Center for Informed Consent Integrity

Informed Consent: A Monthly Review

March 2020

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 Center for Informed Consent Integrity, a program of the GE2P2 Global Foundation. The Foundation is solely responsible for its content. Comments and suggestions should be directed to:

Editor
Paige Fitzsimmons, MA
Associate Fellow
GE2P2 Global Foundation
paige.fitzsimmons@ge2p2global.org

Publisher
David R. Curry
President & CEO
GE2P2 Global Foundation
david.r.curry@ge2p2global.org

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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Please note that at the end of each edition we present a set of appendices including a glossary, tools for assessment and guidance documents.
GENOMIC MEDICINE/GENE EDITING

Germline Genome Editing Research: What Are Gamete Donors (Not) Informed About in Consent Forms?
Research Article
Emilia Niemie, Heidi Carmen Howard
The CRISPR Journal, February 2020; 3(1) 2020
Open Access
Abstract
The potential for using germline genome editing (GGE) in humans has garnered a lot of attention, both for its scientific possibilities as well as for the ethical, legal, and social challenges it ignites. The ethical debate has focused primarily on the suggestions of using GGE to establish a pregnancy (i.e., to offer it in a clinical setting), which is, to date, illegal in many jurisdictions. The use of GGE in research (where a pregnancy would not be established) has received much less attention, despite the fact that it raises serious ethical and social issues as well. Herein, we report on the analysis of informed consent forms for egg and sperm donation used in a widely publicized study where genome editing was used to correct a disease-causing genetic mutation in human embryos. Importantly, embryos were created using eggs and sperm obtained specifically for these experiments. The analysis indicates deficiencies in how the forms addressed various issues, including limited and potentially misleading information about the sensitive nature of the study, the lack of an explicit mention of genomic sequencing, as well as the poor readability of the forms. Furthermore, the arguably high compensation of U.S.$5,000 for egg donors raises questions about undue inducement to participate in research. Moreover, since the procurement of eggs involves serious health risks, it may be questioned whether research requiring such a procedure should be pursued. If such experiments are continued, donors should be informed about all relevant aspects in order to make informed decisions about participating.

Informed Consent for Genetic Testing in Autopsy
Editorial
Ken Gatter
Archives of Pathology & Laboratory Medicine, 2020
Open Access
Excerpt
As next generation sequencing, whole exome sequencing, and other genetic tests become cheaper and more prevalent, pathologists will likely incorporate genetic testing into routine autopsies. Such testing has great promise for helping diagnose and treat living and future family members, but also raises questions about whether current consenting practices for autopsy are adequate. How is informed consent in the autopsy context different from informed consent in the typical clinical setting? Should we require specific consent for genetic autopsy testing?...

BIOMEDICAL RESEARCH

Trust and consent: a prospective study on parents’ perspective during a neonatal trial
Original Research
Sonia Dahan, Camille Jung, Gilles Dassieu, Xavier Durrmeyer, Laurence Caeymaex
Abstract

Objective

This study aimed to describe how parents and physicians experienced the informed consent interview and to investigate the aspects of the relationship that influenced parents’ decision during the consent process for a randomised clinical trial in a tertiary neonatal intensive care unit (NICU). The secondary objective was to describe the perspectives of parents and physicians in the specific situation of prenatal informed consent.

Setting

Single centre study in NICU of the Centre Hospitalier Intercommunal de Créteil, France, using a convenience period from February to May 2016.

Design

Ancillary study to a randomised clinical trial: Prettineo. Records of interviews for consent. Population: parents and physicians. Mixed study including qualitative and quantitative interview data about participants’ recall and feelings about the consent process. Interviews were reviewed using thematic discourse analysis.

Results

Parents’ recall and understanding of the study’s main goal and design was good. Parents and physicians had a positive experience, and trust was one of the main reasons for parents to consent. Misunderstanding (bad comprehension) was the main reason for refusal. Before birth, three situations can compromise parents’ consent: the mother already consented to participate in other studies, the absence of the father during the interview and the feeling that the baby’s birth is not an imminent possibility.

Conclusions

Confronting parents and physicians’ perspectives in research can help us reach answers to sensitive issues such as content and timing of information. Each different types of study raises different ethical dilemmas for consent that might be discussed in a more individual way.

Dynamic consent management for clinical trials via private blockchain technology

Original Research

Giuseppe Albanese, Jean-Paul Calbimonte, Michael Schumacher, Davide Calvaresi

Journal of Ambient Intelligence and Humanized Computing, 14 February 2020

Abstract

Clinical trials (CTs) are essential for the advancement of medical research, paving the way for the development and adoption of new treatments, and contributing to the evolution of healthcare. An essential factor for the success of a CT is the appropriate management of its participants and their personal data. According to the current regulations, collecting and using personal data from participants must comply with rigorous standards. Therefore, healthcare institutes need to obtain freely given, specific, informed, and unambiguous consent before being able to collect the data. Some of the major limitations of the current technological solutions are the lack of control over the granularity of consent grants, as well as the difficulty of handling dynamic changes of consent over time. In this paper, we present SCoDES, an approach for trusted and decentralized management of dynamic consent in clinical trials, based on blockchain technology (BCT). The usage of blockchain provides a set of features that allow maintaining consent information with trust guarantees while avoiding the need for a dedicated or centralized third trusted party. We provide a full implementation of SCoDES, made available as a self-contained infrastructure, with the possibility to interact with external services, and using hyperledger as a blockchain framework.

Editor’s note: The SCoDES project is an applied research project on blockchains involving five Hautes Ecoles from French-speaking Switzerland... Its goal is to develop knowledge within the field of blockchain and smart contracts by studying and developing practical cases of use and transferring the acquired knowledge to the regional economic actors.
**Research Consent Models Used in Prospective Studies of Neurologically Deceased Organ Donors: A Systematic Review**

*Research Article*

Frederick D’Aragon, Karen E. A. Burns, Amanda Yaworski, Amanda Lucas, Erika Arseneau, Emilie Belley-Cote, Sonny Dhanani, Anne-Julie Frenette, François Lamontagne, François Lauzier, Aemal Akhtar, Simon Oczkowski, Bram Rochwerg, Maureen O. Meade

*Journal of Empirical Research on Human Research Ethics, 13 February 2020*

**Abstract**

Research to inform the care of neurologically deceased organ donors is complicated by a lack of standards for research consent. In this systematic review, we aim to describe current practices of soliciting consent for participation in prospective studies of neurologically deceased donors, including the frequency and justification for these various models of consent. Among the 74 studies included, 14 did not report on any regulatory review, and 13 did not report on the study consent procedures. Of the remaining 47 studies, 24 utilized a waiver of research consent. The most common justification for a waiver of research consent related to the fact that neurologically deceased donors are not considered human subjects. In conclusion, among studies of neurologically deceased donors, research consent models vary and are inconsistently reported. Consensus and standardization in the application of research consent models will help to advance this emerging field of research.

**Remote Consent Clinical Research**

*Commentary*

Sriram Preethi

*Clinical Trials and Practice, 30 October 2019; 1(1) pp 39-41*

**Open Access**

**Abstract**

Recruitment in clinical research trials can be challenging in trials that are time-sensitive and/or are rare disease and critical care trials. One of the hurdles for recruitment in these types of clinical trials is due to the consent process, and the need to have consent of the patient within a certain timeframe, or the patient unable to consent for themselves. This paper will discuss the usage of the utilization of remote consent options for these trials.

**TECHNOLOGY/OTHER MEDIATION**

**An assessment of provider satisfaction with the use of a standardized visual aid for informed consent for appendectomy in children**

Brittany L. Johnson, Eric H. Rosenfeld, Brittany D. Carter, Monica E. Lopez, Annalyn S. DeMello, David E. Wesson, Mary L. Brandt

*Journal of Pediatric Surgery, 1 February 2020*

**Abstract**

**Purpose**

We previously validated a visual aid for the use in the consent process for an appendectomy showing improved parental satisfaction and understanding. In this study, we evaluated provider satisfaction and perceived value of using the visual aid.

**Methods**

An IRB approved survey was developed assessing provider experience with use of the visual aid. This was distributed and analyzed via Research Electronic Data Capture (RedCap) Database.
Results
We administered 58 surveys (45% response rate). Participants included faculty (n = 2), fellows (n = 1), residents (n = 6), and physician assistants (n = 17). The visual aid was used > 10 times by 50% of providers. The most common reason for not using the visual aid was not remembering it was available. Nearly half (40%) did not feel the visual aid added any time. 9/20 (45%) felt it added a small amount of time. Slightly over half of providers (52%) felt using the visual aid significantly increased family ability to give informed consent and made the consenting process easier for both providers and families.

Conclusion
Using a visual aid in consenting families for appendectomy does not add significant time and subjectively improves the process for providers and increases provider perception of parental understanding.

The effects of a humorous video on memory for orthodontic treatment consent information
Original Article
Timothy P. Levine
American Journal of Orthodontics and Dentofacial Orthopedics, February 2020; 157(2) pp 240-244
Abstract
Introduction
Communication of treatment information is critical in orthodontics. The challenge lies in doing so effectively such that patients will understand and remember, which is the definition of true informed consent. Previous studies have established that information is more readily remembered when presented using multimedia presentations. Likewise, humor has been shown to increase information retention.

Methods
Two videos, 1 humorous (H) and 1 unhumorous (U), were produced with identical information about orthodontic treatment consent. Thirty-eight new orthodontic patients were randomly selected and divided into H (n = 20) and U (n = 18) video groups. Identical questionnaires with multiple-choice responses to judge memory of the content were completed by both groups immediately after watching the video (T1) and 6 weeks later (T2). A one-tailed Welch's t test was used to analyze the scores.

Results
At T1, there was no significant difference in the scores of the questionnaire between H and U groups, whereas at T2, there was a significant difference between groups. The intragroup score difference was also analyzed, with a significant decrease from T1 to T2 in the U, but not H, group. Subjective questions were also asked regarding content. No significant differences were found between the groups regarding the informativeness of each video; however, willingness to watch again and memorability of the content were significantly higher in the H group.

Conclusions
Patients who received orthodontic treatment information presented with humor retained significantly more of that information after 6 weeks compared with patients who received the same information without humor. Patients who received the humorous content subjectively stated they were more likely to rewatch the video and also found the information presented in this manner to be more memorable.

Multimedia in improving informed consent for caesarean section: A randomised controlled trial
Original Article
Alice Truong, Lenore Ellett, Lauren Hicks, Gabrielle Pell, Susan P. Walker
Obstetrics & Gynaecology, 28 January 2020
Abstract
Background
Multimedia modules have been used as an adjunct to improve patient knowledge and recall for various elective surgical procedures, but have been incompletely evaluated in patients undergoing caesarean section.
**Aims**  
To compare the use of a supplementary multimedia module with written information in improving the informed consent process prior to elective caesarean section.

**Materials and methods**  
This was a prospective randomised controlled trial (ACTRN12616000430437). Primary outcomes were knowledge and anxiety scores immediately following the intervention and on the day of surgery. Secondary outcomes were patient satisfaction, length of stay, time to cessation of analgesia, and patient assessment of the consent types.

**Results**  
Seventy-five patients completed the study. Both multimedia module and written information groups demonstrated a significant increase in knowledge scores with no difference between the groups. In the multimedia-assisted consent group, scores improved from baseline by +2.31 (P < 0.001) immediately after watching the multimedia module and by +2.41 (P < 0.001) on the day of surgery. In the written information group, scores improved by +1.76 (P < <0.001), and +2.31 (P < 0.001) respectively. There was no adverse impact on anxiety in either group. Patient-reported understanding (92.4% vs 78.5%, P = 0.001), and helpfulness (90.1% vs 73.3%, P = 0.001) was significantly higher in the multimedia module group than in the written information group. The multimedia module was assessed as ‘slightly too long’ and provided ‘slightly too much information’.

**Conclusions**  
Multimedia modules are a valuable adjunct to traditional processes of obtaining informed consent for elective caesarean section and should be offered and made available to patients prior to surgery.

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**BIOBANKING**

**Relationships of health information orientation and cancer history on preferences for consent and control over biospecimens in a biobank: A race-stratified analysis**  
Soo Jung Hong, Bettina Drake, Melody Goodman, Kimberly A. Kaphingst  
*Journal of Genetic Counselling, 28 January 2020*

**Abstract**  
In this study, we investigated how patients’ self-reported health information efficacy, relationship with health providers, and cancer history are associated with their preferences for informed consent and need for control over biobank biospecimens. We recruited 358 women aged 40 and older (56% African American; 44% European American) and analyzed the data using multivariable regression models. Results show that African American participants’ health information efficacy was significantly and negatively associated with their need for control over biospecimens and preference for a study-specific model. European American participants’ dependency on doctors was a significant and negative predictor of their preference for a study-specific model. Several significant interaction effects, which varied across races, were found with regard to health information efficacy, personal cancer history, need for control, and preference for a study-specific model.  
The study findings suggest it is important to consider health information efficacy, relationship with providers, and need for control when developing large diverse biobanks.
**COGNITIVE CHALLENGES**

**Eliciting consent from patients with dementia in general X-ray departments: Law, ethics and interpretation of context [CONFERENCE PAPER]**

Katie Kelly, Lisa Booth, Paul K. Miller  
**United Kingdom Imaging and Oncology Congress 2020: Pathways and Communication, 1-3 June 2020; ACC, Liverpool**  
*Open Access*  
**Abstract**

*Background*

While the numbers of individuals suffering from dementia syndromes in the UK steadily increase, many practitioners in the allied healthcare professions, and particularly junior staff, still feel ill-equipped for face-to-face communicative encounters with such individuals (Miller et al., 2019; Tullo et al., 2016). An elemental feature of effective communication in healthcare contexts is the seeking of proper consent to perform given procedures. The propositions above, however, raise questions regarding how ‘properly’ consent is being acquired when dementia is at stake. This paper, thus, reports findings from a qualitative study of general radiographers’ experiences of acquiring consent from patients with dementia, specifically exploring participants’ interpretations of correct legal and ethical practice therein.

*Methods*

With institutional ethical approval, N=6 general radiographers with less than ten years of clinical experience were recruited to sit for extended interviews. Verbatim transcripts were analysed using the domain-established techniques of Interpretative Phenomenological Analysis (Miller et al., 2017).

*Results*

Four key areas of extremely variable interpretation and practice were identified. (1) How to assess capacity for informed consent; (2) How to effectively modify communication when gaining consent; (3) Managing carer involvement during consent-acquisition and; (4) Constituting the ‘best interest’ of the patient.

*Conclusion*

Participants’ own accounts often indicated that they were often not lawfully implementing the Mental Capacity Act (MCA) when acquiring consent. Moreover, as previously identified by Miller et al. (2019), the situational confusion did little for participants’ confidence, with prospectively damaging import for future encounters. Stronger training in practical application of the MCA is recommended.

**Consent conundrums: patient consent in neuroscience nursing**

John Finch  
**British Journal of Neuroscience Nursing, 25 February 2020; 16(1)**  
**Abstract**

In BJNN 15(4) and BJNN 15(5), John Finch looked in detail at the role of the Mental Capacity Act 2005 and its accompanying Code in the practice of neuroscience nurses. He concluded, as have others, that the guidance offered by the Act and the Code falls short of what neuroscience nurses need in their practice. In this article, he turns his attention to the treatment of patients who can and do consent to proposed treatment. The law relating to such patients in this matter offers neither an act nor a code. The law is to be found in court decisions. It might, at first sight, appear that a practice situation in which a patient with undoubted mental capacity or, at least, sufficient mental capacity to understand and accept what is proposed, presents no legal problem. But a closer examination of mental processes encountered in patients who may be in pain, distress and pressing need reveals that communication between the treater and the treated may be subtle and complex, and that the meeting of minds required in law to ensure that a patient has genuinely agreed to a detailed proposal is anything but simple.
‘Delusional’ consent in somatic treatment: the emblematic case of electroconvulsive therapy

Original Research
Giuseppe Bersani, Francesca Pacitti, Angela Iannitelli

Journal of Medical Ethics, 13 February 2020

Abstract
Even more than for other treatments, great importance must be given to informed consent in the case of electroconvulsive therapy (ECT). In a percentage of cases, the symbolic connotation of the treatment, even if mostly and intrinsically negative, may actually be a determining factor in the patient’s motives for giving consent. On an ethical and medicolegal level, the most critical point is that concerning consent to the treatment by a psychotic subject with a severely compromised ability to comprehend the nature and objective of the proposed therapy, but who nonetheless expresses his consent, for reasons derived from delusional thoughts. In fact, this situation necessarily brings to light the contradiction between an explicit expression of consent, a necessary formality for the commencement of therapy, and the validity of this consent, which may be severely compromised due to the patient’s inability to comprehend reality and therefore to accept the proposal of treatment, which is intrinsic to this reality. With the use of an electric current, the symbolic experience associated with anaesthesia, and the connection to convulsions, ECT enters the collective consciousness. In relation to this, ECT is symbolic of these three factors and hooks on to the thoughts, fears, feelings and expectations of delusional patients. These are often exemplified in the violent intervention of the persecutor in the patient with schizophrenia, the expected punishment for the ‘error’ committed for which the depressed patient blames himself and the social repression of the maniacal patient’s affirmation of his inflated self-esteem.

A review of informed consent and how it has evolved to protect vulnerable participants in emergency care research

Rajpal Nandra, Alan F. Brockie, Faisal Hussain

European Federation of National Associations of Orthopaedics and Traumatology (EFORT) Open Reviews, 3 February 2020; 5(2)

Open Access

Highlights
- A vulnerable participant in research lacks capacity to consent or may be exposed to coercion to participate. Capacity may be temporarily impaired due to loss of consciousness, hypoxia, pain and the consumption of alcohol or elicit substances.
- To advance emergency care, providing life-threatening measures in life-threatening circumstances, vulnerable patients are recruited into research studies. The urgent need for time-critical treatment conflicts with routine informed consent procedures.
- This article reviews ethical considerations and moral obligations to safeguard these participants and preserve their autonomy.
- A particular focus is given to research methodology to waive consent, and the role of ethics committees, research audits, research nurses and community engagement.
- Research on the acutely unwell patient who lacks capacity is possible with well-designed research trials that are led by investigators who are sufficiently trained, engage the community, gain ethical approval to waive consent and continuously audit practice.

Editor’s note: EFORT Open Reviews publishes high-quality instructional review articles across the whole field of orthopaedics and traumatology. It is published by The British Editorial Society of Bone & Joint Surgery (BESBJS).
Consent for Research on Violence against Children: Dilemmas and Contradictions

Abstract
The increasing visibility of violence involving children has led to a recognition of the need to research its underlying dynamics. As a result, we now have a better understanding of the complexities involved in this kind of research, associated with children’s developmental characteristics and social status, exposure to violence, and compromised parenting of caregivers. This paper discusses the issues raised by parental consent in research on violence against children, specifically the dilemma of children’s rights to participation and protection, and proposes changes in research practice in this domain.

Admission and discharge criteria for adolescents requiring inpatient or residential mental health care

Objective
This scoping review sought to locate and describe criteria relating to admission to and discharge from inpatient mental health care for adolescents aged 11 to 19 years in the literature.

Introduction
In the United Kingdom (UK) and internationally, it is estimated that one in 10 children and adolescents has a diagnosable mental health problem. Children and adolescents with the highest levels of need are cared for in hospital, but there is a high demand for beds and a general lack of agreement regarding the criteria for admission to, and discharge from, such units.

Inclusion criteria
We considered research studies that focused on criteria for admission to and discharge from inpatient mental healthcare units for adolescents aged 11 to 19 years. We included all quantitative and qualitative research designs and text and opinion papers.

Methods
We searched MEDLINE, Embase, PsycINFO, CINAHL, ERIC, British Nursing Index, Applied Social Sciences Index and Abstracts, ProQuest Dissertations and Theses, the Cochrane Central Register of Controlled Trials, OpenGrey, ETHOS and websites of professional organizations for English language citations from 2009 to February 2018. Potentially relevant citations were retrieved in full and their citation details imported into the JBI System for the Unified Management, Assessment and Review of Information. Full texts of selected citations were assessed in detail against the inclusion criteria by two independent reviewers. Findings were extracted directly into tables accompanied by a narrative summary relating to the review objectives.

Results
Thirty-five citations were included: quantitative research studies (n = 18), qualitative research studies (n = 1), and textual and opinion publications (n = 16). Of the quantitative research studies, 16 used a retrospective cohort design using case note reviews and two were prospective cohort studies. The qualitative study used interviews. The research studies were conducted in nine countries: USA (n = 7), UK (n = 3), New Zealand (n = 2), Israel (n = 2), Canada (n = 1), Norway (n = 1), Ireland (n = 1), Greece (n = 1) and Turkey (n = 1). The 16 textual and opinion publications included book chapters (n = 3), reviews (n = 3), policy and guidance
documents (n = 3), reports (n = 3) and service specifications (n = 4). The majority of these were published in the UK (n = 10), with the remainder published in Ireland (n = 2), Australia (n = 2), and USA (n = 2). Research was conducted across a variety of settings including child and adolescent mental health service inpatient and outpatient units, emergency departments and adult psychiatric units. Length of stay, where recorded, ranged from < 1 day to 351 days. Several categories emerged from the data: type of admission process, referral or point of access, reasons for admission to inpatient mental health care, assessment processes, criteria for discharge and reasons for non-admission.

**Conclusion**

There is little evidence identifying which behavioral or symptomatic indicators suggest that admission is required, beyond retrospective identification of diagnoses attributed to adolescents who become inpatients. The threshold of severity of risk or need is not currently articulated. No studies were identified that drew on the perspectives of adolescents and their families or carers regarding criteria warranting admission to inpatient mental health care, which indicates an important area for future investigation.

## RIGHTS/LEGAL/LEGISLATIVE

### [An ethical evaluation of presumed consent for organ donation in Switzerland]
Clavien C.
*Revue médicale Suisse, 19 February 2020; 16(682) pp 370-373*

**Abstract**

Following a current trend in European countries, Switzerland is about to decide to adopt (or reject) a presumed consent legislation for organ donation. In such a system, every citizen is considered as a potential organ donor except in case of expressed refusal during lifetime. The presumed consent system raises ethical and practical issues that need to be carefully understood and weighed before deciding on its fate. This article reviews the most pressing ethical issues and provides the empirical data necessary for assessing the presumed consent legislation in Switzerland. At the end of the analysis, the reader will be able to form her own informed opinion on the issue.

*Editor’s note: This is a French language publication.*

### GDPR: Is your consent valid?

*Research Article*

Stephen Breen, Karim Ouazzane, Preeti Patel

*Business Information Review, 17 February 2020*

**Abstract**

The General Data Protection Regulation (GDPR) 2018 imposes much greater demands on companies to address the rights of individuals who provide data, that is, Data Subjects. The new law requires a much more transparent approach to gaining consent to process personal data. However, few obvious changes to how consent is gained from Data Subjects to comply with this. Many companies are running the risk of non-compliance with the law if they fail to address how data are obtained and the lack of true consent which Data Subjects currently give to their data being processed. Consent is a complex philosophical principle which relies on the person giving the consent being in full possession of the facts, this article explores the philosophical background of consent and examines the circumstances which were the point of departure for the debate on consent and attempts to develop an understanding of it in the context of the growing influence of information systems and the data-driven economy. The GDPR has gone further than any other regulation or law to date in developing an understanding of consent to address personal data and privacy concerns.
**Physician’s obligations to inform about complications based on a recent warning from drug authorities**

Duttge G, Meyer T

*Medizinische Klinik, Intensivmedizin und Notfallmedizin, 7 February 2020*

**Abstract**

**Background**

Based on a recent warning from the drug authorities about increased suicidality among users of hormonal contraceptives, this article discusses the legal consequences of translating novel findings from clinical trials into altered contents of gaining informed consent during the medical consultation.

**Methods and Results**

Comprehensive information in accordance with 630e German Civil Code (BGB) requires that rare drug reactions be mentioned by the prescribing physician, when they are associated with serious sequelae. This act regulates the treating physician’s obligations to inform about complications for both preventive and curative treatment options. In this paper, we refer to the scientific evidence level of data from clinical trials as the key feature for implementing altered medical information in the proper conduct of acquiring the consent of the patient in line with 630e BGB. The article discusses how additions and amendments to the package leaflet and the expert information will impact on the obligations for the treating party to provide information for the patient in order to obtain informed consent. In particular, we focus on the relationship between the obligations for the physician prescribing oral contraceptives on an individual case and the generalized information conditions according to 11 and 11a German Medicinal Products Act.

**Discussion**

Current warnings of the drug authorities in the form of red-hand letters do not necessarily have legal consequences for gaining informed consent during the medical consultation.

*Editor’s note: This is a German language publication*

CULTURAL/COUNTRY CONTEXT

**Facilitators, barriers, and recommendations related to the informed consent of Marshallese in a randomized control trial**

*Research Article*

Rachel S Purvis, Leah R Eisenberg, Christopher R Trudeau, Christopher R Long, Pearl A McElfish

*Clinical Ethics, 2 February 2020*

**Abstract**

**Background**

The Pacific Islander population is the second fastest growing population in the United States and Arkansas is home to the largest Marshallese population in the continental US. The Marshallese community have significant health disparities with high prevalence of diabetes, heart disease, and obesity compared to the general US population. Using a community-based participatory research approach, researchers and Marshallese community stakeholders identified diabetes as the top health issue for research.

**Methods**

From 2014 to 2018, a randomized control trial was conducted comparing standard diabetes management education with a culturally adapted family model of standard diabetes management education delivered in participants’ homes by Marshallese community health workers and certified diabetes educators. Interviews were held with Marshallese participants to document their experiences with and perceptions of the informed consent process for this randomized control trial.

**Results**
Participants provided feedback on the process of enrolling in the study, describing barriers and facilitators to giving informed consent from their perspective, and offering recommendations for improving the informed consent process.

Conclusion
Findings suggest that informed consent with underserved communities, including immigrant and migrant populations who do not speak English or have limited English proficiency, is possible, and that using a community-based participatory research approach can help facilitate the informed consent process.

Translations of informed consent documents for clinical trials in South Africa: are they readable?
[M.A. DISSERTATION]
Makiti Thelma Leopen
University of Cape Town, Maternal and Child Health in the Department of Pediatrics and Child Health, February 2019

Abstract
Introduction
Obtaining informed consent is an ethical prerequisite for enrollment in clinical research. There is a perception that informed consent documents used in biomedical research are lengthy, overly complex and above the reading capability of typical research participants. In South Africa, ethical committees regulating research on human participants (HRECs) are mandated by the Department of Health’s National Health Research Ethics Council’s (NHREC) guidelines to ensure that researchers have made special considerations for vulnerable groups when conducting research. This includes considerations made for populations with low literacy. For example, the Standard Operating Procedure (SOP) of the University of Cape Town’s Human Research Ethics Committee (UCTHREC), requires that the language used in informed consent documents should be directed at a reading level of grade 6 to 8 and that common, everyday words should be used rather than complex language syntax. The HREC expects researchers to translate the approved English version documents into local languages such as isiXhosa and Afrikaans. Since ethics committee focus approval on the English language consent documents and only acknowledge translated versions, a potential gap in this process is whether the translated versions meet the same required readability levels. This study aims to investigate whether translated versions of English language informed consent documents used at a single busy clinical research site are readable and meet the readability levels specified by UCTHREC.

Methodology
A quantitative descriptive statistical design was used to explore readability levels of informed consent documents used at a single clinical research facility based in a semi-rural community. Informed consent documents approved by UCTHREC over the past thirteen years (2004 to 2017) that met the inclusion criteria were analysed for readability. The LIX readability test tool was used to calculate readability scores and the levels of reading difficulty. These scores were then matched to a grade level conversion chart to determine the equivalent number of education years required to be able to easily understand the information. Readability levels were determined for isiXhosa and Afrikaans translations of the documents and compared to the levels of the English document.

Results
The results indicate that informed consent documents used at this single clinical research facility, independent of language type, are difficult to read. A total of 259 sub-sections of informed consent documents from 10 different studies were analysed. The analysis showed that informed consent documents were classified as “very difficult to read” according to the LIX readability tool in a large proportion of English, isiXhosa and Afrikaans languages: 41 (16%), 255 (98%), and 85 (33%) of informed consent sections respectively. Of all the subsections of English, isiXhosa and Afrikaans documents respectively, 98 (38%), 0 (0%) and 126 (49%) were classified as “difficult to read”, while 79 (31%), 3 (1%) and 38 (15%) were found to have an “average” readability level. Twenty eight (11%), 1 (0%) and 10 (4%) were found to be “easy to read” and 13 (5%), 0 (0%) and 0 (0%) had a “very easy” readability level. The mean LIX readability scores across
English, isiXhosa, and Afrikaans languages were respectively 42.27 (95% CI 41.20 – 43.34) corresponding to a readability level of “average”, 74.64 (95% CI 73.79–75.49), corresponding to “very difficult to read” and 46.73 (95% CI 45.66-47.8) “difficult to read”. These findings suggest a high level of difficulty in reading of the text in the Informed consent documents.

Conclusion
Translations of Informed consent documents used at a single busy clinical research site are difficult to read and are written at high school to tertiary reading level. These reading levels are above the recommended level prescribed by the site’s research ethics committee (UCTHREC). Local ethics committees should employ more stringent guidelines and checks to ensure readability of translated informed consent documents. Researchers and Sponsors should include readability outcomes in the design and with submissions of new protocols.

MEDICAL/SURGICAL

Mohammed M Dungarwalla, Edmund Bailey
Dental Update, 17 February 2020; 47(2)
Abstract
The consent process remains a pillar of excellent clinical care. The changes in the law after the Montgomery ruling in 2015 has changed the shape of consent, and now, taking adequate consent can be extensive and sometimes confusing for clinicians and patients. Dentists are sometimes faced with the unenviable task of weighing up what patients should know versus what they want to know. This paper aims to describe the consent process for more common oral surgical procedures, helping clinicians to allow their patients to make informed decisions.

Transparent Defaults and Consent for Participation in a Learning Health Care System: An Empirical Study
Research Article
Vilius Dranseika, Jan Piasecki
Abstract
We report a preregistered study that was designed to answer three questions about using transparent defaults to increase participation in a hypothetical learning health care system. Do default options influence consent to participate in learning activities within a learning health care system? Does transparency about default options decrease the effect of the defaults? Do people reconsider their choice of participation once they are informed about the defaults applied? In our study, application of the defaults did not have influence on rates of consent, nor did transparency about defaults have an effect on the rates of consent. Participants were also not likely to change their choice after being informed that defaults were applied to their previous choice. In general, our study raises doubts that defaults (both covert and transparent) can be used as an effective means in significantly increasing participation in learning health care systems.

How many facts make an "informed patient"? Practical challenges for junior doctors in acquiring surgical informed consent
Josephine de Costa, Alan De Costa, Mandy Shircore
ANZ Journal of Surgery, 6 February 2020; 89 (S1) pp 106-1063
Abstract

Purpose
In addition to technical surgical skills, the complete surgeon requires skills in communication and consenting patients. This protects patients, hospitals, and doctors themselves, but also promotes best practice. However, surgical informed consent (SIC) is commonly acquired by junior doctors (defined as PGY1 until completion of specialist training). Little is known about the quality of SIC that doctors at this level may acquire. This study aimed to synthesize known evidence on challenges faced by junior doctors on this issue.

Methodology
The authors conducted a systematic review of all English-language studies published from 1 January 2007 looking at junior doctors (considered to be from PGY1 to the end of specialist training) and any issues that arose around acquiring SIC. A qualitative synthesis was then conducted.

Results
Junior doctors understanding of the legal standards of consent, including both capacity/competence and the concepts of material risk, varied considerably across studies. Documentation and discussion of possible complications in surgery was found to be highly variable within both trainees and consultants consenting practices. Few junior doctors discussed alternative treatment options, including the possibility of having no treatment; evidence on discussion of benefits and recovery were conflicting. Overall documentation of the SIC process was poor.

Conclusions
While junior doctors are commonly responsible for acquiring SIC, this study shows that there are significant practical deficiencies in how they discharge this duty. As a result, SIC acquired by junior doctors may not always comply with required legal standards, which may open up this cohort, and their hospitals, to legal action.

Montgomery in, Bolam out: are trainee surgeons ‘material risks’ when taking consent for cataract surgery?

Review Article
M. Omar Qadir, Yusuf Abdallah, Helen Mulholland, Imran Masood, Stephen A. Vernon, Simon N. Madge
Eye, 4 February 2020

Abstract
Trainee involvement in cataract surgery is vital to allow proper training of the next generation of ophthalmic surgeons. However, recent changes in the UK Law, coupled with open publication of National Cataract Dataset results, lead us to conclude that the status of being a trainee is itself a material risk that now needs to be divulged to patients during the consent process. The opinions of current trainee surgeons in the UK were sampled via questionnaire and clinical negligence counsel was involved in the authorship of the paper in order to analyse the legal issues at stake. Attitudes towards consent regarding trainee involvement in UK cataract surgery need to change.

Informed consent for invasive procedures in the emergency department

Max M. Feinstein, Janet Adegboye, Joshua D. Niforatos, Richard M. Pescatore
The American Journal of Emergency Medicine, 28 January 2020

Abstract
Background
Informed consent for procedures in the emergency department (ED) challenges practitioners to navigate complex ethical and medical ambiguities. A patient’s altered mental status or emergent medical problem does not negate the importance of his or her participation in the decision-making process but, rather, necessitates a nuanced assessment of the situation to determine the appropriate level of participation. Given the complexities involved with informed consent for procedures in the ED, it is important to understand the experience of key stakeholders involved.
Methods
For this review, we searched Medline, the Cochrane database, and Clinicaltrials.gov for studies involving informed consent in the ED. Inclusion and exclusion criteria were designed to select for studies that included issues related to informed consent as primary outcomes. The following data was extracted from included studies: Title, authors, date of publication, study type, participant type (i.e. adult patient, pediatric patient, parent of pediatric patient, patient's family, or healthcare provider), number of participants, and primary outcomes measured.

Results
Fifteen articles were included for final review. Commonly addressed themes included medical education (7 of 15 studies), surrogate decision-making (5 of 15 studies), and patient understanding (4 of 15 studies). The least common theme addressed in the literature was community notification (1 of 15 studies).

Conclusions
Studies of informed consent for procedures in the ED span many aspects of informed consent. The aim of the present narrative review is to summarize the work that has been done on informed consent for procedures in the ED.

Infringement of the right to surgical informed consent: negligent disclosure and its impact on patient trust in surgeons at public general hospitals – the voice of the patient
Gillie Gabay, Yaarit Bokek-Cohen
BMC Medical Ethics, December 2019; 20(1)

Abstract
Background
There is little dispute that the ideal moral standard for surgical informed consent calls for surgeons to carry out a disclosure dialogue with patients before they sign the informed consent form. This narrative study is the first to link patient experiences regarding the disclosure dialogue with patient-surgeon trust, central to effective recuperation and higher adherence.

Methods
Informants were 12 Israelis (6 men and 6 women), aged 29-81, who underwent life-saving surgeries. A snowball sampling was used to locate participants in their initial recovery process upon discharge.

Results
Our empirical evidence indicates an infringement of patients' right to receive an adequate disclosure dialogue that respects their autonomy. More than half of the participants signed the informed consent form with no disclosure dialogue, and thus felt anxious, deceived and lost their trust in surgeons. Surgeons nullified the meaning of informed consent rather than promoted participants' moral agency and dignity.

Discussion
Similarity among jarring experiences of participants led us to contend that the conduct of nullifying surgical informed consent does not stem solely from constraints of time and resources, but may reflect an underlying paradox preserving this conduct and leading to objectification of patients and persisting in paternalism. We propose a multi-phase data-driven model for informed consent that attends to patients needs and facilitates patient trust in surgeons.

Conclusions
Patient experiences attest to the infringement of a patient's right to respect for autonomy. In order to meet the prima facie right of respect for autonomy, moral agency and dignity, physicians ought to respect patient's needs. It is now time to renew efforts to avoid negligent disclosure and implement a patient-centered model of informed consent.

Consent for Emergency Treatment: Emergency Department Patient Recall and Understanding
Ashley LaFountain
Wright State University CORE Scholar, Scholarship in Medicine Papers, 2019
Abstract
Informed consent is an important ethical and legal requirement that underlies the concept of patient autonomy. This prospective survey study was conducted to assess patient recall and understanding of consent for treatment in adult emergency department (ED) patients at an urban level 1 trauma center with annual volume of 95,000, Miami Valley Hospital. Out of a total 293 patients, most individuals reported only receiving a verbal explanation of the consent document (45%) or not reading the document at all (36%). About half of the patients recalled consenting to treatment (N=144, 49%) and over one third of patients could not recall anything that they consented to during the consent process. These results demonstrate poor understanding of the informed consent document.

GENERAL/OTHER

Unethical informed consent caused by overlooking poorly measured nocebo effects
J. Howick
Journal of Medical Ethics, 16 February 2020
Open Access
Abstract
Unlike its friendly cousin the placebo effect, the nocebo effect (the effect of expecting a negative outcome) has been almost ignored. Epistemic and ethical confusions related to its existence have gone all but unnoticed. Contrary to what is often asserted, adverse events following from taking placebo interventions are not necessarily nocebo effects; they could have arisen due to natural history. Meanwhile, ethical informed consent (in clinical trials and clinical practice) has centred almost exclusively on the need to share intervention risks with patients to preserve their autonomy. Researchers have failed to consider the harm caused by the way in which such risk information is shared. In this paper, I argue that the magnitude of nocebo effects must be measured using control groups consisting of untreated patients. And, because the nocebo effect can produce harm, the principle of non-maleficence must be taken into account alongside the principle of autonomy when obtaining (ethical) informed consent.

Ethical Issues of Informed Consent: Students as Participants in Faculty Research
Phatcharapon Tulyakul, Soontareeporn Meeping
Global Journal of Health Science, 15 February 2020; 12(3)
Open Access
Abstract
Educators may face an ethical dilemma when they conduct research by using their own students as participants. The dual role conflict, coercion, confidentiality, misconstruction, and unawareness of the informed consent documents have been discussed as ethical issues in such faculty research. The educators as the researchers should be aware of these ethical dilemmas and attempt to implement the informed consent effectively. Thus, this article explores the ethical considerations of informed consent for the educational setting that students are recruited in the faculty research. Furthermore, this article represented recommendations for potentially resolving the ethical dilemmas of informed consent surrounding this phenomenon which consisted of eliminating dual role conflict and coercion, guarding confidentiality, and promoting good construction and awareness of the informed consent documents.
[Consent management and workflows for cross-sectoral patient records and teleconsultations]
Bauer J, Rohner-Rojas S, Holderried M
Der Radiologe, 14 February 2020

Abstract
Cross-enterprise electronic patient records are a key element in the design of interoperable medical care networks and process chains. However, the different requirements concerning type, performance and quality assurance of available communication services within the different healthcare sectors still require that the hospitals participate in various secure communication networks which have to be bridged for cross-sectoral communication. Cross-institutional pathways for telemedicine, however, can be mapped both within and across sectoral boundaries via automated process chains using the IHE (Integrating the Healthcare Enterprise) defined integration profile CrossEnterprise Document Sharing (XDS) and associated integration profiles. The provision of medical documents in a cross-institutional patient record outside of defined medical pathways requires differentiated authorization management. In this respect, consent documents according to the IHE APPC (Advanced Patient Privacy Consents) profile enable the documentation of the patient's consent, including information about planned authorized people, document types, period and type of document access allowed. Providing access control to medical documentation by the patients themselves is an essential part of the required focusing of medical services on patients. New interoperability standards optimized for use on mobile devices, such as FHIR (Fast Healthcare Interoperability Resources), will enable simplified delivery of patient-centered health records and other medical services on mobile platforms in the future.

Editor's note: This is a German language publication. Der Radiologe is an internationally recognized publication. The journal is devoted to all aspects of radiology and serves to further train radiologists who are resident and who work in the clinic.

The peculiar case of the Standards of Care: Ethical ramifications of deviating from informed consent in transgender-specific healthcare
Practices and concepts
M. Lipshie-Williams
Ethics, Medicine and Public Health, April – June 2020; 13

Summary
In this article, we discuss the alternate model of consent that has become dominant for the provision of transgender-specific health care within the United States, referred to here as the Standards of Care model. This model, which requires medical professionals to provide official opinions on a transgender patient’s readiness to accept and undergo care, stands in contrast to the majority model of medical consent in the US, namely individually provided informed consent. Here, we review the informed consent model, including the basic ethical components of this model and the essential elements of medical decision-making capacity. We then consider the Standards of Care model. We situate its origins in pathological understandings of gender variance and review the current requirements of the model. Consideration is given to logical inconsistencies within the current Standards of Care model, which holds that gender variance is non-pathological and affirming care is medically necessary, but that adult patients requesting such care require psychiatric diagnoses and are unable to consent to their own care. We then consider the bioethical meaning of the Standards of Care model, which others have proposed cedes some of the patient autonomy offered by informed consent for an inflated reliance on nonmaleficence. We align ourselves with this position. We continue this interpretation to suggest that the Standards of Care model ultimately fails to deliver this proffered nonmaleficence.
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BLOCKCHAIN

Using cryptography to keep exchanges secure, blockchain provides a decentralized database, or “digital ledger”, of transactions that everyone on the network can see. This network is essentially a chain of computers that must all approve an exchange before it can be verified and recorded.

Initial citation from Informed Consent Monthly Review

BOLAM TEST

A test that arose from English tort law, which is used to assess medical negligence. Bolam holds that the law imposes a duty of care between a doctor and his patient, but the standard of that care is a matter of medical judgement.

Initial citation from Informed Consent Monthly Review

CULTURAL AND LINGUISTIC DIVERSITY (CALD)

Cultural and linguistic diversity (CALD) refers to the range of different cultures and language groups represented in a population. In popular usage, CALD communities are those whose members identify as having non-mainstream cultural or linguistic affiliations by virtue of their place of birth, ancestry or ethnic origin, religion, preferred language or language spoken at home.

Editor’s Note: This term is often referenced in an Australian context.

Initial citation from Informed Consent Monthly Review

DEFERRED CONSENT

Informed consent obtained after a specific intervention which it references, termed deferred consent or retrospective consent.

Editor’s note: Sometimes referred to as waived consent

Initial citation from Informed Consent Monthly Review

DYNAMIC CONSENT

Term used to describe personalised online consent and communication platforms. Such platforms are primarily designed to achieve two objectives: 1) facilitate the consent process and 2) facilitate two-way, ongoing communication between researchers and research participants.

Initial citation from Informed Consent Monthly Review

ECONSENT

Electronic informed consent (eConsent) provides the same information, but in an electronic format that may include multimedia...
components such as images, audio, video, diagrams, reports, call out boxes and a digital signature which may aid the consenting process.

*Initial citation from Informed Consent Monthly Review*

**Exception from Informed Consent (EFIC)**

A pathway that allows investigators to enroll patients without consent from the patient, their family, or their legally authorized representatives.

*Initial citation from Informed Consent Monthly Review*

**Free, Prior and Informed Consent (FPIC)**

The standard FPIC, as well as Indigenous Peoples’ rights to lands, territories and natural resources are embedded within the universal right to self-determination. The normative framework for FPIC consists of a series of international legal instruments including the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), the International Labour Organization Convention 169 (ILO 169), and the Convention on Biological Diversity (CBD), among many others, as well as national laws... FPIC is a specific right that pertains to Indigenous Peoples and is recognized in the UNDRIP. It allows them to give or withhold consent to a project that may affect them or their territories. Once they have given their consent, they can withdraw it at any stage. Furthermore, FPIC enables them to negotiate the conditions under which the project will be designed, implemented, monitored and evaluated.

*Editor’s Note: We see this term of art as potentially contributing more widely because of its clarification of what IC might mean.*

*Initial citation from Informed Consent Monthly Review*

**Learning Health System (LHS)**

A Learning Healthcare System is defined... as a system in which, “science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience.”

*Initial citation from Informed Consent Monthly Review*

**Presumed Consent**

The idea that someone is believed to have given permission for something unless they say they do not, used, for example, in some countries for organ donation.

*Initial citation from Informed Consent Monthly Review*

**Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)**

The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) is a network of independently established regional fora for ethical review committees, health researchers and invited partner organizations. The primary objective of SIDCER is to contribute to human subject protections globally by developing local capacity for ethical review of research involving human subjects and for developing policies on the ethics of health research.

*Initial citation from Informed Consent Monthly Review*
TOOLS FOR ASSESSMENT

**Atlas.ti**
ATLAS.ti is a powerful workbench for the qualitative analysis of large bodies of textual, graphical, audio and video data.
*Initial citation from Informed Consent Monthly Review*

**Constant Comparison Method**
Constant comparison is the data-analytic process whereby each interpretation and finding is compared with existing findings as it emerges from the data analysis.
*Initial citation from Informed Consent Monthly Review*

**Decision-Making Capacity Assessments (DMCA)**
Adults are presumed to be independent decision-makers regarding their personal and financial affairs. When a person's decision-making capacity (DMC) in specific domains, however, comes into question due to diseases such as dementia and other chronic conditions, standardized Decision-Making Capacity Assessment (DMCA) processes aligned with legislation are needed.
*Initial citation from Informed Consent Monthly Review*

**DICE**
Web-based electronic informed consent application.
*Initial citation from Informed Consent Monthly Review*

**Flesch-Kincaid Readability Scale**
Readability test that tell what level of education someone needs to easily read a piece of text.
*Initial citation from Informed Consent Monthly Review*

**Gillick Competence**
The [term used] ... to identify children aged under 16 who have the legal competence to consent to immunization, providing they can demonstrate sufficient maturity and intelligence to understand and appraise the nature and implications of the proposed treatment, including the risks and alternative courses of actions. Gillick competence is a functional ability to make a decision.
*Initial citation from Informed Consent Monthly Review*

**Grounded Theory approach**
Grounded theory sets out to discover or construct theory from data, systematically obtained and analysed using comparative analysis.
*Initial citation from Informed Consent Monthly Review*
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<th>Term</th>
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<tr>
<td>Likert Scale</td>
<td>A five (or seven) point rating scale [used] to measure attitudes directly, it allow[s] the individual to express how much they agree or disagree.</td>
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<td>Meaning Equivalence</td>
<td>Multi-dimensional database that allows the sorting and mapping of important concepts through exemplary target statements of conceptual situations, and relevant statements of shared meaning.</td>
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<tr>
<td>Reusable Learning Objectives (MERLO)</td>
<td>Multi-dimensional database that allows the sorting and mapping of important concepts through exemplary target statements of conceptual situations, and relevant statements of shared meaning.</td>
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<td>Oxford Video Informed Consent Tool (OxVIC)</td>
<td>Personalised video consent tool to enhance patient satisfaction in the preoperative consenting process.</td>
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<td>REDCap</td>
<td>REDCap is a secure web application for building and managing online surveys and databases.</td>
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<td>Research Kit</td>
<td>ResearchKit, developed by Apple, is an open-source software framework designed to streamline the process of screening and consenting participants into research studies.</td>
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<tr>
<td>The System Usability Scale (SUS)</td>
<td>Provides a quick and reliable tool for measuring usability. It consists of a 10-item questionnaire with five response options for respondents; from Strongly agree to Strongly disagree.</td>
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<td>Teach Back</td>
<td>Teach-back is a way to confirm that the educator has explained to the patient what is important and in a manner that the patient understands. Patient understanding is confirmed when the patient explains it back in their own words to the educator. It can also help the clinician identify explanations and communication strategies that are most commonly misunderstood by patients.</td>
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**GUIDANCE DOCUMENTS**

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<tr>
<td>Declaration of Helsinki (DOH)</td>
<td>The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.</td>
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**International Ethical Guidelines for Health-Related Research Involving Humans/CIOMS Guidelines**

The aim of the guidelines is to provide internationally vetted ethical principles and detailed commentary on how universal ethical principles should be applied, with particular attention to conducting research in low-resource settings.

*Initial citation from Informed Consent Monthly Review*

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**PRISMA Guidelines**

PRISMA is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses. PRISMA focuses on the reporting of reviews evaluating randomized trials, but can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions.

*Initial citation from Informed Consent Monthly Review*

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**Revised Common Rule Guidelines**

On January 19, 2017, the US Department of Health and Human Services and fifteen other federal agencies issued revisions to the regulations governing human subjects research (called the Common Rule)... The Revised Common Rule broadens the types of research that qualify for exemption. Several exempt categories have been revised, and there are new categories of exemptions. These changes to exemption will apply to research that is federally funded or supported.

*Initial citation from Informed Consent Monthly Review*