

**Center for Informed Consent Integrity**

***Informed Consent: A Monthly Review***

***October 2019***

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This digest aggregates and distills key content around 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. We acknowledge that this scope yields an indicative and not an exhaustive digest product.

*Informed Consent: A Monthly Review* is a service of the GE2P2 Global Foundation's Center for Informed Consent Integrity, which is solely responsible for its content. Comments and suggestions should be directed to:

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

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## GENOMIC MEDICINE/GENE EDITING

### **Patient Preferences for Use of Archived Biospecimens from Oncology Trials When Adequacy of Informed Consent Is Unclear**

Jeffrey Peppercorn, Eric Campbell, Steve Isakoff, Nora K. Horick, Julia Rabinb, Katharine Quaina, Lecia V. Sequista, Aditya Bardiaa, Deborah Collyare, Fay Hlubockyf, Debra Mathewsg

**The Oncologist, 6 September 2019**

#### *Abstract*

#### *Background*

Oncology research increasingly involves biospecimen collection and data sharing. Ethical challenges emerge when researchers seek to use archived biospecimens for purposes that were not well defined in the original informed consent document (ICD). We sought to inform ongoing policy debates by assessing patient views on these issues.

#### *Materials and Methods*

We administered a cross-sectional self-administered survey to patients with cancer at an academic medical center. Survey questions addressed attitudes toward cancer research, willingness to donate biospecimens, expectations regarding use of biospecimens, and preferences regarding specific ethical dilemmas.

#### *Results*

Among 240 participants (response rate 69%), virtually all (94%) indicated willingness to donate tissue for research. Most participants (86%) expected that donated tissue would be used for any research deemed scientifically important, and virtually all (94%) expected that the privacy of their health information would be protected. Broad use of stored biospecimens and data sharing with other researchers increased willingness to donate tissue. **For three scenarios in which specific consent for proposed biobank research was unclear within the ICD, a majority of patient's favored allowing the research to proceed: 76% to study a different cancer, 88% to study both inherited (germline) and tumor specific (somatic) mutations, and 70% to permit data sharing.** A substantial minority believed that research using stored biospecimens should only proceed with specific consent.

#### *Conclusion*

When debates arise over appropriate use of archived biospecimens, the interests of the research participants in seeing productive use of their blood or tissue should be considered, in addition to addressing concerns about potential risks and lack of specific consent.

#### *Implications for Practice*

This survey evaluated views of patients with cancer regarding the permissible use of stored biospecimens from cancer trials when modern scientific methods are not well described in the original informed consent document. The vast majority of patients support translational research and expect that any biospecimens they donate will be used to advance knowledge. When researchers, policy makers, and those charged with research oversight debate use of stored biospecimens, it is important to recognize that research participants have an interest in productive use of their blood, tissue, or data, in addition to considerations of risks and the adequacy of documented consent.

*Editor's note: The Oncologist is the official journal of the Society for Translational Oncology. This article also appears under BIOMEDICAL RESEARCH*

### **Biobanks in the Era of Genomic Data**

Juliann Savatt, Cassandra J. Pisieczko, Yanfei Zhang, Ming Ta Michael Lee, W. Andrew Faucett, Janet L. Williams

**Current Genetic Medicine Reports, 30 August 2019 7(3) pp 153-161**

## *Abstract*

### *Purpose of Review*

Biobank research brings together participants, their samples and data, and researchers to provide a productive and efficient resource that advances discovery, prevention, diagnosis, and treatment. This mini-review addresses the importance of governance issues regarding consent, privacy and confidentiality, data sharing, and return of results in biobanks that utilize genomic sequencing data.

### *Recent Findings*

With the availability of genomic sequencing data, there is renewed attention to the value of biobank research. Governance components of consent, data sharing, privacy protections, and disclosure of research results vary widely among biobanks currently established. There is no consensus standard of best practice for managing genomic data regardless of the biobank infrastructure.

### *Summary*

Understanding the various biobank research program components will aid genetics providers and other healthcare providers as they interact with biobank researchers and participants. Governance structures for biobanks will need to be informed by the engagement of participants, researchers, and regulatory agencies. Education concerning the importance of biobank research, transparency of governance structure, and the relationship of genomic data to the improvement of individual health is critical to support continued biobank research.

*Editor's note: This article also appears under BIOBANKING.*

## **Attitudes Regarding Enrollment in a Genetic Research Project: An Informed Consent Simulation Study Comparing Views of People With Depression, Diabetes, and Neither Condition**

### *Research Article*

Jane Paik Kim, Katie Ryan, Laura Weiss Roberts

**Journal of Empirical Research on Human Research Ethics, 22 July 2019; 14(4)**

### *Abstract*

In this study, participants with a self-reported history of depression, diabetes, or no illness underwent a simulated informed consent process for a hypothetical genetic study related to depression or diabetes. Participants completed a survey assessing their perceived understanding of the research process, perceptions of its risks and benefits, their satisfaction with the informed consent process, and their readiness to make a hypothetical enrollment decision. All participants indicated strong readiness to make an enrollment decision regarding the research characterized in the simulation. Participants reported understanding the consent process relatively well and being generally satisfied with it. Greater concerns were expressed regarding psychosocial risks than biological risks for genetic studies on mental disorders. Our study documented positive attitudes toward volunteering for research that involved the collection of genetic data.

## **Overvaluing individual consent ignores risks to tribal participants**

### *Comment*

Krystal S. Tsosie, Joseph M. Yracheta, Donna Dickenson

**Nature Reviews Genetics, 15 July 2019; 20 pp 497–498**

### *Excerpt*

Genomic studies often rely on individual-based consent approaches for tribal members residing outside of their communities. This consent model fails to acknowledge the risks to small groups such as tribes, which can implicate the community as a whole...

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### **Informed Consent Process in the New Millennium**

#### *Short Communication*

Ranabir Pal, Swapan K Paul

**Bengal Physician Journal, May-August 2018; 5(2) pp 22-24**

#### *Open Access*

#### *Abstract*

In this new millennium, the clinical trial is inseparably linked with an upgrade of health care by generating invaluable data in preventive, promotive and curative health. Globally research experts have concerns

regarding ensuring financial and other compensations along with optimum health benefits for research participants in clinical trials in the emerging market economy. A significant number of human healthy volunteers (participants) take part in researches in both developed and developing countries. Participants are frequently unaware that the informed consent process is mandatory for investigators, funders and participants and their free will must be documented. There are sparse published medical works of literature that attempted to assess the extent to which all the norms of the informed consent process are followed in Indian settings in this area to the best of our knowledge. We need to conduct researches on the preparedness of the clinical trials participants towards their awareness of the criticality of the informed consent process and their motives for participation. This narrative review enlightened the facts that very patient, extensive and careful transparent narration and dissemination of the information can only ensure truly informed and autonomous decision improving the validity of the study.

*Editor's note: This article also appears under CULTURAL/COUNTRY CONTEXT*

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## **SOCIAL SCIENCE RESEARCH**

### **What Qualitative Researchers Must Do When Ethical Assurances Disintegrate? Recognise Internal Confidentiality, Establish Process Consent, Reference Groups, Referrals for Participants and a Safety Plan [Conference Paper]**

Martin Tolich

**World Conference on Qualitative Research, 17 September 2019**

#### *Abstract*

Informed consent and confidentiality are the two mainstays of qualitative research ethics, yet they have a propensity to disintegrate in an emergent, iterative research design. This chapter examines how to approach this uncharted territory by having researchers take full responsibility for ethical considerations by using more robust forms of consent like process consent; recognising the dual faces of confidentiality, distinguishing external confidentiality from internal confidentiality. Other responsibilities in post ethics review environment include recognising and addressing big ethical moments. At times, participants and researchers ethical protections disintegrate too. When participants are at risk, furnish referrals (i.e. suicide watch phone numbers). When researchers are at risk work off a safety plan. Additionally, given this unpredictability, researchers should create a standing reference group to assist answering the fourth question above: what to do when the project raises ethical questions not foreseen in formal ethics review or by the researcher.

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## **TECHNOLOGY/OTHER MEDIATION**

### **HealthLit4Kids Animation: inclusive and informed participants [Conference Extract]**

*eCite Digital Repository*

C Mainsbridge, R Nash, S Elmer, K Patterson, V Cruickshank, A McDonald, E Burke, R Dick

**Engagement Transforms 2019 (ET19), 6 September 2019, Hobart, Tasmania**

#### *Abstract*

HealthLit4Kids is an education program designed for use in schools. Teachers invite children to participate in classroom-based health literacy development activities. The learning culminates with the development of an Artefact (creative piece accompanied with a description). Consent must be obtained from a parent or guardian and the child prior to uploading the HealthLit4Kids Artefact to the Open Education Resource and prior to the inclusion of each Artefact in research and evaluation. English is an additional language for 30% of the families at 2 of the 5 schools currently engaged with HealthLit4Kids, and limited literacy made it difficult

to engage with "traditional" information sheets and informed consent processes. In response to these identified needs, the researchers developed a short, animated resource to support an informed consent process: 1. HealthLit4Kids Information Video 2. Parent/Child Information and Consent Video 3. Parent Term 1 Focus Group Information and Consent Video 4. Parent Term 3 Focus Group Information and Consent Video

### **The Effect of an Educational and Interactive Informed Consent Process on Patients with Cervical Spondylotic Myelopathy Caused by Ossification of the Posterior Longitudinal Ligament**

Young-Seok Lee, Dae-Chul Cho, Joo-Kyung Sung, Inbo Han, Chi-Heon Kim, Ji-Yoon Kim, Kyoung-Tae Kim  
**Spine, 6 September 2019**

*Open Access*

*Abstract*

*Objective*

In this study, an educational and interactive informed consent (EIC) program was proposed for patients with OPLL-CSM to improve their comprehension level during the informed consent process.

*Summary of Background Data*

Cervical spondylotic myelopathy caused by ossification of the posterior longitudinal ligament (OPLL-CSM) is a slow progressive disease, and it is difficult for patients to understand the disease. Few studies have evaluated very specific programs to improve the informed consent process for these patients.

*Methods*

This prospective study evaluated patients with OPLL-CSM who either underwent the proposed EIC process (n=63) or the standard consent process (n = 124). The standard consent process only included a physician-patient interview. During the EIC process, information was provided regarding OPLL-CSM through information booklets, a video, verbal information, and initial and second physician-patient interviews. After the second physician-patient interview, the patient was requested to answer 14 medical questions to assess their knowledge about OPLL-CSM. The proposed EIC process took approximately 90 minutes. They were asked to report the most useful educational method and the most effective method of reinforcing verbal communication.

*Results*

The mean questionnaire scores were higher in the EIC group than in the control group ( $p < 0.001$ ). Video was selected by 50/63 patients (79.4%) as the most useful EIC process method, and the most effective method of reinforcing verbal communication was video (n = 61; 96.8%). Patients in the EIC group reported having higher satisfaction with surgery ( $p = 0.024$ ) than did those in the control group.

*Conclusions*

The proposed EIC process was shown to result in good patient comprehension and recall regarding OPLL-CSM. Using a video was the most informative and effective reinforcement of verbal communication. The enhanced educational group had better knowledge and improved satisfaction following surgery. The EIC process might help physicians educate and counsel patients regarding OPLL-CSM and its treatment.

*Editor's note: Spine is an international, peer-reviewed, bi-weekly periodical which describes itself as the leading subspecialty journal for the treatment of spinal disorders*

### **A video decision aid improves informed decision-making in patients with advanced cancer considering palliative radiation therapy**

*Brief Report*

Kavita V. Dharmarajan, Chasity B. Walters, Tomer T. Levin, Carol Ann Milazzo, Christopher Monether, Robin Rawlins-Duell, Roma Tickoo, Daniel E. Spratt, iShona Lovie, jGina Giannantoni-Ibelli, Beryl McCormick

**Journal of Pain and Symptom Management, 28 August 2019**

*Abstract*

*Context*

Advanced cancer patients have unrecognized gaps in their understanding about palliative radiation therapy (PRT).

#### *Objectives*

To build a video decision aid for hospitalized patients with advanced cancer referred for PRT and prospectively test its efficacy in reducing decisional uncertainty, improving knowledge, increasing treatment readiness and readiness for palliative care consultation, and its acceptability among patients.

#### *Methods*

Forty patients with advanced cancer hospitalized at Memorial Sloan Kettering Cancer Center watched a video decision aid about PRT and palliative care. Patients' conceptual and logistical knowledge of PRT, decisional uncertainty, treatment readiness, and readiness for palliative care consultation were assessed before and after watching the video with a 6-item knowledge survey, the decisional uncertainty subscale of the Decisional Conflict Scale, and Likert instruments to assess readiness to accept radiation treatment and/or palliative care consultation, respectively. A post-video survey assessed the video's acceptability among patients.

#### *Results*

After watching the video, decisional uncertainty was reduced (28.3 vs. 21.7,  $p=0.02$ ); knowledge of PRT improved (60.4 vs. 88.3,  $p<0.001$ ); and PRT readiness increased (2.0 vs. 1.3,  $p=0.04$ ). Readiness for palliative care consultation was unchanged ( $p=0.58$ ). Patients felt very comfortable (70%) watching the video and would highly recommend it (75%) to others.

#### *Conclusion*

Among hospitalized patients with advanced cancer, a video decision aid reduced decisional uncertainty, improved knowledge of PRT, increased readiness for PRT, and was well-received by patient viewers.

### **Characteristics of patients having telemedicine versus in-person informed consent visits before abortion in Utah**

Sara Daniel, Sarah Raifman, Shelly Kaller, Daniel Grossman

**Contraception, 4 September 2019**

#### *Abstract*

##### *Objective*

This study aimed to evaluate demographic and service delivery differences between patients using telemedicine relative to an in-person visit to satisfy Utah's state-mandated informed consent visit, which must occur at least 72 h before the abortion.

##### *Study design*

We conducted a retrospective cohort study with data from Planned Parenthood Association of Utah (PPAU), which included all informed consent and abortion encounters from January 1, 2015 – March 31, 2018. We evaluated the following for each encounter by informed consent type (telemedicine vs. in-person): demographics, distance to a PPAU facility, length of time between informed consent and abortion visits, and gestational age at time of abortion.

##### *Results*

Of the 9175 informed consent visits, 91% were in-person ( $n=8395$ ) and 9% were via telemedicine ( $n=780$ ), which ranged from 5% in 2015 to 16% in 2018. Compared to in-person patients, telemedicine patients were slightly older (27 vs. 25 median years,  $p<.001$ ), more likely to live out of state (47% vs. 4%,  $p<.001$ ) and further away from PPAU clinics offering informed consent visits (104 miles vs. 10 median miles,  $p<.001$ ). Among those who received abortion care at PPAU (6233), telemedicine informed consent patients were more likely to have medication abortions (adjusted odds ratio 1.68, 95% confidence interval 1.28–2.19) compared to in-person informed consent patients.

##### *Conclusions*

PPAU's telemedicine option for completing the abortion informed consent visit appears to be of particular interest to patients who live further from clinics, including out of state, as it could help reduce travel burdens imposed by Utah's mandatory delay law.



### *Implications*

Telemedicine provision of state-mandated informed consent is feasible and could be used in other states where similar mandatory delays before abortion are required and where telemedicine is allowed.

## **Legal authorized representative experience with smartphone-based electronic informed consent in an acute stroke trial**

### *Original research*

Diogo C Haussen, Leah Craft, Shannon Doppelheuer, Gabriel Martins Rodrigues, Alhamza R Al-Bayati, Krishnan Ravindran, Meagan Schultz, Loretta Sutherly, Kiva M Schindler, Michael R Frankel, Raul G Nogueira

**BMJ Journal of Neurointerventional Surgery, 17 September 2019**

### *Open Access*

### *Abstract*

### *Background*

The pilot use of a smartphone platform for electronic informed consent (e-Consent) in large vessel occlusion acute stroke (LVOS) trials has recently been reported. The degree of satisfaction from Legal Authorized Representatives (LARs) with regard to this process remains to be established.

### *Methods*

A single-center study evaluating the experience of LARs with the use of e-Consent in a LVOS randomized trial of an investigational drug administered within 12 hours of last known normal was carried out. A structured survey was used to evaluate the experience of the LARs with the e-consenting process.

### *Results*

From February to November 2018, 60 consecutive patients were e-Consented. Of these, 53 LARs completed the survey. The median (IQR) age of the patients was 63 (53–70) years, baseline/discharge National Institutes of Health Stroke Scale score was 17 (12–20)/3(1–12), and 45% were independent at discharge. The survey was applied in person in 43% of cases and via telephone in 57%. Median LAR age was 48 (39–59) years, 64% were female, and a multi-ethnic composition was observed. Forty percent of LARs had less than tertiary level of education (high-school or less). Regarding the e-Consent, 98% of LARs reported to be ‘clear’ and 83% felt ‘very comfortable’ in signing. The overall experience was ‘excellent/good’ in 91%. Despite the positive general impression regarding the use of e-Consent, 12 LARs (22%) would have preferred paper consent. Multivariable regression indicated that lower educational status (tertiary education or less: OR 5.09, 95% CI 1.02 to 25.48;  $p=0.04$ ) and lower baseline ASPECTS score (OR 0.63, 95% CI 0.41 to 0.96;  $p=0.03$ ) were independently associated with preference for paper consent.

### *Conclusions*

e-Consent was overall very well perceived by LARs in a randomized clinical trial of LVOS. A minority of proxies, who were more commonly less formally educated, would have preferred paper consenting.

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## **BIOBANKING**

### **Biobanks in the Era of Genomic Data**

Juliann Savatt, Cassandra J. Pisieczko, Yanfei Zhang, Ming Ta Michael Lee, W. Andrew Faucett, Janet L. Williams

**Current Genetic Medicine Reports, 30 August 2019 7(3) pp 153-161**

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review addresses the importance of governance issues regarding consent, privacy and confidentiality, data sharing, and return of results in biobanks that utilize genomic sequencing data.

#### *Recent Findings*

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#### *Summary*

Understanding the various biobank research program components will aid genetics providers and other healthcare providers as they interact with biobank researchers and participants. Governance structures for biobanks will need to be informed by the engagement of participants, researchers, and regulatory agencies. Education concerning the importance of biobank research, transparency of governance structure, and the relationship of genomic data to the improvement of individual health is critical to support continued biobank research.

*Editor's note: This article also appears under GENOMIC MEDICINE/GENE EDITING*

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## **COGNITIVE CHALLENGES**

### **Informed consent and ethical reporting of research in clinical trials involving participants with psychotic disorders**

Guy M. Weissinger, Connie M. Ulrich

**Contemporary Clinical Trials, September 2019; 84**

#### *Abstract*

Informed consent is critical for protecting vulnerable individuals interested in research participation, like those with psychotic disorders (e.g. schizophrenia, schizoaffective disorder, schizophreniform disorder, etc.). Individuals with psychotic disorders may have fluctuating capacity to consent and capacity assessment prior to research participation can help determine decisional status. However, there is little research on how, or if, these assessments are conducted in clinical research. A systematic review of randomized medication or device trials that specifically recruited individuals with psychotic disorders to understand the use and reporting of capacity assessment to consent was conducted. A total of 646 articles were reviewed using a developed questionnaire on ethical reporting of consent practices and capacity assessment. Less than 10% (n = 34; 5.3%) of the studies reported an assessment of capacity to provide informed consent and less than half of those used a standardized assessment. Sixty-four (9.9%) of the articles reported capacity to provide informed consent in the study's inclusion and exclusion criteria. Additionally, 66 (10.2%) of the articles did not provide a statement about institutional review board (IRB) approval; and given the large number of medication and device trials, one out of five articles (n = 134; 20.7%) reported no statement about potential conflicts of interest. Future research should continue to examine these issues and to better understand the benefits and challenges of research participation with psychotic individuals and their decisional capacity in this context.

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## **CULTURAL/COUNTRY CONTEXT**

### **Improving Translation and Cultural Appropriateness of Spanish-Language Consent Materials for Biobanks**

Kathleen M. Brelsford, Ernesto Ruiz, Catherine M. Hammack, and Laura M. Beskow

*Open Access*

*Abstract*

A growing proportion of prospective research participants in the United States speak limited or no English. We conducted cognitive interviews with native Spanish speakers to test Spanish-language translations of simplified and traditional biobank consent forms. Comprehension was generally high and did not differ by form. Most of those who received the simplified form felt it contained the right amount of information, compared with fewer than half of those who received the traditional form. Qualitative results allowed us to identify overarching issues related to tone, formality, and voice that may affect prospective participants' trust and willingness to participate. Certain characteristics of written Spanish are seemingly at odds with recommended actions to simplify consent forms; thus, even when significant empirical effort has been expended to develop simplified consent materials in English, additional work is needed to ensure the accuracy, comprehensibility, and cultural-congruence of Spanish-language translations.

### **Informed Consent in Thailand: What Standard Is It? Which One Should It Be?**

Khajorndej Direksoonthorn

**Asia Pacific Journal of Health Law & Ethics, July 2019; (12)3 pp 1-32**

*Open Access*

*Abstract*

The concept of informed consent has long been observed in the Thai medical community. However, an appropriate standard prescribing a physician's duty to disclose medical information has never been comprehensively discussed in Thailand. Moreover, to the best of my knowledge, the Supreme Court of Thailand has never decided any case where a party claims informed consent as a cause of action either. This paper seeks to fill that gap. I also anticipate that this kind of cause of action will definitely be the disputed issue for the Supreme Court to decide in the foreseeable future.

In this paper, I provide the analysis of the current statute governing informed consent in Thailand. More importantly, I argue that the appropriate standard of disclosure for Thailand should be the professional or physician-based standard. The physician has a duty to disclose only the information other reasonable physicians would reveal to their patients in similar circumstances. For Thailand, this standard is more suitable than the patient-centered standard in terms of both cultural and legal contexts. The standard can effectively safeguard the patient autonomy as well as work to his/her advantage in litigation. The U.S. doctrine of informed consent is comparatively discussed throughout the paper.

### **Informed Consent Process in the New Millennium**

*Short Communication*

Ranabir Pal, Swapan K Paul

**Bengal Physician Journal, May-August 2018; 5(2) pp 22-24**

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*Editor's note: This article also appears under BIOMEDICAL RESEARCH*

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## **RIGHTS/LEGAL/LEGISLATIVE**

### **Contested Organ Harvesting from the Newly Deceased: First Person Assent, Presumed Consent, and Familial Authority**

Mark J Cherry

**The Journal of Medicine and Philosophy: A Forum for Bioethics and Philosophy of Medicine, 16 September 2019; 44(5) pp 603–620**

#### *Abstract*

Organ procurement policy from the recently deceased recasts families into gatekeepers of a scarce medical resource. To the frustration of organ procurement teams, families do not always authorize organ donation. As a result, efforts to increase the number of organs available for transplantation often seek to limit the authority of families to refuse organ retrieval. For example, in some locales if a deceased family member has satisfied the legal conditions for first-person prior assent, a much looser and easier standard to satisfy than informed consent, organ retrieval may proceed despite the family's objections. Some countries have replaced voluntary consent to organ donation with forms of organ conscription. Often referred to under the misnomer "presumed consent," such policies legalize the harvesting of organs at death, unless individuals exercise official options to opt out. As this article explores, however, there are good grounds for affirming the authority of the family to consent to or to deny organ donation on behalf of recently deceased family members, as well as to reject first-person assent and "presumed consent" policies of organ procurement. Insofar as individuals have failed clearly and competently to provide informed consent to organ donation, moral authorization for the use of the person and his body ought to be grounded on the foundational authority of the family, rather than the state's supposed interests in obtaining organs for transplantation.

### **Public knowledge and attitudes towards consent policies for organ donation in Europe. A systematic review**

Alberto Molina Pérez, David Rodríguez-Arias, Janet Delgado-Rodríguez, Myfanwy Morgan, Mihaela Frunza, Gurch Randhawa, Jeantine Reiger-Van de Wijdeven, Eline Schiks, Sabine Wöhlke, Silke Schicktanz  
**Transplantation Reviews, 2019; 33(1) pp 1-8**

#### *Abstract*

Background: Several countries have recently changed their model of consent for organ donation from opt-in to opt-out. We undertook a systematic review to determine public knowledge and attitudes towards these models in Europe. Methods: Six databases were explored between 1 January 2008 and 15 December 2017. We selected empirical studies addressing either knowledge or attitudes towards the systems of consent for deceased organ donation by lay people in Europe, including students. Study selection, data extraction, and quality assessment were conducted by two or more reviewers independently. Findings: Awareness of the consent model was lower in opt-out countries than in opt-in countries. A majority of the public agrees with opt-in, regardless of the law in their own country. There are ambivalent attitudes regarding the opt-out system. The public tend to prefer opt-in and mandatory choice over opt-out when several options are offered. Interpretation: The assumption that people in opt-out countries are aware of the legal requirements to be excluded from the pool of potential donors is not supported by the results of this review. This is a concern, since ignorance hinders people's autonomy regarding organ donation decision-making. Higher awareness of consent model in opt-in countries may reflect greater efforts to inform the public through

campaigns to motivate donation. Legal moves towards opt-out are at odds with people's expressed preferences. Main limitations of this review are the lack of data from some countries, study population heterogeneity, and methodological shortcomings.

### **Vaccine Controversies: the Case for Freedom and Informed Consent**

*Guest Editorial*

Jane M. Orient

**Journal of American Physicians and Surgeons, September 2019; 24(3)**

*Excerpt*

...There is increasing pressure to add HPV vaccine to the long list of vaccines already mandated for school attendance, and to reduce exemptions for all vaccines. In California, which already eliminated all exemptions except medical ones, proposed legislation would severely constrain permitted contraindications and subject physicians who write for exemptions to intense scrutiny. AAPS has written letters to several state legislatures concerning the need for informed consent for all medical interventions, including vaccines, and a statement to congressional committees opposing federal vaccine mandates.<sup>5</sup> Other than AAPS and a new organization, Physicians for Informed Consent (<https://physiciansforinformedconsent.org/>), medical organizations generally do not oppose mandates...

### **(Un)informed Consent: Studying GDPR Consent Notices in the Field**

Christine Utz, Martin Degeling, Sascha Fahl, Florian Schaub, and Thorsten Holz. 2019

**2019 ACM SIGSAC Conference on Computer and Communications Security (CCS '19), November 11–15, 5 September 2019**

*Abstract*

Since the adoption of the General Data Protection Regulation (GDPR) in May 2018 more than 60 % of popular websites in Europe display cookie consent notices to their visitors. This has quickly led to users becoming fatigued with privacy notifications and contributed to the rise of both browser extensions that block these banners and demands for a solution that bundles consent across multiple websites or in the browser. In this work, we identify common properties of the graphical user interface of consent notices and conduct three experiments with more than 80,000 unique users on a German website to investigate the influence of notice position, type of choice, and content framing on consent. We find that users are more likely to interact with a notice shown in the lower (left) part of the screen. Given a binary choice, more users are willing to accept tracking compared to mechanisms that require them to allow cookie use for each category or company individually. We also show that the widespread practice of nudging has a large effect on the choices users make. Our experiments show that seemingly small implementation decisions can substantially impact whether and how people interact with consent notices. Our findings demonstrate the importance for regulation to not just require consent, but also provide clear requirements or guidance for how this consent has to be obtained in order to ensure that users can make free and informed choices.

### **Concise Consent Forms Appreciated—Still Not Comprehended: Applying Revised Common Rule Guidelines in Online Studies**

*Research Article*

Evan K. Perrault, Seth P. McCulloch

**Journal of Empirical Research on Human Research Ethics, 6 June 2019; 14(4)**

*Abstract*

As informed consent documents have historically gotten lengthier, recent revisions to federal Common Rule guidelines now require consent forms that are “concise” and presented in ways that “facilitate comprehension.” The current research sought to apply these guidelines by developing a consent process for an online study that was only 71 words and also allowed participants a choice to either continue directly to

the study or learn more about the study to which they were consenting. All participants (100%, N = 429) decided to continue directly to the study, choosing to forgo additional information about the study and the institutional review board (IRB) approval process. Participants indicated they liked this streamlined consent process, even though on average they only comprehended about half of the information this streamlined process contained. A plurality of participants indicated they would like to see this style of streamlined consent continued in future online studies. However, if we want to continue referring to informed consent as informed, future research should be welcomed and supported by IRBs to seek ways to apply the newest Common Rule guidelines while increasing comprehension; otherwise, informed consent will likely always remain an oxymoron.

### **Broad-scale informed consent: A survey of the CTSA landscape**

Redonna Chandler, Kathleen T. Brady, Rebecca N. Jerome, Milton Eder, Erin Rothwell, Kimberly A. Brownley, Paul A. Harri

**Journal of Clinical and Translational Science, 27 June 2019**

*Open Access*

*Abstract*

*Introduction*

Research opportunities associated with the proliferation of the electronic health record (EHR), big data initiatives, and innovative approaches to trial design can present challenges for obtaining and documenting informed consent. Broad-scale informed consent (a term used herein to describe institutional models, rather than the Common Rule's strict regulatory definition for "broad consent") may facilitate the use of existing data and samples and speed the pace of research by minimizing barriers to consent. We explored the use of broadscale informed consent within the Clinical Translational Science Award (CTSA) Program Network.

*Methods*

We surveyed CTSA Hubs concerning policies, practices, experiences, and needs within three domains of broad-scale informed consent: (1) participant recontact; (2) biospecimens; and (3) clinical data sharing.

*Results*

Of 61 CTSA Hubs surveyed, 37 (61%) indicated ongoing work related to at least 1 domain of broad-scale informed consent; 18 Hubs (30%) reported work in all 3 domains. The EHR predominated as the implementation system across all three domains. Research and IT leadership and the Institutional Review Board were most commonly endorsed as institutional drivers, while systems/technical issues and impact on clinical workflow were the most commonly reported barriers.

*Conclusions*

While survey results indicate considerable variability in the implementation of broad-scale informed consent across the CTSA consortium, it is clear that all CTSA Hubs are actively considering policy and process related to these concepts. Next steps cluster within three areas: training and workforce development, streamlined policies and templates, and implementation strategies that facilitate integration into clinical workflow.

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### **FREE PRIOR INFORMED CONSENT**

### **From Individual to Collective Consent: The Case of Indigenous Peoples and UNDRIP**

*Research Article*

Richard Healey

**International Journal on Minority and Group Rights, 13 September 2019**

*Abstract*

Much of the debate around requirements for the free, prior, and informed consent of indigenous peoples has focused on enabling indigenous communities to participate in various forms of democratic decision-making

alongside the state and other actors. Against this backdrop, this article sets out to defend three claims. The first two of these claims are conceptual in nature: (i) Giving (collective) consent and participating in the making of (collective) decisions are distinct activities; (ii) Despite some scepticism, there is a coherent conception of collective consent available to us, continuous with the notion of individual consent familiar from discussions in medical and sexual ethics. The third claim is normative: (iii) Participants in debates about free, prior, and informed consent must keep this distinction in view. That is because a group's ability to give or withhold consent, and not only participate in making decisions, will play an important role in realising that collectives' right to self-determination.

*Editor's note: The UNDRIP is the United Nations Declaration of the Rights of Indigenous Peoples*

### **The Transformative Potential of Indigenous-Driven Approaches to Implementing Free, Prior and Informed Consent: Lessons from Two Canadian Cases**

*Research Article*

Martin Papillon, Thierry Rodon

**International Journal on Minority and Group Rights, 13 September 2019**

*Abstract*

While it is increasingly recognised as a core element of the emerging international Indigenous rights regime, the implementation of the principle of free, prior and informed consent (FPIC) remains contested. As the comparative literature shows, if and how fpic is implemented depend both on the institutional context and on the agency of actors involved. Faced with deep power asymmetries and strong institutional resistance to their understanding of fpic as a decision-making right, a number of Indigenous groups in Canada have taken advantage of the uncertain legal context to unilaterally operationalise fpic through the development of their own decision-making mechanisms. Building on two case studies, a mining policy adopted by the Cree Nation of James Bay and a community-driven impact assessment process established by the Squamish Nation, this article argues Indigenous-driven mechanisms can be powerful instruments to shape how fpic is defined and translated in practice.

### **Mobilising Free, Prior and Informed Consent (FPIC) from Below: A Typology of Indigenous Peoples' Agency**

*Research Article*

Almut Schilling-Vacaflor, Riccarda Flemmer

**International Journal on Minority and Group Rights, 30 Aug 2019**

*Abstract*

Based on rich empirical data from Bolivia, Colombia, and Peru – the three Latin American countries where the implementation of prior consultation processes is most advanced – we present a typology of indigenous peoples' agency surrounding prior consultation processes and the principle of free, prior and informed consent (FPIC). The typology distinguishes between indigenous actors (1) mobilising for a strong legal interpretation of FPIC, (2) mobilising for meaningful and influential FPIC processes, (3) mobilising against prior consultation processes, and (4) blockading prior consultation processes for discussing broader grievances. We identify the most prominent indigenous strategies related to those four types, based on emblematic cases. Finally, we critically discuss the inherent shortcomings of the consultation approach as a model for indigenous participation in public decision-making and discuss the broader implications of our findings with regard to indigenous rights and natural resource governance.

### **The Politics of Free, Prior and Informed Consent: Indigenous Rights and Resource Governance in Ecuador and Yukon, Canada**

*Research Article*

Roberta Rice



*Abstract*

What are the institutional arrangements required to implement a genuine process of free, prior and informed consent (fpic)? This article provides a comparative perspective on the politics of consent in the context of relations between Indigenous peoples, states and extractive industries in Canada and Latin America. The case of Ecuador is presented as an emblematic example of a hybrid regime in which Indigenous communities have the right to free, prior and informed consultation, not consent, concerning planned measures affecting them, such as mineral, oil and gas exploitation. In the case of Yukon, Canada, the settlement of a comprehensive land claim with sub-surface mineral rights has provided the institutional basis for the implementation of a genuine fpic process, one that includes participatory decision-making power over natural resource development projects. The article concludes with a discussion on the necessary conditions for moving governments from a consultation to a consent regime.

**Sustainable exploitation of natural resources in Kenya : a case for communities' free, prior and informed consent in oil and gas projects**

Rodgers Otieno Odhiambo

**Africa Nazarene University Law Journal, 2019; 7(1) pp 1 - 23**

*Abstract*

This article attempts to analyse the development of free, prior and informed consent (FPIC) as an international law principle, its nature and its essence. Further, the article seeks to illustrate the advantages of the principle in natural resource development. Indeed, the principal aim of this article is to bring the development of an international law principle useful in the exploitation of natural resources to the attention of Kenyan legal scholars and policymakers. This is crucial in the context of Kenya which has no experience in the exploration and exploitation of oil and gas, and in view of the fact that the country has embarked on various legal and policy reforms within the extractive sector. Being a frontier market, Kenya needs to learn the nuances within the oil and gas sector. It would therefore be imperative to examine the jurisprudence of international bodies and the activities of other international actors with regard to communities' participatory rights, while recognising that a new standard of international law has developed which recognises that there is a duty to obtain the FPIC of local and indigenous communities when undertaking extraction of natural resources activities within their locality. Thus, the paper seeks to explore the development of the duty to obtain FPIC in international instruments such as declarations, treaties and Acts by international bodies. The article concludes by making a strong case for the entrenchment of FPIC within the policy and legal framework governing the extractive sector in Kenya.

**Indigenous Peoples, Consent and Rights; Troubling Subjects [Book]**

Stephen Young

**Routledge, 19 December 2019; 272 pages**

*Summary*

Analysing how Indigenous Peoples come to be identifiable as bearers of human rights, this book considers how individuals and communities claim the right of free, prior and informed consent (FPIC) as Indigenous peoples.

The basic notion of FPIC is that states should seek Indigenous peoples' consent before taking actions that will have an impact on them, their territories or their livelihoods. FPIC is an important development for Indigenous peoples, their advocates and supporters because one might assume that, where states recognise it, Indigenous peoples will have the ability to control how non-Indigenous laws and actions will affect them. But who exactly are the Indigenous peoples that are the subjects of this discourse? This book argues that the subject status of Indigenous peoples emerged out of international law in the late 1970s and early 1980s. Then, through a series of case studies, it considers how self-identifying Indigenous peoples, scholars, UN institutions and NGOs dispersed that subject-status and associated rights discourse through international and



national legal contexts. It shows that those who claim international human rights as Indigenous peoples performatively become identifiable subjects of international law – but further demonstrates that this does not, however, provide them with control over, or emancipation from, a state-based legal system. Maintaining that the discourse on Indigenous peoples and international law itself needs to be theoretically and critically re-appraised, this book problematises the subject-status of those who claim Indigenous peoples' rights and the role of scholars, institutions, NGOs and others in producing that subject-status. Squarely addressing the limitations of international human rights law, it nevertheless goes on to provide a conceptual framework for rethinking the promise and power of Indigenous peoples' rights...

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## **MEDICAL/SURGICAL**

### **To Consent, or Not to Consent, That Is the Question; Ethical Issues of Informed Consent for the Use of Donor Human Milk in the NICU Setting**

Kelly McGlothen-Bell, Lisa Cleveland, Britt Frisk Pados

**Advances in Neonatal Care, October 2019; 19 (5) pp 371–375**

#### *Abstract*

#### *Background*

Evidence supports the superiority of mother's own milk (MOM) in reducing the comorbidities common to prematurity and very low birth weight. In situations where an insufficient amount of MOM is available or maternal contraindications prevent its use, pasteurized donor human milk (DHM) is a viable substitution. When DHM is deemed best, a common practice in many neonatal intensive care units (NICUs) is for parents to provide their consent. However, no universal mandate for informed consent exists. Often, healthcare providers present and obtain the consent for DHM use prior to delivery or shortly after birth and this consent may be “bundled” along with other standardized NICU treatment consents. This approach is likely less than ideal since it provides insufficient time for decision making and often precedes the mother's ability to initiate the expression of her own milk.

#### *Purpose*

To review the history of DHM use and the ethics surrounding the consenting process including the ethical principles involved in infant feeding decision making. We argue for the standardization and consistent use of informed consent for DHM in the NICU and offer clinical practice implications.

#### *Findings/Results/Implications for Practice and Research*

Providers face several challenges in the consenting process for the use of DHM in the NICU setting. These include limited time to support parents and educate them appropriately during the decision-making process. Standardized and consistent use of informed consent is essential to address the ethical concerns surrounding the use of DHM in the NICU setting.

### **Transplant candidates' perceptions of informed consent for accepting deceased donor organs subjected to intervention research and for participating in post-transplant research**

#### *Original Article*

Elisa J. Gordon, Elizabeth Knopf, Caitlin Phillips, Adam Mussell, Jungwha Lee, Robert M. Veatch, Peter Abt, Sue Dunn, Peter P. Reese

**American Journal of Transplantation, 24 September 2019**

#### *Abstract*

Deceased donor organ intervention research holds promise for increasing the quantity and quality of organs for transplantation by minimizing organ injury and optimizing function. Such research will not progress until ethical, regulatory, and legal issues are resolved regarding whether and how to obtain informed consent from transplant candidates offered intervention organs given time constraints intrinsic to distribution. This

multi-center, mixed-methods study involved semi-structured interviews using open- and closed-ended questions to assess wait-listed candidates' preferences for informed consent processes if offered an organ after undergoing intervention. Data were analyzed thematically. Sixty-one candidates participated (47% participation rate). Most were male (57%), white (61%), with a mean age of 56 years. Most candidates (79%) desired being informed that the organ offered was an intervention organ before accepting it, and were likely to accept an intervention organ if organ quality was good (defined as donor age 30) (81%), but fewer candidates would accept an intervention organ if quality was moderate (i.e., donor age 50) (26%). Most perceived informed consent important for decision-making, while others considered it unnecessary given medical necessity to accept an organ and trust in their physician. Our findings suggest that most candidates desire an informed consent process before accepting an intervention organ and post-transplant data collection.

### **Informed consent guidelines for ionising radiation examinations: A Delphi study**

C.W.E.Younger, C.Douglas, H.Warren-Forward

**Radiography, 16 September 2019**

*Abstract*

*Introduction*

Informed consent for ionising radiation medical imaging examinations is currently undertaken inconsistently in Australian radiographic practice. There is no uniform informed consent process, and opinions vary about how it should be undertaken, and by whom, if indeed it needs to be undertaken at all.

To ensure that patients' rights are maintained, the informed consent process must be consistent, proactive in the provision of information, and must empower the patient to formulate and ask questions about their care, and to make voluntary decisions.

*Methods*

The Delphi technique utilises a group of experts whose individual responses are used to create a collective consensus on a process. This ten-expert (five radiographer, five radiologist) Delphi study examined a basic modelling of the process of informed consent for ionising radiation medical imaging examinations and made recommendations for an ideal process.

*Results*

A series of consensus statements were developed, seeking to rectify areas of the process that were inconsistent, unclear, or ethically unsound. These statements were then considered alongside current codes of professional practice, and Australian law on the duty of disclosure. A model of the ideal process was then developed using these consensus statements and adhering to codes of practice.

*Conclusion*

The final process model has a continuity of care and a continuity of information provision. The model eliminates the radiographer as a delegatee, and emphasises physician involvement. The referrer and the radiologist have a shared responsibility of providing risk disclosure information.

*Implications for Practice*

For a non-pregnant adult, the ionising radiation dose from conventional radiography is considered insignificant, and does not require risk disclosure, ameliorating the time commitment needed for the process.

### **Balancing values and obligations when obtaining informed consent: healthcare professionals' experiences in Swedish paediatric oncology**

*Regular Article*

Anna Schröder Håkansson, Pernilla Pergert, Jonas Abrahamsson, Margaretha Stenmarker

**Acta Paediatrica Nurturing the Child, 13 September 2019**

*Abstract*

*Aim*

To explore Swedish healthcare professionals' (HCPs) clinical experiences of the informed consent process (ICP) and to compare experiences between the professions.

#### *Methods*

In this nationwide study six paediatric oncologists (POs) and eight research nurses (ReNs) from all Swedish paediatric oncology centres were interviewed. The material was analysed using Grounded theory, a qualitative constant comparative method.

#### *Results*

The participants' main concern was how to fulfil research obligations without putting too much strain on a family in acute crisis, which led to the core category of balancing values and obligations of both healthcare and research. To handle the challenges the participants' struggled to safeguard the families from psychological harm, tried to adjust to the families, and gradually introduced research while building trust. The conceptual model developed in the study highlights potential consequences of this balancing act with a risk of diminishing the family's autonomy through HCPs acting authoritatively (in particular POs) or with overprotection (in particular ReNs).

#### *Conclusion*

Paediatric oncology is a research integrated healthcare environment. The HCPs need personal, professional and institutional support regarding ICP-related ethical issues, decisions and implications in this intertwined context. Furthermore, HCPs need to be aware of the potential long-term risk of developing professional moral distress.

### **“Uninformed” Consent: Patient Recollection From Surgical Consent in Hand Surgery—A Quality Improvement Initiative**

#### *Research Article*

Monica Yu, Herbert P. von Schroeder

**HAND, 5 September 2019**

#### *Abstract*

##### *Background*

Informed surgical consent is necessary and routine; however, it can have significant inadequacies. Our purpose was to investigate patient recollection of the surgical consent process and evaluate adequacy from the patient's perspective.

##### *Methods*

A quality improvement framework was used. Two patient surveys capturing information recall and satisfaction of the consent process were administered in 5 consecutive hand clinics. All patients who previously underwent elective hand surgery were included.

##### *Results*

There was exceptionally low recall of the risks and benefits of surgery in 103 consecutive patients who underwent hand surgery. Patients under age 35 had slightly better recall of surgical risks. Unexpected postoperative events affected patient perceptions of the consent process.

##### *Conclusions*

Patients who have undergone elective hand surgery have poor recollection of the information discussed during the surgical consent process, and therefore the process is lacking. Surgeons may falsely assume that the consent process is sound because it is erroneously perceived as being sufficient by most patients.

### **Is There a Difference Between the Readabilities of Informed Consent Forms Used for Elective and Emergency Procedures in Turkey?**

#### *Research Article*

Mehmet Giray Sönmez, Leyla Öztürk Sönmez, Betül Kozanhan, Zerrin Defne Dündar

**Therapeutic Innovation & Regulatory Science; 5 September 2019**

#### *Abstract*

### *Background*

Informed consent is an important aspect of ethical medical practice. In legal terms, making an intervention without informed consent may mean negligence or malpractice and may lead to legal action, maltreatment, and even attack against the doctor. This study aims to evaluate the readability of informed consent forms (ICFs) used for elective (urology and general surgery) and emergency procedures (emergency medicine and intensive care) by comparing through readability formulas.

### *Methods*

Elective and emergency ICFs were accessed through the web sites of national health care associations. A total of 387 consent forms were evaluated and the same forms were included only once. A total of 35 consent forms were evaluated for emergency procedures, while a total of 55 consent forms were evaluated for elective procedures. Ateşman and Bezirci-Yılmaz formulas defined for determining the readability level of Turkish texts and Gunning fog and Flesch Kincaid formulas measuring the general readability level were used for calculating the readability level of consent forms.

### *Results*

Even though elective ICFs are more readable compared to those of emergency procedures according to Bezirci-Yılmaz formulas, this was statistically insignificant ( $P = .54$ ). The readability of elective consent forms was found to be at a significantly more difficult level to read compared to Ateşman, Gunning fog, and Flesch Kincaid formulas ( $P = .002$ ,  $P < .001$ ,  $P < .001$ , respectively).

### *Conclusion*

Even though the procedure is emergency or elective, a difficult readability level may cause problems for the doctor in legal phases. Readable and understandable consent forms should be available to be able to explain morbidity and mortality and improve prognosis. Education level of our country should also be considered while preparing these consent forms.

## **Utilization of a Parental Approach to Informed Consent in Intravenous Tissue Plasminogen Activator Administration Decision-Making: Patient Preference and Ethical Considerations**

### *Research Article*

Ann M. Murray, Ashley B. Petrone, Amelia K. Adcock

**Neurology Research International, 5 September 2019**

### *Abstract*

#### *Objective*

While administration of intravenous tissue plasminogen activator (IV-tPA) is the standard of care in acute ischemic stroke and has been shown to have statistically significant benefit, there can also be potentially life-threatening complications; however, there is no standard informed consent approach. (e purpose of this study was to present a parental, technical, and general model of informed consent for IV-TPA and to determine which approach was preferred.

#### *Methods*

Survey respondents were asked to hypothetically decide whether or not to provide consent for their family member to receive IV-tPA. Respondents were presented with 3 informed consent models: one emphasizing parental qualities, one emphasizing statistical data, and one representing a general consent statement. After being presented each model, the respondents had to select their preferred consent model, as well as rate their level of agreeability toward their family member receiving the medication following each approach.

#### *Results*

(e results of 184 surveys showed respondents were equally as likely to give consent for their family member to receive IVTPA following all three approaches; however, respondents were significantly more likely to prefer the parental approach compared to a technical or general approach.

#### *Conclusion*

Our results indicate that while paternalism is generally discouraged in the medical community, some degree of parental language may be preferred by patients in tough decision-making situations toward consent to receive medical interventions.

## **Signature Informed Consent for Long-Term Opioid Therapy in Patients with Cancer: Perspectives of Patients and Providers**

### *Original Article*

Karleen Giannitrapani, Soraya Fereydooni, Azin Azarfar, Maria J. Silveira, Peter A. Glassman, Amanda Midboe, Amy Bohnert, Maria Zenoni, Robert D. Kerns, Robert A. Pearlman, Steven M. Asch, William Becker, Karl A. Lorenz

**Journal of Pain and Symptom Management, 30 August 2019**

### *Abstract*

#### *Context*

Signature informed consent (SIC) is a part of a Veterans Health Administration (VHA) ethics initiative for patient education and shared decision-making with long-term opioid therapy (LTOT). Historically, patients with cancer-related pain receiving LTOT are exempt from this process.

#### *Objectives*

Our objective is to understand patients' and providers' perspectives on using signature informed consent for LTOT in patients with cancer-related pain.

#### *Methods*

Semi-structured interviews with 20 opioid prescribers and 20 patients who were prescribed opioids at two large academically-affiliated VHA Medical Centers. We employed a combination of deductive and inductive approaches in content analysis to produce emergent themes.

#### *Results*

Potential advantages of SIC are that it can clarify and help patients comprehend LTOT risks and benefits, provide clear upfront boundaries and expectations, and involve the patient in shared decision-making. Potential disadvantages of SIC include time delay to treatment, discouragement from recommended opioid use, and impaired trust in the patient-provider relationship. Providers and patients have misconceptions about the definition of SIC. Providers and patients question if SIC for LTOT is really informed consent. Providers and patients advocate for strategies to improve comprehension of SIC content. Providers had divergent perspectives on exemptions from SIC. Oncologists want SIC for LTOT to be tailored for patients with cancer.

#### *Conclusion*

Provider and patient interviews highlight various aspects about the advantages and disadvantages of requiring SIC for LTOT in cancer-related pain. Tailoring SIC for LTOT to be specific to cancer related concerns and to have an appropriate literacy level are important considerations.

# # # #

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