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

Center for Informed Consent Integrity

Informed Consent: A Monthly Review

August 2022

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.

Each month we monitor *Google Scholar* for the search terms "consent", "informed consent", and "assent" in title and available text. After careful consideration, a selection of these results appear in the digest. We also monitor other research analysis and guidance beyond the journal literature globally. 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:

Editor
Paige Fitzsimmons, MA
Associate Director, Center for Informed Consent Integrity
GE2P2 Global Foundation
paige.fitzsimmons@ge2p2global.org

We organize content in each edition using subject categories to help readers navigate. We expect that these categories will evolve over time. Active subject areas in this edition include:

Subject Area	Page
COVID-19	2
BIOMEDICAL RESEARCH	4
SOCIAL SCIENCE RESEARCH	7
BIOBANKING	8
CAPACITY TO CONSENT	9
TECHNOLOGY/OTHER MEDIATION	10
RIGHTS/LEGAL/LEGISLATIVE	11
FREE PRIOR INFORMED CONSENT (FPIC)	13
CULTURAL/COUNTRY CONTEXT	13
MEDICAL/SURGICAL	16
GENERAL/OTHER	18

No new content was identified for the following established categories:

COMPASSIONATE USE/EXPANDED ACCESS
GENOMIC MEDICINE/GENE EDITING
HEALTH DATA
HUMANITARIAN CONTEXT

Please note that we maintain a glossary, an inventory of tools for assessment, as well as standards and guidance documents on our website.

COVID-19

The patient suffering from acute respiratory failure COVID-19 related who refuses medical treatment: an emblematic case

Francesca Maghin, Massimo Salvetti, Maria Lorenza Muiesan, Adelaide Conti

Internal and Emergency Medicine, 2 July 2022

Open Access

Abstract

Respiratory failure related to COVID-19 may evolve into acute respiratory distress syndrome, which may require invasive treatment. Through the analysis of a concrete clinical case, we want to clarify how to manage patients suffering from serious acute pathologies, which require timely intervention, even invasive, but refuse medical treatment. The Italian law 219/2017 states strongly the freedom of the patient to choose, independently whether to start or stop at any time any type of medical treatment through their informed consent. The law, of course, addresses in several parts the problem of the refusal of the subject to certain choices. The law also provides that if the patient refuses therapies or interventions, putting his life at risk, the doctors need to engage in further communication with the support of other professionals, informing the patient of the consequences, promoting every support action, and involving family members. Judgment on the level of impaired capacity, which makes a patient incompetent to make therapeutic decisions, should ideally reflect the balance between respecting patient autonomy and protecting the patient from the consequences of a wrong decision. For the physicians, it is a matter of balancing the need to save the life of the person, or at least to avoid the establishment of permanent damage, with the subject itself expressly stated, including an explicit refusal to carry out maneuvers or therapies or interventions when it is in danger of life, even if such treatments could save it.

Developing and Implementing Electronic Consent Procedures in Response to Covid-19 Restrictions

Julie R Bromberg, Evelyn Nimaja, Andrew W Kiragu, Karla A Lawson, Lois Lee, Isam W Nasr, Charles Pruitt, Stephanie M Ruest, Michael J Mello

Ethics and Human Research, July 2022; 44(4) pp 39-44

Abstract

The Covid-19 pandemic resulted in unprecedented restrictions on many public, private, and workplace activities throughout the United States and elsewhere. When restrictions were imposed, we were conducting a type III hybrid effectiveness-implementation trial in 10 pediatric trauma centers. In response to several pandemic-based restrictions, we had to develop procedures for engaging with potential research participants while limiting nonclinical, in-person interactions. This manuscript describes the procedures and challenges of obtaining electronic informed consent and assent in a multisite trauma center-based research study. We developed, tested, and trained staff to implement three options for obtaining informed consent. Twenty-five participants were enrolled in the effectiveness-implementation multisite trial during the first six months of utilization of the consent options, with eleven of these individuals enrolled using hybrid or electronic consent procedures. The challenges we identified involving electronic consent procedures included confusion over who would complete the electronic consent process and difficulties reconnecting with families. Lessons learned can strengthen electronic consent and assent procedures for future studies. More research is needed to further strengthen this process and increase its utilization.

A mother's perspective of consent for maternal and neonatal COVID-19 testing: can we do more?

Research

Natalie Anne East, Sunitha Ramaiah, Kimberley Morris, Sangeeta Pathak

British Journal of Midwifery, 28 June 2022; 30(7)

Abstract

Background

There is ongoing research on the effects of COVID-19 on pregnancy and whether vertical viral transmission occurs.

Aims

This study aimed to determine maternal opinions of COVID-19 testing for pregnant women and newborns in order to influence future clinical practice while advancing global knowledge of the impact of testing on patient experiences.

Methods

This service evaluation assessed the opinions of 292 pregnant women who were tested for COVID-19 along with their newborn babies using nasopharyngeal swabs and the SARS-CoV-2 reverse transcription polymerase chain reaction test between 28 April and 21 May 2020.

Results

Many women felt their own (60%) and their baby's (61%) swab was compulsory and did not feel sufficiently informed about the risks and benefits for themselves (43%) or their baby (52%) being tested. Some women did not understand the implications of a positive test for themselves (43%) or their baby (42%). Most participants reported they would agree to themselves (97%) and their baby (86%) being tested in future pregnancies.

Conclusion

Communication to pregnant women regarding the COVID-19 swabbing process is critical and requires improvement. This service evaluation highlighted where women felt under-informed. These areas should be covered in more detail for consenting women for COVID-19 testing in future.

Participants' informed consent in adaptive, platform drug trials in hospitalized COVID-19 patients: Not all approaches are ethically acceptable

Commentary

Rafael Dal-Ré, Arthur L Caplan, Teck Chuan Voo

European Journal of Internal Medicine, 27 June 2022

Open Access

Excerpt

…Obtaining participants' informed consent is one of the basic safeguards for ensuring ethically conducted clinical research. Investigators must provide potential participants all reasonable relevant trial information so that they can make an informed decision. How investigators seek participants' informed consent should be consistent with international ethical standards. First, informed consent must be obtained from patients with capacity. If a patient is incapable of consenting (e.g., intubated patient), the investigator must seek informed consent from their legal representative. During the pandemic, at the trial design stage, investigators of the four aforementioned ad-RCTs (Table 1) decided that deferred consent was an acceptable approach as they realized that many potential trial participants would be incapable of providing consent and having access to the patient's legal representative could be extremely difficult to obtain. Their decisions were backed by the research ethics committees involved in the review and approval of the ad-RCTs' protocols. Patients unable to consent were included in the trial and informed consent obtained once they were able to provide it (or when the legally authorized representative became available), rendering the consent deferred. However, deferred consent must fulfil several conditions to be ethically acceptable. Second, trial investigators should seek the

informed consent of potential participants before randomization, which ensures that all participants receive the same information on the trial procedures and available treatments in all study arms. This is applicable to any RCT, but it is even more relevant when it is likely that the legal representative of many participants will be involved. The participant's legal representative should decide considering to what extent study participation promotes the individual's clinical interests, and to this end should know all the therapies under assessment…

Consent for orthopaedic trauma surgery during the COVID-19 pandemic

Selmi H, Davies A, Walker J, Heaton T, Sabharwal S, Dani M, Fertleman M, Reilly P

BMJ Open Quality, 1 June 2022, 11(2)

Abstract

Introduction

The COVID-19 pandemic has brought a series of new challenges to the management of surgical patients. The consent process relies on a foundation of open and non-coerced discussion between clinician and patient, which includes all the potential risks of surgery. This must be updated to incorporate the additional risks of surgery during the pandemic including infection with the SARS-CoV-2 and increased risks of complications with the potential requirement for intensive care support.

Aim

The aim of this multi-cycle quality improvement project was to ensure all patients were fully informed of the risks of developing COVID-19 and the possible need for intensive care unit (ICU) support.

Methods

We investigated the quality of the consent process for patients undergoing surgery for trauma at our major trauma centre. Our baseline data collection included a review of all orthopaedic trauma consent forms over a 4-week period in March 2020. We subsequently undertook three further Plan-Do-Study-Act (PDSA) cycles over separate 4-week periods. First, in June 2020, after education measures and presentation of baseline data, second in July 2020 after further education and regular digital reminders were sent to staff, and third in September 2021 after the implementation of an electronic consent form.

Results

At baseline, only 2.6% of consent forms mentioned the risk of COVID-19 and none mentioned the risk of requiring ITU support. Through three PDSA cycles this increased to 97% of cases where consent forms displayed the additional risks of COVID-19 and the potential need for ITU admission.

Conclusion

Our quality improvement project improved the informed consent procedure at our trust. By incorporating these additional risks into the template of an electronic consent form, we hope to achieve sustained improvement in practice.

::::::
::::::

BIOMEDICAL RESEARCH

Keys to improving the informed consent process in research: Highlights of the i-CONSENT project

Editorial

Jaime Fons-Martinez, Cristina Ferrer-Albero, Javier Diez-Domingo

Health Expectations, 27 July 2022

Open Access

Excerpt

The ethical and legal governance of all aspects of informed consent in research is becoming increasingly extensive and complex. Instead of a single directive, informed consent is governed by a series of international

rules applied to biomedical research, clinical trials and biobanks, while various ethical guidelines for research have been published by different international bodies.

Informed consent is an essential part of any research involving humans, but the array of available guidelines can complicate the informed consent process for sponsors, researchers and participants. Sponsors, in particular, find it difficult to adapt the informed consent process to the characteristics of the participants. Moreover, because of the length and complexity of informed consents, some participants may misconstrue key points and agree to participate in a trial that they do not fully understand. In these cases, the decision on their participation is mainly based on discussions with the researcher, which lacks traceability…

Success rate of acquiring informed consent and barriers to participation in a randomized controlled trial of laparoscopic versus open surgery for non-curative stage IV colon cancer in Japan

Journal Article

Tomonori Akagi, Kosuke Suzuki, Yohei Kono, Shigeo Ninomiya, Tomotaka Shibata, Yoshitake Ueda, Hidefumi Shiroshita, Tsuyoshi Etoh, Akio Shiomi, Masaaki Ito, Jun Watanabe, Kohei Murata, Yasumitsu Hirano, Manabu Shimomura, Shunsuke Tsukamoto, Yukihide Kanemitsu, Masafumi Inomata

Japanese Journal of Clinical Oncology, 22 July 2022

Abstract

Background

Successful achievement of randomized controlled trials (RCTs) is dependent on the acquisition of informed consent (IC) from patients. The aim of this study was to prospectively calculate the proportion of participation in a surgical RCT and to identify the reasons for failed acquisition of IC.

Methods

A 50-insitution RCT was conducted to evaluate oncological outcomes of open and laparoscopic surgery for stage IV colon cancer (JCOG1107: UMIN-CTR 000000105). The success rate of obtaining IC was evaluated in eight periods between January 2013 and January 2021. In addition, reasons for failed acquisition of IC were identified from questionnaires.

Results

In total, 391 patients were informed of their eligibility for the trial, and 168 (42%) were randomly assigned to either the laparoscopic surgery group (n = 84) or open surgery group (n = 84). The success rate of IC acquisition ranged from 33 to 58% in three periods. The most common reasons for failed IC acquisition were the patients' preference for one approach of surgery based on recommendations from referring doctors and family members, and anxiety/unhappiness about randomization.

Conclusions

The success rate of acquiring IC from patients for an RCT of laparoscopic versus open surgery for stage IV colon cancer was lower than the expected rate planned in the protocol. To obtain the planned rate, investigators should make efforts to inform patients and their families about the medical contributions a surgical RCT can make and recognize that the period in equipoise may be limited.

Future informed consent research – a step in the wrong direction!

JM Clements, LJ Convie, SJ Kirk, M Clarke

British Journal of Surgery, 22 July 2022; 109(Suppl 4)

Open Access

Abstract

Introduction

Over 300 million invasive procedures occur globally every year, each requiring patient informed consent. No single outcome measure exists for measurement of the informed consent process. A core outcome set (COS)

for informed consent for therapy consisting of 9 outcomes has been developed to define what outcomes matter to key stakeholders in the informed consent process. We aimed to identify the frequency of uptake of the COS consent outcomes in future randomised control trials.

Methods

A systematic review of prospectively registered randomised control trial protocols was performed. The online trial registries World Health Organisation (WHO) International Clinical Trials Registry Platform (ICTRP) and the US National Library of Medicine ClinicalTrials.gov were searched. All studies assessing interventions designed to improve the informed consent process were considered.

Results

627 registered protocols were identified of which 22 met the inclusion criteria. Only two core outcomes were reported in any prospective interventional consent trial protocols. Patient satisfaction with the consent process and patient satisfaction with the amount of information were observed which employed unvalidated tools. Patient knowledge was the predominant primary outcome measure (n=20). Unvalidated measurement tools were used in all cases. Patient anxiety, decisional regret and decisional conflict were the only outcomes consistently measured using validated measurement tools.

Conclusion

The use of unvalidated outcome measurement tools in future consent trials are widespread. This review has highlighted the clear disconnect between chosen outcomes in future consent trial protocols and an established informed consent COS, limiting the potential value of outputs in future consent trials.

Take-home message

A clear disconnect exists between the outcome measures used in prospective consent randomised trials and an established core outcome set for informed consent for therapy.

When is it impractical to ask informed consent? A systematic review

Review Article

Sara JM Laurijssen, Rieke van der Graaf, Wouter B van Dijk, Ewoud Schuit, Rolf HH Groenwold, Diederick E Grobbee, Martine C de Vries

Clinical Trials, 1 July 2022

Abstract

Background

Informed consent is one of the cornerstones of biomedical research with human subjects. Research ethics committees may allow for a modification or a waiver of consent when the research has social value, involves minimal risk, and if consent is impractical to obtain. While the conditions of social value and minimal risk have received ample attention in research ethics literature, the impractical condition remains unclear. There seem to be different interpretations of the meaning of impractical within academic literature. To address this lack of clarity, we performed a systematic review on the interpretation of impractical.

Methods

First, we examined international research ethics guidelines on their usage and interpretation of impractical. Next, we used international ethical guidelines to identify synonyms of the term “impractical.” Accordingly, PubMed, Embase, and Web of Science were searched for articles that included “informed consent” and “impractical” or one of its synonyms.

Results

We found that there were only a few international ethics guidelines that described what could be considered impractical. Out of 2329 identified academic articles, 42 were included. Impractical was used to describe four different conditions: (1) obtaining informed consent becomes too demanding for researchers, (2) obtaining informed consent leads to invalid study outcomes, (3) obtaining informed consent harms the participant, and (4) obtaining informed consent is meaningless for the participant.

Conclusion

There are conditions that render conventional informed consent truly impractical, such as untraceable participants or harm for participants. At the same time, researchers have a moral responsibility to design an

infrastructure in which consent can be obtained, even if they face hardship in obtaining consent. In addition, researchers should seek to minimize harm inflicted upon participants when harm may occur as a result of the consent procedure. Invalidity of research due to consent issues should not be regarded as impractical but as a condition that limits the social value of research. Further research is essential for when a waiver of informed consent based on impractical is also reasonable.

Toward Meeting the Obligation of Respect for Persons in Pragmatic Clinical Trials

Morain SR, Kraft SA, Wilfond BS, Mcguire A, Dickert NW, Garland A, Sugarman J

The Hastings Center Report, 1 May 2022; 52(3) pp 9-17

Abstract

Research ethics oversight systems have traditionally emphasized the informed consent process as the primary means by which to demonstrate respect for prospective subjects. Yet how researchers can best fulfill the ethical obligations of respect for persons in pragmatic clinical trials (PCTs)-particularly those that may alter or waive informed consent-remains unknown. We propose eight dimensions of demonstrating respect in PCTs: (1) engaging patients and communities in research design and execution, (2) promoting transparency and open communication, (3) maximizing agency, (4) minimizing burdens and promoting accessibility, (5) protecting privacy and confidentiality, (6) valuing interpersonal interactions with clinicians and study team members, (7) providing compensation, and (8) maximizing social value. While what respect requires in the context of PCTs will vary based on the nature of the PCT in question, the breadth of these dimensions demonstrates that respect obligations extend beyond informed consent processes.

::::::
::::::

SOCIAL SCIENCE RESEARCH

When is public private? Tweets, privacy and consent in health research

Sabitra Kaphle, Rachel Kornhaber, Susan Hunt, Roger Watson, Michelle Cleary

Nurse Education in Practice, August 2022; 63

Introduction

Online social media platforms provide opportunities for the global community to share and express their views, opinions, reactions, and feelings openly. The use of social media for the purpose of information sharing surged during the COVID-19 pandemic due to mandated physical distancing requirements. This is a seemingly consensual catharsis at a time of heightened need for alternative social activity and critical information sharing. Communication on open social media platforms has created opportunities for researchers to access and analyse rich, publicly available data to study a range of topics and issues. The creation of this abundant public data has also led to fundamental methodological and ethical challenges for social science researchers. Namely, is the use of this public data for research a breach of privacy and confidentiality? Are social media users becoming involuntary research participants as their communications and personal information are mined and published on without participant insight and informed consent? In this discussion, we aim to highlight some of the critical methodological and ethical issues that researchers must consider while using Twitter as a data source to publish from.

Assessment of Social Trust in Relatives of Discharged Patients With Personal Consent and Other Relatives of Patients

Research Article

Hamid Reza Moretza Bagi, Zhila Khamnian, Forough Hatami, Samad Shams Vahdati, Reza Yazdani, Sama Rahnemayan

Journal of Patient Experience, 6 July 2022

Abstract

Lack of social trust in the physician–patient relationship will disrupt health. Since social trust has not been sufficiently studied in patients' companions, this study investigates and compares social trust and its dimensions in companions of patients discharged against medical advice with total patients' companions in the emergency room. In this cross-sectional descriptive-comparative study, 385 patients' companions were enrolled. This study was done by a questionnaire with five subscales: honesty, frankness, cooperative tendency, confidence, and trust. Data were analyzed using descriptive statistics and analytical statistics methods. In this study, there was no significant difference between the mean score of social trust between companions of patients discharged against medical advice (61.11 ± 9.01) and patients discharged after treatment (62.27 ± 6.97). There was a significant relationship between the mean score of the 2 groups only in the frankness domain (P-value = .001). The level of social trust in the patients' companions was moderate in both groups. Companions of discharged patients after completing the treatment process are more explicit than the companions of patients discharged against medical advice.

Co-creation with research participants to inform the design of electronic informed consent

Evelien De Sutter, David Geerts, Pascal Borry, Kristien Coteur, Dorien Bamps, Heleen Marynissen, Els Ampe, Els Geenens, Marleen Depré, Isabelle Huys

Digital Health, 6 June 2022; 8 pp 1–11

Open Access

Abstract

Objective

This study aimed to provide recommendations for a personalized electronic informed consent interface that is adapted to research participants' needs and could enable a longitudinal interaction between the participants and the research team.

Methods

The co-creation process consisted of three co-creation workshops, one focus group discussion, and four semi-structured interviews. In total, 24 participants, who had taken part in four disparate clinical studies in Belgium, were involved. Descriptive statistics and qualitative content analysis were applied to analyze the survey data and audio recordings.

Results

Varying perceptions on the type and amount of information described in an informed consent form were reported. Other findings were related to the structure and presentation of information, setting preferences for data sharing, and electronically signing new informed consent versions. Regarding the long-term interaction, most of the participants wanted to receive progress updates, including the results, of the study in which they had taken part. They proposed to receive a notification, preferably via email, in case new information is made available on the electronic informed consent interface.

Conclusions

To optimally support the design of an electronic informed consent interface, it is key to understand the research participants' needs. Study findings suggest that an electronic informed consent interface may be a promising technological application to interactively provide study-related information and to keep participants informed during and after the clinical study.

::::::
::::::

BIOBANKING

Perspectives from a Predominantly African American Community about Biobank Research and a Biobank Consent Form

Laura K Sedig, E Hill De Loney, Sarah B Bailey, Kayte Spector-Bagdady, Bianca Ghita, Lydia Koh Krienke, Raymond Hutchinson

Ethics and Human Research, July 2022; 44(4) pp 26-33

Abstract

Minority populations have been underrepresented in clinical trials, as well as in research biobanks that are created to conduct research with participants' biospecimens and related medical and research data. Biobank research raises issues about informed consent and privacy and the confidentiality of participants' personal data. Our study involved three focus groups of 10 adults each that were conducted in a medically underserved, predominantly African American community to elucidate questions and concerns regarding an institutional biobank. Transcripts from the discussion were qualitatively analyzed. Three main themes that arose from the focus groups included the importance of trust, the importance of the community in research, and suggestions to improve trust. The concerns identified in this study provide a starting point for future research to help research institutions become more trustworthy to the communities they serve.

::::::
::::::

CAPACITY TO CONSENT

(Re)Conceptualising 'good' proxy decision-making for research: the implications for proxy consent decision quality

Victoria Shepherd

BMC Medical Ethics, 18 July 2022; 23(75)

Open Access

Abstract

People who are unable to make decisions about participating in research rely on proxies to make a decision based on their wishes and preferences. However, patients rarely discuss their preferences about research and proxies find it challenging to determine what their wishes would be. While the process of informed consent has traditionally been the focus of research to improve consent decisions, the more conceptually complex area of what constitutes 'good' proxy decision-making for research has remained unexplored. Interventions are needed to improve and support proxy decision-making for research but are hampered by a lack of understanding about what constitutes decision quality in this context. A global increase in conditions associated with cognitive impairment such as dementia has led to an urgent need for more research into these conditions. The COVID-19 pandemic and subsequent necessity to conduct research with large numbers of critically ill patients has made this need even more pressing. Much of the empirical research centres on the desire to improve decision accuracy, despite growing evidence that authenticity is more reflective of the aim of proxy decisions and concerns about the methodological flaws in authenticity-focused studies. Such studies also fail to take account of the impact of decision-making on proxies, or the considerable body of research on improving the quality of healthcare decisions. This paper reports a concept synthesis of the literature that was conducted to develop the first conceptualisation of 'good' proxy decisions about research participation. Elements of decision quality were identified across three stages of decision-making: proxy preparedness for decision-making which includes knowledge and understanding, and values clarification and preference elicitation; the role of uncertainty, decisional conflict, satisfaction and regret in the decision-making process; and preference linked outcomes and their effect. This conceptualisation provides an essential first step towards the future development of interventions to enhance the quality of proxy decision-making and ensure proxy decisions represent patients' values and preferences.

::::::
::::::

TECHNOLOGY/OTHER MEDIATION

Autonomous patient consent for anaesthesia without preoperative consultation: a qualitative feasibility study including low-risk procedures

Original Research Article

MarijeMarsman, Wisse M.F. van den Beuken, Wilton A. van Klei, Teus H.Kappen

BJA Open, September 2022

Abstract

Background

Informed consent for anaesthesia is mandatory and requires provision of information and subsequent consent during consultation between anaesthesiologist and patient. Although information can be provided in an electronic format, it is unknown whether this a valid substitute for a consultation. We explored whether provision of digital information is equivalent to oral consultation and whether it enables patients to give electronic informed consent (e-consent) for anaesthesia.

Methods

Qualitative feasibility study using semi-structured interviews in 20 low-risk adults scheduled for minor surgery under general anaesthesia or procedural sedation at a university hospital. Data were analysed using a thematic content analysis approach. During the interviews, patients followed an application that provides information and subsequent e-consenting.

Results

The mean age was 50 yr and patients had good digital skills. Fifteen patients (75%) had previous experience of anaesthesia. The digital application provided enough information for all patients, but eight (40%) preferred consultation with an anaesthesiologist, mainly for personal contact. Patients had different information needs, with previous experiences leading to lower information needs. Nineteen patients had sufficient information to consent autonomously. Most patients considered separate anaesthesia consent superfluous to the surgical consent.

Conclusion

The digital application provided sufficient information and patients valued the information offered and the advantage of processing information at their own pace. This information made patients feel empowered to autonomously consent to anaesthesia without consultation. Remarkably, consent for anaesthesia was considered unimportant, because patients felt they had 'no choice' if they wanted to undergo surgery.

Animation Supported Consent Before Elective Laparoscopic Cholecystectomy

Original Scientific Report

Emre Doganay, David S. Wald, Sam Parker & Frances Hughes

World Journal of Surgery, 28 June 2022

Open Access

Abstract

Background

Patient understanding of surgical procedures is often incomplete at the time they are performed, invalidating consent, and exposing healthcare providers to complaints and claims of failure to inform. Remote consultations, language barriers and patient factors can hinder an effective consent pathway. New approaches are needed to support communication and shared decision-making.

Methods

Multi-language digital animations explaining laparoscopic cholecystectomy were introduced at The Royal London Hospital for patients who attended for elective surgery (www.explainmyprocedure.com/lapchole). Patients completed questionnaires on the day of their procedure both before and after introduction of the animations. We assessed patient-reported understanding of the procedure, its intended benefits, the possible risks, and alternatives to treatment in 72 consecutive patients, 37 before (no animation group) and after 35 after introducing the animations into the consent pathway (animation group). Patient understanding in the two groups was compared.

Results
The two groups were well matched in respect of age, sex and whether English was their first spoken language. The proportions of patients who reported they completely understood the procedure, its benefits, risks, and alternatives in the no animation group were 54, 57, 38 and 24% and in the animation group, 91, 91, 74 and 77%, respectively; $p < 0.01$ for each comparison.
Conclusion
The integration of multi-language laparoscopic cholecystectomy video animations into the patient consent pathway was associated with substantial improvement in reported understanding of the procedure, benefits, risks, and alternatives to treatment. This approach can be applied across all surgical disciplines in a standardised manner in an era of accelerated elective work and remote consultations.

Enhancing informed consent through use of patient-specific 3D printing in skull base neurosurgery: 3D printing in skull base neurosurgery

Shan Yasin Mian, Shubash Jayasangaran, Aishah Qureshi, Mark Hughes
Journal of Neurological Surgery, 27 June 2022
Abstract
Objectives
Informed consent is fundamental to good practise. We hypothesised that a personalised 3D printed model of skull base pathology would enhance informed consent and reduce patient anxiety. Design Imaging (DICOM) files were 3D printed. After a standard pre-surgery consent clinic, patients completed part-1 of a structured questionnaire. They then interacted with their personalised 3D printed model. They then completed part-2 seeking to explore perceived involvement in decision-making, anxiety, concerns (emotional) and lesion anatomical location, surgical risks (factual). Descriptive statistics were used to report responses and text classification tools were used to analyse free text responses.
Setting and participants
14 patients undergoing elective skull base surgery (with pathologies including skull base meningioma, craniopharyngioma, pituitary adenoma, Rathke cleft cyst, and olfactory neuroblastoma) were prospectively identified at a single unit.
Results
After model exposure, there was a net trend towards reduced patient-reported anxiety and enhanced patient-perceived involvement in treatment. 13/14 patients (93%) felt better about their operation and 13/14 patients (93%) thought all patients should have access to personalised 3D models. After exposure, there was a net trend towards improved patient-reported understanding of surgical risks, lesion location, and degree of feeling informed. 13/14 patients (93%) felt the model helped them understand the surgical anatomy better. Analysis of free text responses, after exposure found 47% positive sentiment, 35% neutral, and 18% negative.
Conclusions
In the context of skull base neurosurgery, personalised 3D printed models of skull base pathology can improve surgical consent and reduce patient anxiety.

::::::
::::::

RIGHTS/LEGAL/LEGISLATIVE

The Legal Requirements for—and Limits to—the Donor's and the Patient's Consent

Book Chapter
Silvia Deuring
Brain Organoids in Research and Therapy, 10 July 2022; pp 131-190 [Springer]
Abstract

Research with and on brain organoids implicates well-known problems of consent: under which circumstances is consent required, when is it valid, and how far does it reach? In some cases, these problems are exacerbated by the applicability and complex interplay of specific statutes such as the Transplantation Act, the Transfusion Act, and the regulations on medicinal products. For that reason, this article seeks to provide an overview of the problems of consent within the various contexts of brain organoid use.

Consent and Deidentification of Patient Images in Dermatology Journals: Observational Study

Japbani K Nanda, Michael Armando Marchetti

JMIR dermatology, 6 July 2022; 5(3)

Excerpt

Publication of patient images contributes to research and education in dermatology. However, it is important to protect patients' privacy and rights. The Committee on Publication Ethics (COPE) and the International Committee of Medical Journal Editors (ICMJE) have provided best practices and recommendations, respectively, for the protection of patients' rights in scholarly publications [1,2]. Nonetheless, requirements for the deidentification of patient images and for the acquisition of consent to publish such images vary across governing bodies and journals. Our objective was to describe leading dermatology journals' instructions regarding deidentification and consent to publish patient images as well as the content and readability of consent forms…

Consent in organ transplantation: putting legal obligations and guidelines into practice

Research

Farrah Raza, James Neuberger

BMC Medical Ethics volume, 5 July 2022; 23(69)

Open Access

Abstract

Consent in medical practice is a process riddled with layers of complexities. To some extent, this is inevitable given that different medical conditions raise different sets of issues for doctors and patients. Informed consent and risk assessment are highly significant public health issues that have become even more prominent during the course of the Covid-19 pandemic. In this article we identity relevant factors for clinicians to consider when ensuring consent for solid organ transplantation. Consent to undergo solid organ transplantation is more complex than most surgical and other clinical interventions because of the many factors involved, the complexity of the options and the need to balance competing risks. We first outline the context in which consent is given by the patient. We then outline the legal principles pertaining to consent in medical practice as it applies in the UK and the implication of recent legal judgments. The third section highlights specific complexities of consent in organ transplantation and identifies relevant factors in determining consent for organ transplantation. The fourth section offers practical recommendations. We propose a novel 'multi-factor approach' to informed consent in transplantation which includes understanding risk, effective communication, and robust review processes. Whilst understanding risk and communication are a given, our suggestion is that including review processes into the consent process is essential. By this we specifically mean identifying and creating room for discretion in decision-making to better ensure that informed consent is given in practice. Discretion implies that health care professionals use their judgement to use the legal judgements as guidance rather than prescriptive. Discretion is further defined by identifying the relevant options and scope of clinical and personal factors in specified transplantation decisions. In particular, we also highlight the need to pay attention to the institutional dimension in the consent process. To that end, our recommendations identify a gap in the current approaches to consent. The identification of areas of discretion in decision-making processes is essential for determining when patients need to be involved. In other words, clinicians and healthcare professionals need to consider carefully when there is room for direction and where there is little or no room for exercising discretion. In sum, our proposed approach is a modest contribution to the on-going debate about consent in medicine.

Sufficient informed consent to medical treatment of adults: legal and ethical perspectives from Malawi

Eva Maria Mfutso Bengo, Adamson Muula, Joseph Mfutso Bengo

Malawi Medical Journal, June 2022; 34(2) pp 143-150

Open Access

Abstract

This special communication discusses the current legal and ethical requirements for informed consent to medical treatment of adults in Malawi. It analyzes the scope of the laws and code of ethics on professional discipline, including criminal privilege for surgeries and clarifies when insufficient disclosures entitle patients to compensation under civil law. Inconsistencies and uncertainties in the law are made apparent. It evaluates to which degree disclosure standards of other Commonwealth jurisdictions (e.g. the case of Montgomery) would be suitable for the health care setting of a country like Malawi that is characterized by shortages of resources, high illiteracy rates and a communitarian cultural context. Doctor-patient communication is not alien to African culture and part of sufficient informed consent. In order to balance the need for efficiency in health care delivery, accountability for quality care, fairness and effective patient-doctor communication the authors suggest to adopt the reasonable patient test only, if a defence of heavy workload on case-to-case basis is introduced at the same time. This does not dispense the need for organisational diligence on part of the institutional health care provider within its capacity.

::::::
::::::

FREE PRIOR INFORMED CONSENT (FPIC)

The evolution and development of the principle of free, prior and informed consent in South Africa

Original Article

Naledzani Mukwevho

South African Journal on Human Rights, 27 June 2022

Abstract

This article traces the evolution of the principle of free, prior and informed consent within the South African developmental context. Internationally, free prior and informed consent presupposes that communities have the right to give or withhold consent to proposed development projects on the lands that they own, occupy or otherwise use. Specific to South Africa, research reveals that although the country has not formally adopted the free, prior and informed consent principle within its development system, the spirit of the principle has permeated the development discourse in the country through development policies, legislation and case law. All major development policies in South Africa embody the public participation element, which is a precursor to free, prior and informed consent. Several Acts of parliament specifically require that communities' consent must be sought and obtained before any development may take place in their territories. This sentiment has recently been augmented by court cases, both at High Court and Constitutional Court levels.

::::::
::::::

CULTURAL/COUNTRY CONTEXT

Informed consent: who are we informing?

Michele O'Shea
Rural Remote Health, 26 July 2022; 22(3)
Open Access
Abstract
Communication is the foundation of informed consent in research. This article relays the reflections of an American urogynecology fellow and researcher in Kenya on the topic of informed consent. After learning of how a previous foreign researcher's presence in the community had violated the trust that women placed in women's health research, she reflects on how the standard eurocentric approach to obtaining written informed consent in research may sow breakdowns in communication and also perpetuate distrust in research. Particularly for settings in which the language is primarily spoken, or where there are varying literacy levels, the standard research consent should be reimagined to make the informed consent process more equitable and less of an exercise in documentation. Communication of research study information to patients must take into account the diverse and evolving ways in which patients best consume information, and in such a way that it ultimately enhances their autonomy.

Disparities in Comprehension of the Obstetric Consent According to Language Preference Among Hispanic/Latinx Pregnant Patients

Rose L. Molina, Emily Adams, Ricardo Aguayo, Samantha Truong, Michele R. Hacker
Cureus, 21 July 2022; 14(7)
Open Access
Abstract
Background
We assessed understanding of the obstetric consent form between patients with English and Spanish language preference.
Methods
This observational study included pregnant patients who identified as Hispanic/Latinx with English or Spanish language preference (defined as what language the patient prefers to receive healthcare information) and prenatal care providers at a large academic medical center from 2018 to 2021. Patient demographics, language preference, literacy, numeracy, acculturation, comprehension of the obstetric consent, and provider explanations were collected.
Results
We report descriptive statistics and thematic analysis with an inductive approach from 30 patients with English preference, 10 with Spanish preference, and 23 providers. The English group demonstrated 72% median correct responses about the consent form; the Spanish group demonstrated 61% median correct responses. Regardless of language, the participants demonstrated limited understanding of certain topics, such as risks of cesarean birth.
Discussion
Overall comprehension of key information in an obstetric consent form was low, with differences in language groups, which highlights opportunities for improvements in communication across language barriers. Innovations in the communication of critical pregnancy information for patients with limited English proficiency need to be developed and tested.

The Need to Adjust the Informed Consent for Jewish Patients for Treatments Involving Porcine Medical Constituents

Original Paper
Ya'arit Bokek-Cohen
Journal of Immigrant and Minority Health, 18 July 2022
Abstract

In order to obtain full informed consent for medical treatments, it is imperative to provide patients of diverse ethnic backgrounds with all relevant information. Since the pig is considered an impure animal in Judaism, Jewish patients may wish to be informed of porcine-derived substances used in treating. The present study is the first to explore the level of knowledge of Jewish participants as to whether the medical use of pig is permitted by their religion, and the extent to which they believe it should be permitted. 714 Jewish participants completed a study questionnaire that included 15 medical uses of pigs. Findings indicated that the knowledge of Jewish law regarding these uses is a significant mediator in predicting the attitude toward the permissibility of these uses. I conclude with practical recommendations as to how to enhance cultural competence and improve the informed consent process when treating Jewish patients with porcine-derived constituents.

Patient Perception of Informed Consent and Its Associated Factors among Surgical Patients Attending Public Hospitals in Dessie City Administration, Northeast Ethiopia

Research Article

Hana Gebrehiwot, Nathan Estifanos, Yosef Zenebe, Tamrat Anbesaw

Critical Care Research and Practice, 1 July 2022

Open Access

Abstract

Background

Poor perception of informed consent compromises patients' autonomy and self-determination; as a result, they feel powerless and unaccountable for their treatment. This study aimed to assess patients' perception of informed consent and its associated factors among surgical patients attending public hospitals in Dessie City Administration, Northeast Ethiopia.

Methods

Facility-based cross-sectional study was conducted on 422 surgical patients. A systematic sampling technique was used to select the study participants. Data were collected using a pretested structured interviewer-administered questionnaire. EpiData version 3.1 was used for data entry, and then data were exported to SPSS version 25 for analysis. Multivariable logistic regression analysis was done to identify factors associated with the outcome variable among the participants. Variables with value less than 0.05 were considered statistically significant factors.

Results

The prevalence of poor perception of informed consent for surgical procedures was found to be 33.2% (95% CI: 28.8–37.8). In multivariable analysis, educational status with inability to read and write (AOR = 5.71; 95% CI: 2.76–11.80) and basic ability to read and write (AOR = 6.03; 95% CI: 2.57–14.16), rural residence (AOR = 3.71; 95% CI: 1.94–7.07), marital status being widowed and divorced (AOR = 3.85; 95% CI: 1.83–8.08), language of written informed consent different from mother tongue (AOR = 4.196; 95% CI: 1.12–15.78), poor patient-physician relationship (AOR = 2.35; 95% CI: 1.31–4.24), and poor knowledge of surgical informed consent (AOR = 3.05; 95% CI: 1.56–5.97) were significantly associated with poor perception of surgical informed consent.

Conclusion

In this study, one-third of surgical patients appear to have poor perceptions of informed consent for surgical procedures. Educational status, being rural residents, being widowed/divorced, language of written informed consent, poor patient-physician relationship, and poor knowledge of surgical informed consent were variables that are independent predictors of poor perception of informed consent for surgical procedures. The ministry of health and healthcare providers should develop a plan to raise patients' awareness about the informed consent process for surgical procedures.

Family-oriented informed consent in China's clinical settings: A sociological and ethical study

PhD Thesis

Jingru Li
University of Otago, 2022
Abstract
In China's clinical settings, it is common for families to make decisions about the information and treatments that a patient will receive. This practice or model is referred to as 'family-oriented informed consent'. It differs from the 'individual model' practiced in many Western countries. A standard explanation for this difference is based on perceived differences between Chinese and Western cultures. On this view it is argued that family-oriented informed consent is most compatible with the strong familial culture in China, while patient-centred informed consent reflects Western individualism.

This study aims to understand how and why families are involved in informed consent in China, and to critically assess the arguments for and against this involvement. It does this through a sociological investigation and an ethical analysis. Semi-structured, in-depth interviews were conducted with 13 patients, 14 family caregivers, and nine health professionals in Tianjin and Beijing, two mega cities in China. A thematic analysis approach was used to analyse the empirical material. The findings confirm the prevalence of the family-oriented practice. For family participants, two reasons were most often mentioned to support family-oriented informed consent: "reducing harms" and "increasing benefits". Most patient participants preferred to make decisions on their own. Only a small number of patient participants indicated a preference for family-oriented model. They mainly referred to their reliance on the family for funding and care. As for medical professional participants, most of them disapproved of the family-oriented model but felt too powerless to act on the side of patients in face of family's requirement as the decision makers.

On the basis of these findings, I argue that family-oriented informed consent is empirically groundless and ethically wrong, and that 'patient-oriented informed consent' should be adopted instead. Besides familial culture, the findings indicated at least four other factors explaining the family-oriented model, including doctor-patient mistrust, insufficient public funding to healthcare, the conflicting legal stipulations, and poor communication. Moreover, the argument that the practice benefits patients is specious, as in many ways it can be more harmful to patients. Argument based on cultural differences is also dubious because it incorrectly assumes that family-oriented pattern only exists in China, and that Chinese people do not support individual autonomy. Having shown the problems with family-oriented pattern, I move to argue in support of 'patient-centred model'. On this model, patients should have the authority in informed consent, and doctors should be sensitive to patients' requirement about family involvement. This model is both contextually sensitive and morally justifiable to China's clinical context because it is in line with most Chinese patients' preference for self-determination and is beneficial to patients. To make this possible, it is important to specify patient's individual right to informed consent in law and to stipulate medical professionals' legal duty to respect patient's autonomy. Improvement in doctor-patient communication and more government funding in the healthcare sector are equally important means for a better implementation.

::::::
::::::

MEDICAL/SURGICAL

Informed Consent before coronary angiography and percutaneous coronary intervention from the patient's perspective: A picture is worth a thousand words

A. Brand, C. Crayen, A. Hamann, S. Martineck, L. Gao, H. Brand, S.M. Squier, K. Stangl, F. Kendel, V. Stangl
IJC Heart & Vasculature, August 2022; 41
Abstract
Background
Patients scheduled for coronary angiography may feel insufficiently informed about the planned procedure. We aimed to evaluate the patient-rated quality of the Informed Consent (IC) process and to investigate the efficacy of medical graphics to assist and improve the IC procedure.
Methods

A graphic-based information broschure illustrating central steps of the procedure was created in collaboration with scientific illustrators. In a randomized, controlled, prospective trial, 121 patients undergoing coronary angiography/PCI were randomized to a group obtaining the usual IC (Control group) or to a group that additionally obtained a graphic-based IC (Comic group). The perceived quality of the IC was compared between groups using single items of the Client Satisfaction Questionnaire-8 and self-designed single items.

Results

Only 67.8% of patients stated to have completely read the standard written IC sheet. The quality of the IC was perceived to be very good in 45.0% of patients in the Comic group compared to 24.6% in the Control group (p =.023). 57.4% of the Control group compared to 76.7% of the Comic group stated that all of their questions were satisfactorily adressed (p =.015). 43.3% of the Comic group, in contrast to only 18.0% of the Control group, declared to feel „very satisfied“ with the obtained IC procedure (p =.002). The acceptance of this new IC approach was very high: no patient expressed feelings of not being taken seriously when reading medical graphics.

Conclusions

Our data confirm pronounced limitations of the usual IC practice. The use of medical graphics positively impacts on patient-evaluated endpoints and may significantly improve the IC procedure.

Informed consent for suspension microlaryngoscopy: what should we tell the patient? A consensus statement of the European Laryngological Society

Frederik G. Dikkers, Michel R. M. San Giorgi, Rico N. P. M. Rinkel, Marc Remacle, Antoine Giovanni, Małgorzata Wierzbicka, Riaz Seedat, Guillermo Campos, Guri S. Sandhu

European Archives of Oto-Rhino-Laryngology, 12 July 2022

Open Access

Abstract

Introduction

Informed consent for any surgical intervention is necessary, as only well-informed patients can actively participate in the decision-making process about their care, and better understand the likely or potential outcomes of their treatment. No consensus exists on informed consent for suspension microlaryngoscopy (SML).

Materials and methods

Informed consent procedures in nine countries on five continents were studied.

Results

Several risks can be discerned: risks of SML as procedure, anesthesiologic risks of SML, specific risks of phonosurgery, risks of inadequate glottic exposure or unexpected findings, risks of not treating. SML has recognized potential complications, that can be divided in temporary (minor) complications, and lasting (major) complications.

Conclusion

SML is a safe procedure with low morbidity, and virtually no mortality. Eleven recommendations are provided.

Patients’ satisfaction and associated factors towards preoperative informed consent process: A cross-sectional study

Tamiru Tilahun Ayele, Tadese Tamire Negash, Keder Essa oumer, Aderajew Mekuanint, Diriba Teshome, Efrem Fenta, Yewlsew Fentie, Aragaw Tesfaw Ashenafi Tolosa

Annals of Medicine and Surgery, 4 July 2022; 79

Abstract

Background

Informed consent is a process that needs time and effort to satisfy patients' desires. Patient dissatisfaction on preoperative informed consent process may be caused by multiple factors of clinical practice. This study aimed to assess patients' satisfaction and associated factors of informed consent process among elective surgical patients.

Methods

A cross-sectional study was conducted on 404 postoperative patients who signed the informed consent for elective surgery. A systematic sampling technique was applied to select the study participants. Modified Leiden perioperative patient satisfaction tool was adapted to assess patients' satisfaction with preoperative informed consent process. Data were entered in to Epi-data version 4.20 and exported to SPSS version 20 for analysis. Bivariate and multivariable logistic regression was computed to identify independent variables associated with patient satisfaction towards preoperative informed consent process. A p-value of less than 0.05 was used to declare the statistical significance.

Results

The overall satisfaction of patients with preoperative informed consent process was 70.3%. Multivariable logistic regression analysis revealed that, being male (AOR: 4.75, 95% CI: 2.47–9.16), primary school (AOR: 8.42, 95% CI: 4.74–7.55), secondary school (AOR: 2.17, 95% CI: 5.74–8.62), rural residence (AOR: 1.8, 95% CI: 2.1–3.9) and received general anesthesia (AOR: 2.92, 95% CI: 1.62–5.26) were significantly associated with patients' satisfaction with the informed consent process.

Conclusion

The overall patients' satisfaction on preoperative informed consent process was relatively low. Being male, low level of education, living in rural area, and receiving general anesthesia were significantly associated with patients' satisfaction on informed consent process. Surgeons and anesthesia professionals need to work more to improving the satisfaction of patients with preoperative informed consent process. Researchers are expected to do periodic assessment of patients' level of satisfaction and factors affecting satisfaction.

::::::
::::::

GENERAL/OTHER

Privacy Behaviour: A Model for Online Informed Consent

Original Paper

Gary Burkhardt, Frederic Boy, Daniele Doneddu, Nick Hajli

Journal of Business Ethics, 14 July 2022

Open Access

Abstract

An online world exists in which businesses have become burdened with managerial and legal duties regarding the seeking of informed consent and the protection of privacy and personal data, while growing public cynicism regarding personal data collection threatens the healthy development of marketing and e-commerce. This research seeks to address such cynicism by assisting organisations to devise ethical consent management processes that consider an individual's attitudes, their subjective norms and their perceived sense of control during the elicitation of consent. It does so by developing an original conceptual model for online informed consent, argued through logical reasoning, and supported by an illustrative example, which brings together the autonomous authorisation (AA) model of informed consent and the theory of planned behaviour (TPB). Accordingly, it constructs a model for online informed consent, rooted in the ethic of autonomy, which employs behavioural theory to facilitate a mode of consent elicitation that prioritises users' interests and supports ethical information management and marketing practices. The model also introduces a novel concept, the informed attitude, which must be present for informed consent to be valid. It also reveals that, under certain tolerated conditions, it is possible for informed consent to be provided unwillingly and to remain valid: this has significant ethical, information management and marketing implications.

Malpractice Claims and Ethical Issues in Prison Health Care Related to Consent and Confidentiality

Review

Oana-Maria Isailă, Sorin Hostiuc

Healthcare, 12 July 2022

Open Access

Abstract

Respecting the consent and confidentiality of a patient is an underlying element in establishing the patient's trust in the physician and, implicitly, obtaining the patient's compliance. In particular, cases of inmate patients require increased attention in order to fulfill this goal against a background of institutional interferences, which, in certain situations, may endanger the autonomy of the physician and their respect for the inmate's dignity. The purpose of this article is to depict the characteristics of consent and confidentiality in a prison environment, in special cases, such as hunger strikes, violent acts, HIV testing, COVID-19 measures, and drug use, bringing into focus the physician and the inmate in the context of the particular situation where the target is disciplining someone in order for them to conform to social and juridical norms. Respecting the dignity of the inmate patient requires an adequate approach of informed consent and confidentiality, depending on each case, considering the potential unspoken aspects of the inmate's account, which can be key elements in obtaining their compliance and avoiding malpractice claims.

Ethics Considerations Regarding Donors' and Patients' Consent

Book Chapter

Jeremy Sugarman

Brain Organoids in Research and Therapy, 10 July 2022; pp 121-130 [Springer]

Abstract

Informed consent is a crucial factor in determining whether particular uses of brain organoids for research and clinical translation are ethically acceptable. In the context of basic research, the consent of donors whose tissues are used to derive brain organoids is of primary concern, whereas in clinical translation the consent of both allogeneic donors and patients may be relevant. In this chapter, I examine key ethics considerations related to informed consent for brain organoid research and clinical translation. In order to do so, I first describe both a standard conceptual approach to informed consent that aims at meeting the ethical goal of respecting the autonomy of persons and some of the other ethically relevant functions of informed consent. This conceptual work provides a foundation for mapping ethics considerations related to informed consent in regard to the decision-making capacity and voluntariness of those being asked to consent, disclosure requirements associated with brain organoids in general and for particular proposed uses that involve morally significant aspects, threats to understanding that must be overcome, and considerations for authorization. Finally, I offer some suggestions for grappling with such informed consent challenges related to brain organoids.

The Scope of Consent

Joseph Millum

The Philosophical Quarterly, 2 July 2022

Extract

Suppose you come to my house and I invite you in. 'I'm just heading out', I say, 'but make yourself at home'. I have consented to you remaining in my house, but what else? In your home, you put your feet up on the coffee table, so may you now do that in mine? If I complain that you've left crumbs from eating biscuits in my bed, can you defend yourself on the grounds that I told you to make yourself at home? These questions concern the scope of my consent. How we should ascertain the scope of someone's consent is the topic of Tom Dougherty's book. The book is divided into three main parts, each corresponding to a view about what

fixes the scope of consent: the mental account, the successful communication account, and the evidential account, which Dougherty favours…

# # # #

Informed Consent: A Monthly Review *is an open access publication, subject to the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by-nc/3.0/). Copyright is retained by the ge2p2 global foundation.*

# # # #