This digest is intended to aggregate and distill 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.

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**GENERAL**

**A Survey on Including Risks in the New “Key Information” Section of an Informed Consent Form**
Katelyn Le, Stacy Kopka, Doreen Chaitt, Jerome Pierson, Martha Nason, Tracey Miller
Clinical Research (Alex), _December 2018_; 32(10) pp 18–29

**Abstract**
Informed consent forms (ICFs) are growing longer and more complex.[1–4] The forces behind this trend may be well-intentioned, such as the desire to disclose more accurate and complete information[1]; however, it raises questions about whether important information is buried in lengthy documents, as well as whether ICFs can be structured to better emphasize the information that is most relevant to a study participant. Recent updates to what is generally known as the Common Rule for protection of human subjects in research are in part meant to respond to this trend. Among these updates is the introduction of a new section called “Key Information”—every ICF now must open with the most important information that potential subjects would want to know when deciding to join a study. But what exactly should this new section contain?
This question is crucial to us, a group of writers and reviewers who work with investigators to develop ICFs (the program was described in a 2013 issue of the ACRP Monitor). For groups like ours, it is important to explore how best to implement the new regulations in a way that promotes consistency across different ICFs.

As an initial step, we wanted to understand how to objectively decide which risks to provide as Key Information. A survey was conducted to investigate how institutional review board (IRB) members, medical monitors, and principal investigators (PIs) view which risks should be considered Key Information. The hypothesis was that cohorts would have differing viewpoints on selecting these risks. While the findings of this exploratory study demonstrate variability in viewpoints, they also suggest a number of points of consensus to consider when writing Key Information.

**The ethics of consent**

Peter Ellis  
Journal of Kidney Care, **13 February 2019**; 4(1)  
*Abstract*  
As healthcare professionals, we come into contact with patients on a daily basis, and it is important that the professional relationship we develop with our patients is one built on respect and trust. One important element of this is gaining consent. In this article, Peter Ellis explores what consent is, why it is important and when and how it should be gained.

**The Ever-Changing Landscape of Informed Consent and Whether the Obligation to Explain a Procedure to the Patient May Be Delegated**

Samuel D. Hodge, Maria Zambrano Steinhaus  
Arkansas Law Review, **January 2019**; 71(3)  
*Abstract*  
Informed consent is an integral part of the shared decision making process and requires a patient be informed of the benefits, risks and alternatives to a medical procedure. This information, which requirement has been codified into the law and practice of every healthcare provider, helps a patient decide whether to proceed with the recommended treatment plan. Informed consent has its foundation in the ethical notion of patient autonomy and fundamental human rights. After all, it is the patient’s decision to determine what may be done to his or her body and to ascertain the risks and benefits before undertaking a procedure. On the other hand, a physician’s role is to act as a facilitator in the patient’s decision making process by providing information about the planned treatment and to answer questions. While the roles of the patient and physician seem clearly defined, a number of barriers present challenges in creating a process that guarantees a patient understands a test or procedure. This includes ineffective communication between the doctor and patient. The first part of this article will explore the liability of various health care providers who participate in the informed consent process, such as the physician, nurse, physician assistant and hospital. The second section will examine whether the treating physician may delegate the duty to explain the risks and alternatives of a procedure to another. The controversial decision of Shinal v. Toms, which mandates that the doctor must have a one-on-one exchange with the patient in order to secure a valid informed consent, will also be explored. This recent ruling has sent shock waves throughout the medical community causing a reexamination of their informed consent policies.  

[Editor’s Note: Information on the Shinal v. Toms case can be found here]

**Autonomy Challenges in Epigenetic Risk-Stratified Cancer Screening: How Can Patient Decision Aids Support Informed Consent?**

Maaike Alblas, Maartje Schermer, Yvonne Vergouwe, Ineke Bolt  
Journal of Personalized Medicine, **18 February 2019**; 9(1)  
*Abstract*
Information of an individual's epigenome can be useful in cancer screening to enable personalised decision making on participation, treatment options and further screening strategies. However, adding this information might result in complex risk predictions on multiple diseases, unsolicited findings and information on (past) environmental exposure and behaviour. This complicates informed consent procedures and may impede autonomous decision-making. In this article we investigate and identify the specific features of epigenetic risk-stratified cancer screening that challenge the current informed consent doctrine. Subsequently we describe current and new informed consent models and the principle of respect for autonomy and argue for a specific informed consent model for epigenetic risk-stratified screening programmes. Next, we propose a framework that guides the development of Patient Decision Aids (PDAs) to support informed consent and promote autonomous choices in the specific context of epigenetic cancer screening programmes.

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**YOUNG PERSONS**

**Consent for HIV Testing Among Adolescent Sexual Minority Males: Legal Status, Youth Perceptions, and Associations with Actual Testing and Sexual Risk Behavior**

Kimberly M. Nelson, Kristen Underhill, Michael P. Carey

AIDS and Behavior, 12 February 2019; pp 1-6

**Abstract**

This brief report presents a preliminary investigation of the relations between minor consent laws for HIV testing/treatment and testing behavior among adolescent sexual minority males (ASMM; N = 127; ages 14–17). Most participants had legal capacity to consent without parental/guardian permission (HIV testing: 79%; HIV testing/treatment: 65%). Despite having this legal right, few (15%) had ever tested. Capacity to consent was not associated with HIV testing in this sample; nevertheless, those who had not disclosed their sexual activity to parents/guardians were less likely to have tested. Confidentiality concerns may be a barrier to testing for these youth despite laws intended to enable independent testing.

**Improving the informed consent process among HIV-infected undisclosed minors participating in a biomedical research: insights from the multicenter SNACS study in Senegal**

Fabienne Hejoaka, Marie Varloteaux, Caroline Desclaux-Sall, Sidy Mokhtar Ndiaye, Karim Diop, Aminata Diack, Fatou Niasse, Cecile Cams

Tropical Medicine & International Health, 9 January 2019; 24(3) pp 294-303

**Objectives**

Providing research information in a manageable way to minors participating in biomedical research is a major challenge. Guidance is dramatically lacking regarding best practices for seeking informed consent among undisclosed minors enrolled in HIV-related research. We implemented an informed consent process (IICP) and identified factors associated with the presentation of HIV-infected minors in their studies.

**Methods**

We enrolled study participants attending 12 pediatric HIV clinics in Senegal. Children ≥7 years were provided with standardized IICP, which involves viewing a video and taking part in extended group discussions. Was evaluated by seven basic questions scored 1 or 2 points, with a maximum score of 11 points. A score of 9 or more points. Factors associated with understanding were identified using a stepwise logistic regression model.

**Results**

Overall, 112 children, with a median age of 12.9 years (IQR: 10.2-15.0), participated in the IICP, of whom 37% were HIV disclosed. 71% achieved a satisfactory understanding and gave consent to participate in the research. HIV-infected children were more likely than children to be infected (aOR = 3.2, 95% CI: 1.1-9.6). Age, study and education level were not associated with satisfactory understanding.
Conclusion
These findings provide for guidance in the development of the business of business. The implementation of the pediatric HIV research agenda will require a standardized and operational definition of informed consent, integrating the issue of HIV disclosure.

An Urban Bioethics Approach to Parental Informed Consent for Pediatric Clinical Research
[DISSERTATION]
Flanagan, Ellen
Cecelia Temple University, December 2018
Abstract
In the current healthcare landscape, parents generally make decisions regarding whether or not their children are allowed to take part in clinical research, with the general assumption being that parents know what is best for children. Investigations have been conducted regarding what is likely to lead parents to consent or not consent to their child’s participation in a trial, but research plans seldom incorporate the consideration that not all parents come into the consent process with equal social, academic, and economic footing. Since the burden of the ultimate decision lies primarily on the parents, it is supremely important that they are capable of making a well-informed and thoughtful choice. Bioethical understanding of the influence of parental decisions in clinical research must consider demographic variables and how they may affect parents’ decisions to allow or disallow their child to participate in a clinical trial. Those differences could affect the consent process and have ramifications for the research findings, as research results are affected in numerous ways by which children do, and do not, participate in studies. This paper looks specifically at parents in the process of informed consent for pediatric research, taking into account several social determinants of health and how they affect who participates in research and how that affects research as a whole.

The complexities and contradictions in participatory research with vulnerable children and young people: A qualitative systematic review
Caroline Bradbury-Jones, Louise Isham, Julie Taylor
Social Science & Medicine, October 2018; 214 pp 1-214
Abstract
Participatory research carried out by or with children, has become a well-established and valuable part of the research landscape investigating children's lives, views and needs. So too has a critical agenda about its ethical implications and methodological complexities. One criticism is that the involvement of children who may be considered ‘vulnerable’ or ‘marginalised’ has been slower to take root within mainstream participatory practice. This means that there has been less focus on how groups such as disabled children or children affected by abuse or neglect can shape and challenge adult-dominated types of knowledge and decision-making that are likely to affect them. This article reports on the findings of a qualitative systematic literature review of thirteen contemporary papers. The review was undertaken by a UK team in 2017. The included articles explored some core ethical and methodological issues involved in carrying out participatory research with vulnerable children and young people. It reports on three themes: 1) The extent to which participatory spaces could recalibrate opportunities and attention given to marginalised and silenced groups; 2) The ways in which these children and young people could develop skills and exercise political and moral agency through participatory activity, and, 3) How to facilitate meaningful engagement with individuals and groups and reconcile this with a critical appreciation of the important but limited nature of research as means of political and social change. The review provides a unique, contemporary analysis of participatory research with vulnerable children, illuminating in particular its conceptual complexities and contradictions, particularly regarding power, empowerment and voice. Its overall utility and interest is augmented by the disciplinary and geographical breadth of the included articles, rendering it relevant to many contexts and countries.
COGNITIVE CHALLENGES

Who is informed and who uninformed? Addressing the legal barriers to progress in dementia research and care
Jiska Cohen-Mansfield
Israel Journal of Health Policy Research, 20 February 2019; 8(17)
Abstract
Conduct of research is an essential tool for the evaluation and improvement of health services. In Israel, research on persons with dementia is very limited, with the largest portion of such research involving a few surveys and examining risk factors for dementia. Very few studies describe clinical research, and those that do either include participants at early stages of dementia, or rely completely on caregivers’ perceptions and experiences, often without reference to any individual with dementia. This dearth of research is due, to a substantial extent, to Ministry of Health regulations which do not permit family proxy consent for research involving persons with dementia. Alternative models for regulation of consent for research exist in other countries, including the U.S., and these allow for proxy consent under certain conditions. This paper presents such a model and its underlying ethical principles. It contends that the current state of affairs, which stands in the way of clinical research concerning persons with advanced dementia, is contrary to the interests of such persons, their caregivers, and Israeli society. Therefore, this paper calls for a change in the present regulations and/or law in the cause of advancing knowledge and improving care for persons with dementia.

Consent when prescribing to dementia patients
Johnson, Chris
Australian Medicine, 4 February 2019; 31(2)
Abstract
Responsibility rests with doctors to obtain family consent before giving anti-psychotics to dementia patients in nursing homes, but administrators in the aged care facilities have the responsibility to administer them correctly.

CULTURAL CONTEXT

South African law may impede human health research
Linda Nordling
Science, 22 February 2019; 363(6429)
Summary
South Africa's varied population makes it a magnet for research on public health and human diversity. But a new privacy law called The Protection of Personal Information Act, scheduled to go into effect in 2020, could upend such research. The law aims to protect South Africans from abuse of their personal data and says that such information, including genetic data, must be collected for a specific purpose—and that data subjects need to be "aware of the purpose." But giant sample and data repositories called biobanks are transforming health research around the world by allowing multiple researchers to ask new questions of the same data. At a meeting in Cape Town on 4–5 February, lawyers, ethicists, and researchers discussed how the new South African rule could limit such secondary use of data and hamstring international collaborations.
Second Wave Due Diligence: The Case for Incorporating Free, Prior, and Informed Consent into the Deep Sea Mining Regulatory Regime
Julian Aguon, Julie Hunter
Stanford Environmental Law Journal, 10 February 2019; 38(1) pp 3-55

Abstract
This Article calls for the norm of free, prior, and informed consent (FPIC) for indigenous peoples to be applied to deep sea mining (DSM) projects carried out in the international seabed, particularly in the Pacific region, where numerous indigenous communities stand to be directly and disproportionately impacted by this new extractive industry. Our argument, while novel, relies on core prescriptions of Part XI of the United Nations Convention on the Law of the Sea (UNCLOS) requiring compliance with international law in general, including pertinent rules of international environmental and indigenous rights law. UNCLOS’s clear parameters on the prevention of harm to the marine environment, expounded upon by the International Tribunal for the Law of the Sea in a series of key decisions, have created a due diligence standard that is imposing ever higher duties on an increasingly wide range of actors, including in areas beyond national jurisdiction. This standard is evolving alongside a robust norm requiring the FPIC of indigenous peoples threatened by large-scale extractive activities, even if those activities are not directly carried out on indigenous land. When applied to DSM, whose exploratory stage has already resulted in an array of adverse impacts to Pacific indigenous peoples, these normative legal developments coalesce into a compelling argument for placing impacted indigenous peoples into key decision-making roles. Such an approach, which we call a “second wave” of due diligence, represents a decisive break from a destructive history in which the Pacific served as a proving ground for the experiments of others, and a concrete step toward sustainable, rights-based development in the twenty-first century and beyond.

Consent and its Medicolegal Aspects
Trupti Dani, Vijaya More, Manohar Sarangi

Abstract
The concept of consent comes from the ethical issue of respect for autonomy, individual integrity and self-determination. A more focused approach has been seen in matters related to Medical Negligence since the Consumer Protection Act (CPA) was made applicable to the Medical Profession. Cases of medical negligence are now being filed in consumer courts instead of the regular courts. That is why modern surgeons & Ayurveda practitioners should be aware about their regular duties and should not go under negligent act. While performing Ayurvedic procedure; every Ayurveda practitioner should be aware about medicolegal aspects regarding consent. This article is a preliminary approach to validate whether we can find solution for emerging medicolegal issues regarding consent in medical practice.

Malayna Raftopoulos, Damien Short
Forthcoming in the International Journal of Human Rights, 2019

Abstract
Over 21 years after the United Nations Declaration on the Rights of Indigenous Peoples (September 2007 – hereafter UNDRIP) was passed, it is useful to examine the functionality and utility of a core principle it contains- the notion of Free Prior and Informed Consent (FPIC) with respect to the twin challenges of environmental destruction and a key ‘mitigation’ policy: REDD+. While UNDRIP, and to a lesser extent, the International Labour Organisation Convention No. 169 (ILO 169) has strengthened the legal status of FPIC, its application has proved to be extremely difficult. This article argues that when considering the potential harm of environmental and REDD+ climate change policies there needs to be a greater emphasis placed on the
‘precautionary principle’ when applying FPIC. Demonstrating why precaution needs to be taken in order to ensure human rights, this article argues that increasing the prominence of the precautionary principle within FPIC can impact significantly on the protection of biodiversity as well as the way in which environmental harm, laws and regulations are understood in relation to their social and cultural impact and shape future responses to the climate change crisis.

SURGICAL

Informed Consent for Neurosurgical Innovation [BOOK CHAPTER]
Faith C. Robertson, Tiit Mathiesen, Marike L. D. Broekman
Ethics of Innovation in Neurosurgery, 22 February 2019; pp 11-25
Abstract
While innovation in neurosurgery introduces novel medical devices, lifesaving therapies, and critical advancements in procedural care, it also presents ethical challenges regarding informed consent, particularly as innovative treatment options may provide better patient outcomes, but unprecedented surgical interventions may include unknown risk. The process of informed consent relies on appropriate provision of information to a competent patient in efforts to permit patient autonomy over healthcare decision-making without coercion. Importantly, informed consent is not isolated to a single conversation and document signing but is rather an ongoing process of communication throughout the trajectory of the patient’s care. However, neurosurgical patients are one of the most vulnerable populations, as those eligible for experimental procedures often have illnesses refractory to standard therapies, and alternative treatments may be limited. Furthermore, for disease processes affecting information processing or the ability to participate in high-level cognitive decision-making, an individual’s capacity to partake in informed consent may be hindered. At present, there is limited guidance for how neurosurgeons should approach the informed consent process for novel treatments, and there is controversy over the extent to which a surgeon should discuss the innovative nature of the procedure, the evidence or lack thereof, the associated or unknown risks and benefits, the operating surgeon’s learning curve with respect to experience with the procedure, and the alternative treatment options. This chapter summarizes the importance and difficulties of informed consent within neurosurgery, including patient capacity, content and format of discussion, and coercion—all key factors in the attainment of proper consent and the clinical decision process. We underscore the inherent complexity in balancing scientific evidence, clinical expertise, and patient and family preference when pursuing innovative neurosurgical treatments, in efforts to bring about discussion on improvements we can make within the field. Ultimately, this moral discourse is invaluable in creating a situation where investigators assume a responsibility of ensuring respect for persons, beneficence, and justice as we work to propel the field of neurosurgery forward.

Factors complicating the informed consent process for whole exome sequencing in neonatal and pediatric intensive care units
CJ Diamonstein
Journal of genetic counseling, 8 February 2019; Special Issue
Abstract
Whole exome and whole genome sequencing (WES/WGS) is increasingly utilized in inpatient settings such as neonatal and pediatric intensive care units (ICU), but no research has explored the process of informed consent in this setting. My experience as an inpatient genetic counselor has illuminated factors unique to the ICU that may threaten elements of informed consent such as voluntariness, disclosure, understanding, and capacity. I present three cases that exemplify elements complicating consent counseling for WES/WGS in the ICU, including the emotional state of the parents, involvements of other healthcare providers, environmental
distractions and competing clinical priorities. I offer strategies to navigate these factors based on my experience.

MEDCIAL RESEARCH

Informed consent for functional MRI research on comatose patients following severe brain injury: balancing the social benefits of research against patient autonomy
Tommaso Brunì, Mackenzie Graham, Loretta Norton, Teneille Gofton, Adrian M Owen, Charles Weijer
Journal of Medical Ethics, 25 February 2019; Open Access
Abstract
Functional MRI shows promise as a candidate prognostication method in acutely comatose patients following severe brain injury. However, further research is needed before this technique becomes appropriate for clinical practice. Drawing on a clinical case, we investigate the process of obtaining informed consent for this kind of research and identify four ethical issues. After describing each issue, we propose potential solutions which would make a patient’s participation in research compatible with her rights and interests. First, we defend the need for traditional proxy consent against two alternative approaches. Second, we examine the impact of the intensive care unit environment on the informed consent process. Third, we discuss the therapeutic misconception and its potential influence on informed consent. Finally, we deal with issues of timing in recruiting participants and related factors which may affect the risks of participation.

Well informed physician-patient communication in consultations on back pain – study protocol of the cluster randomized GAP trial
Sebastian Voigt-Radloff, Andrea C. Schöpf, Martin Boeker, Luca Frank, Erik Farin, Klaus Kaier, Mirjam Körner, Katharina Wollmann, Britta Lang, Joerg J. Meerpohl, Ralph Möhler, Wilhelm Niebling, Julia Serong, Renate Lange, Piet van der Keylen, Andy Maun
BMC Family Practice, 25 February 2019; 20(33)
Background
Back pain is one of the most frequent causes of health-related work absence. In Germany, more than 70% of adults suffer from at least one back pain episode per annum. It has strong impact on health care costs and patients’ quality of life. Patients increasingly seek health information on the internet. However, judging its trustworthiness is difficult. In addition, physicians who are being confronted with this type of information often experience it to complicate the physician-patient interaction. The GAP trial aims to develop, implement and evaluate an evidence-based, easy-to-understand and trustworthy internet information portal on lower back pain to be used by general practitioners and patients during and after the consultation. Effectiveness of GAP portal use compared to routine consultation on improving communication and informedness of both physicians and patients will be assessed. In addition, effects on health care costs and patients’ days of sick leave will be evaluated.
Methods
We will conduct a prospective multi-centre, cluster-randomized parallel group trial including 1500 patients and 150 recruiting general practitioners. The intervention group will have access to the GAP portal. The portal will contain brief guides for patients and physicians on how to improve the consultation as well as information on epidemiology, aetiology, symptoms, benefits and harms of treatment options for acute, sub-acute and chronic lower back pain. The GAP portal will be designed to be user-friendly and present information on back pain tailored for either patients or physicians in form of brief fact sheets, educative videos, info-graphics, animations and glossaries. Physicians and patients will assess their informedness and the physician-patient communication in consultations at baseline and at two time points after the consultations under investigation. Days of sick leave and health care costs related to back pain will be compared between control and intervention group using routine data of company health insurance funds.
Discussion
The GAP-trial intends to improve the communication between physicians and their patients and the informedness of both groups. If proven beneficial, the evidence-based and user-friendly portal will be made accessible for all patients and health professionals in back pain care. Inclusion of further indications might be implemented and evaluated in the long term.

Informed Consent and the Ethics of Placebo-Based Interventions in Clinical Practice [BOOK CHAPTER]
Marco Annoni, Franklin G. Miller
Placebos and Nocebos in Headaches, 12 February 2019; pp 135-142
Abstract
In this chapter we explore the ethics of informed consent with respect to the prescription of effective treatments, like acupuncture, that according to evidence-based standards have a prevalent placebo component. First, we review empirical studies demonstrating that placebo effects may significantly modulate symptoms in highly prevalent conditions, taking migraine as our case in point. Next, we chart the ethical implications of prescribing interventions that have been found slightly more effective than placebos and yet significantly better than no treatment—a class of remedies that we label as “placebo-based interventions.” We argue that, provided certain conditions are met, doctors may ethically prescribe placebo-based interventions in nondeceptive ways. By contrast, we contend the prescription of placebo treatments is incompatible with informed consent unless the true nature of the remedy is transparently disclosed to patients.

Development of a Plain Language Decision Support Tool for Cancer Clinical Trials: Blending Health Literacy, Academic Research, and Minority Patient Perspectives
Aisha T. Langford, Sarah T. Hawley, Sue Stableford, Jamie L. Studts, Margaret M. Byrne
Abstract
Despite the promise of clinical trials for improving cancer care, less than 5% of all cancer patients participate. Racial/ethnic minorities continue to be underrepresented in cancer clinical trials (CCTs). To address this gap, we developed a plain language, web-based decision support tool (CHOICES DST) in English and Spanish to support decision-making about CCTs among Blacks and Hispanics. In phase 1 (information collection), we conducted qualitative interviews with 45 cancer patients, completed a thorough literature review, and reviewed results from a telephone survey of 1100 cancer patients. In phase 2 (content generation), we created the first iteration of the CHOICES DST. In phase 3 (usability testing), we gathered user experience and acceptability data from a small sample of cancer survivors (n = 9). The Knowledge, Empowerment, and Values Clarification (KEV) model of decision-making was developed based on data from phase 1. The KEV model and other phase 1 data allowed us to create the CHOICES DST platform. Usability testing of the CHOICES DST showed highly favorable responses from users, satisfaction with content, ease of navigation, and a desire to use the tool. Qualitative results identified addressable points that would benefit from content and navigation-related alterations. The final version of the CHOICES DST was well received and understood by Black and Hispanic participants, and adheres to the mandates for plain language communication. This research provides preliminary data that CHOICES DST holds promise for improving knowledge of CCTs and potentially improving informed decision-making about participation in trials.

The Role of Informed Consent in Biobanks after the General Data Protection Regulation [THESIS]
Nina Savolainen
University of Turku, 2019
Abstract
This Thesis evaluates the role of informed consent in biobank research and the impact of the General Data Protection Regulation (GDPR) for the informed consent procedure when providing biological and related data to biobanks. Aim of the research is to assess especially two derogations which offer relief for the demand of obtaining an informed consent from a sample donor; Recital 33 which allows the use of a broad consent in the field of scientific research, and the research exemption provided in the Article 9(2)(j), which allows re-purposing personal data for scientific purposes without asking a consent from the person whom the data originates from. The applicability and relevance of those provisions will be examined from the perspective of biobank sample donor’s right to privacy and right to data protection. This Thesis suggests the derogations provided in the GDPR will modify the meaning of informed consent in the field of biomedical research. The main findings are that the GDPR did not improve the data autonomy of individuals who participate in biobank research. Instead, the derogations provided are made in favor of the researcher: the aim of the GDPR was to empower individuals control over their data processing, but it seems that scientific research is an acceptable reason to exclude decisional power form individuals.

Clinical Trials Informed Consent: An educational intervention to improve nurses' knowledge and communications skills
Eileen Regan
Clinical Journal of Oncology Nursing, December 2018; 22(6):E152–E158

Background
Teach-back is an evidence-based tool recommended for use during informed consent (IC) discussions. The nurses' role in the IC process is important, particularly for patient education and advocacy.

Objectives
The aim was to initiate and evaluate an educational program for nurses to improve knowledge and communication skills used in IC for cancer clinical trials.

Methods
An educational program was presented to nurses. Anonymous pre-, post-, and one-month postprogram surveys measured nurses' knowledge of research and the importance of and confidence using teach-back during IC discussions.

Findings
Nurses had high research knowledge scores and statistically significant improvement in pre- and post-test scores of conviction and confidence using teach-back. Nurses employed essential elements of teach-back before the program but had greater recognition of elements after the program.

Informed Consent, Fraud and Confidentiality in Psycho-Pedagogic Research Activity
Corina Iurea
Jus et Civitas, 2018

Abstract
This paper analyses the ethical character of the interactions between researchers and the subjects of the psycho-pedagogic research, a topic that has attracted more and more interest. The research activity needs to be ethical, show consideration towards the interests and needs of the participants and of those affected by the research results. While researching, we need to be honest, opened, and have a critical approach about who, what and why we perform the research. Researchers need to avoid any activity that could impact their credibility, objectivity, and impartiality.
Readability of consent forms in veterinary clinical research
Josey Sobolewski1, Jeffrey N. Bryan, Dawn Duval, Allison O’Kell, Deborah J. Tate, Tracy Webb, Sarah Moore
Journal of Veterinary Internal Medicine, 6 February 2019

Background
“Readability” of consent forms is vital to the informed consent process. The average human hospital consent form is written at a 10th grade reading level, whereas the average American adult reads at an 8th grade level. Limited information currently exists regarding the readability of veterinary general medical or clinical research consent forms.

Hypothesis/Objectives
The goal of this study was to assess the readability of veterinary clinical trial consent forms from a group of veterinary referral centers recently involved in a working group focused on veterinary clinical trial review and consent. We hypothesized that consent forms would not be optimized for client comprehension and would be written above the National Institutes of Health-recommended 6th grade reading level.

Animals
None.

Methods
This was a prospective study assessing a convenience sample of veterinary clinical trial consent forms. Readability was assessed using 3 methods: the Flesch-Kincaid (F-K) Grade Level, Flesch Reading Ease Score (FRES), and the Readability Test Tool (RTT). Results were reported as mean (±SD) and compared across specialties.

Results
Fifty-three consent forms were evaluated. Mean FRES was 37.5 ± 6.0 (target 60 or higher). Mean F-K Grade Level was 13.0 ± 1.2 and mean RTT grade level was 12.75 ± 1.1 (target 6.0 or lower). There was substantial agreement between F-K and RTT grade level scores (intraclass correlation coefficient 0.8).

Conclusions and Clinical Importance
No form evaluated met current health literacy recommendations for readability. A simple and readily available F-K Microsoft-based approach for evaluating grade level was in substantial agreement with other methods, suggesting that this approach might be sufficient for use by clinicians and administrators drafting forms for future studies.

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