulations.gov/FDA-2023-D-5259-0002/attachment_1.pdf 8 Pages (109 KB)
Submit either electronic or written comments on the draft guidance by **February 20, 2024**
Summary
The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Master Protocols for Drug and Biological Product Development." The draft guidance addresses the design and analysis of trials conducted under a master protocol as well as the submission of documentation to support regulatory review. The primary focus is on randomized umbrella and platform trials that are intended to contribute to a demonstration of safety and substantial evidence of effectiveness. The considerations in this guidance apply to a range of therapeutic areas. The draft guidance is intended to clarify the Agency's thinking on the use of master protocols in drug and biological product development, which was previously addressed in FDA's guidance entitled "COVID–19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention." FDA is also announcing the withdrawal of the guidance entitled "COVID–19: Master Protocols Evaluating Drugs and Biological Products for Treatment or Prevention.
Excerpt
C. Informed Consent
The informed consent process should cover all treatment arms in the trial to which the subject could be randomized.[13,14] In a platform trial allowing drugs to enter and leave the trial over time, the consent form should be modified over time to reflect the drugs currently under evaluation…
The informed consent process should occur prior to a subject's randomization and avoid substudy-specific consent. Consent that occurs after subjects have been randomized to one of the substudies may result in subjects with different prognostic characteristics across substudies, raising concern about the comparability of each drug group with the shared control group (comprised of control subjects from different substudies). To illustrate the concern, consider a master protocol with two drugs (drug A and drug B) in which the subject consents to screening and randomization to a substudy as part of the master protocol, with a substudy-specific informed consent process to occur after randomization to that substudy; after the substudy-specific consent, the subject is then randomized to the drug or its matched control. With this process, comparing drug A against the shared control arm (including subjects who received either control for drug A or control for drug B) may result in noncomparable groups if subjects who would consent to participating in the drug A substudy differ from subjects who would consent to participating in the drug B substudy.

> 13 Some consent processes allow a subject to be randomized in the trial even if the subject only consents to a subset of the drugs under evaluation; under such a process, subjects should not have the potential to be randomized to drugs for which they do not consent.
> 14 See the guidance for IRBs, Clinical Investigators, and Sponsors Informed Consent (August 2023).

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NEW REGULATORY GUIDANCE REFERENCING CONSENT

FDA: Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations

FDA - **Final rule.**
Summary
The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its regulations to implement a provision of the 21st Century Cures Act (Cures Act). This final rule allows an exception from the requirement to obtain informed consent when a clinical investigation poses no more than minimal risk to the

human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. The final rule permits an institutional review board (IRB) to waive or alter certain informed consent elements or to waive the requirement to obtain informed consent, under limited conditions, for certain FDA-regulated minimal risk clinical investigations.

…

B. Summary of the Major Provisions of the Final Rule

The final rule amends FDA's regulations to allow IRBs responsible for the review, approval, and continuing review of clinical investigations to approve an informed consent procedure that does not include or that alters certain informed consent elements, or to waive the requirement to obtain informed consent, for certain minimal risk clinical investigations. For an IRB to approve a waiver or alteration of informed consent requirements for minimal risk clinical investigations, the rule requires an IRB to find and document five criteria that are consistent with the revised rule entitled "Federal Policy for the Protection of Human Subjects" (the revised Common Rule (January 19, 2017)). FDA believes the amendment provides appropriate safeguards to protect the rights, safety, and welfare of the human subjects participating in such clinical investigations. We are also making conforming amendments to FDA's regulations.

Digital Health Technologies for Remote Data Acquisition in Clinical Investigations; Guidance for Industry, Investigators, and Other Stakeholders; Availability

Food and Drug Administration, HHS.

Final guidance. Scheduled Pub. Date: 12/22/2023 FR Document: 2023-28262 PDF: https://downloads.regulations.gov/FDA-2021-D-1128-0066/attachment_1.pdf 8 Pages (112 KB)

Summary

The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry, investigators, and other stakeholders entitled "Digital Health Technologies for Remote Data Acquisition in Clinical Investigations." This guidance provides recommendations on the use of digital health technologies (DHTs) to acquire data remotely from participants in clinical investigations that evaluate medical products. DHTs for remote data acquisition in clinical investigations can include hardware and/or software to perform one or more functions. Use of DHTs as recommended in this guidance may improve the efficiency of clinical trials for sponsors, investigators, and other stakeholders and may increase the opportunities for individuals to participate in research and make participation more convenient. This guidance finalizes the draft guidance of the same title issued on December 23, 2021.

Consent

F. Risk Considerations When Using Digital Health Technologies

p.19 …3. Informed Consent

FDA regulations at 21 CFR part 50 set forth the requirements for obtaining the informed consent of participants[59] in clinical investigations. DHTs can be used to obtain electronic informed consent in a clinical investigation.[60]

Some considerations for what information to include in the informed consent process regarding the DHT being used in a clinical investigation include but are not limited to the following:

- The informed consent process must describe any reasonably foreseeable risks or discomforts to participants (see sections IV.F.1 and IV.F.2 of this guidance), including reasonably foreseeable risks or discomforts related to the use of the DHT in the clinical investigation.[61] Information regarding what may be done to mitigate serious risks, and risks and discomforts more likely to occur, should also be considered for inclusion.
- When appropriate, a statement must be included indicating that use of the DHT during the clinical investigation may involve risks to the participant (or to the embryo or fetus if the participant is or may become pregnant) which are currently unforeseeable.[62]

- The informed consent process should explain the type of information that will be collected by the DHT and how that information will be used and monitored. When relevant, participants should be informed of what action to take in case of any concerning sign, symptom, or abnormal clinical event (e.g., hypoglycemia or abnormal cardiac rhythm) detected by a DHT, such as seeking emergency medical attention, if appropriate.
- The informed consent process should specify who may have access to data collected through the DHT during or after the clinical investigation (e.g., sponsors, investigators, participants, DHT manufacturers, other specified third parties) and during what time frame.[63]
- An explanation of measures to protect participant privacy and data, and limitations to those measures, when DHTs are used should be included.
- If participants may incur additional expense because they are taking part in the clinical investigation, the consent process must explain the added costs,[64] which could include costs for the participants that may result from using the DHT during the clinical investigation (e.g., data use charges).
- DHTs or other technologies may be covered by end-user license agreements or terms of service as a condition of use, which may, among other things, allow DHT or other technology manufacturers and other parties to gain access to personal information and data collected by the DHT or other technology. When applicable, sponsors and investigators should ensure that the informed consent process explains to participants that their data may be shared outside of the clinical investigation, according to the end-user license agreement or terms of service. End-user license agreements and terms of service typically are lengthy and use complex terminology. Sponsors and investigators proposing use of DHTs for data collection should understand how such agreements or terms of service may affect trial participants and address this information when developing informed consent documents.[65]

61 See 21 CFR 50.25(a)(2).
62 See 21 CFR 50.25(b)(1).
63 In addition, the informed consent process must note the possibility that FDA will inspect records identifying the participants (21 CFR 50.25(a)(5)).
64 21 CFR 50.25(b)(3).
65 For further information, see the Secretary's Advisory Committee on Human Research Protections webpage "Attachment B-Clarifying Requirements in Digital Health Technologies Research," available athttps://www.hhs.gov/ohrp/sachrp-committee/recommendations/april-7-2020-attachment-b/index.html.
66 See 21 CFR 312.57,312.58,312.62, and 312.68.
67 See 21 CFR 812.2(b)(1)(v)and(vi), 812.140, 812.145, and 812.150.
68 See FDA Study Data Standards Resources, available athttps://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources,and the Data Standards Catalog, available athttps://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-catalog.

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SYMPOSIA/CONFERENCES

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

No new symposia/conferences identified.

# # # #

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