DO→IT

Summary of the empirical investigation and survey results

IMI2 Project ID – DO->IT

Big Data for Better Outcomes, Policy Innovation and Healthcare System Transformation

WP4 – Minimum Data Privacy Standards for ICFs and Supporting Materials

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Empirical investigation of current informed consent practices

Summary

The vast scale of data collection along with novel methods to analyse complex data offers great opportunities to improve health outcomes. This evolving data environment also brings challenges around data privacy rights, which traditional forms of consent are not always able to suitably address. Novel models of consent have the potential to add value in this new data environment by facilitating research opportunities while preserving participant rights.

The aim of this empirical investigation is to capture existing and emerging approaches to informed consent in relation to the use of big data in health care research. The first part of this report presents the findings of a rapid review of articles published in scientific journals since 2010. The second part of the report presents findings from a survey that explores experiences and opinions of informed consent procedures.

The review and survey reveal that there is clear interest in developing new models of informed consent and adapting existing models. Developments in ICT account for a significant portion of the innovation happening around informed consent procedures. This ranges from practical alterations to ICFs including adding quizzes, to using smartphones for recruitment purposes and facilitating more interactive forms of consent. Data re-use, data linkage and genome-based research are other drivers of developments around informed consent.

There is substantial heterogeneity in preferences and practices surrounding informed consent. Approaches span across a wide range of levels of openness and degrees of participant-control. Recently, participant-centric forms of consent seem to be increasing in popularity, although survey results indicate that dynamic consent is still in its early stages. Differences in the scope and participant-centric focus of models is likely to reflect differences in the types of data being used. For example, broad consent appears to be particularly popular in the context of biobanks and learning healthcare systems, while more restricted forms of consent might be more prevalent in other contexts such as traditional clinical studies

List of abbreviations

BD4BO - Big Data for Better Outcomes programme
CER - Comparative effectiveness research
CRO - Contract research organisation
DPEC - Data Protection and Ethics Committee

ICF - Informed consent form
ICT - Information and communication technology
IMI2 - Innovative Medicines Initiative 2
IRB - Institutional review board
PRO - Patient-reported outcome

Introduction

More and more data is being collected by researchers, health care systems and a range of other stakeholders. This data, some of which may be sensitive, offers great opportunities to improve research, health care systems and outcomes, but must be supported by mechanisms that preserve participant data privacy rights (Mittelstadt, 2016; Salas-Vega, 2015; Salcher, 2017).

New technologies, the relatively low cost of data collection techniques and the perceived value of data have led to data being collected much more frequently, often seemingly automatically through mobile device apps and other mechanisms. Changes brought about by the increased prevalence of big data in particular make the need for new models of consent especially important, both to preserve participants' rights as well as to promote improvements in research. The range and volume of data collected means there is a greater depth of information available about people.

Improved computing capacities and novel analysis methods allow researchers to make use of increasingly large and comprehensive datasets. These datasets are being linked together, sometimes across geographical settings and clinical or policy areas. While previous research was mostly restricted to identifying associations between exposures and outcomes using a single dataset, the linkage of several datasets – from clinical trials to biobanks, administration, care coordination and even non-health-related data - pushes the frontier of health care research by providing a richer picture of each subject (Weber, 2014; Denaxas, et al., 2012).

Also, technological advances have significantly reduced the resources required to generate, process and store genomic data, giving researchers access to unprecedented levels of personal and potentially reidentifiable data, raising questions around whether the "anonymize or consent" paradigm should be rethought to better reflect a new research environment where access to and sharing of data is becoming increasingly common (Schmidt, 2012).

Given the evolving data environment, evidenced by these changes to data collection, analysis and storage, traditional forms of consent are not always suitable. As an important participant protection mechanism that was developed in an entirely different research and data context, informed consent therefore is being reconsidered. Implemented effectively, these new models of consent have the potential to extend research opportunities while preserving participant rights.

The aim of this empirical investigation is to capture and better understand existing and emerging practices surrounding data privacy and informed consent in relation to the use of big data in health care research. This report presents the findings of a rapid review and a survey among data privacy and ethics experts, describing current and new models and approaches to informed consent. The first part of the report presents the results of the rapid review focusing on informed consent models discussed in articles published in scientific journals since 2010. It examines the rationale behind these new models, as well as how they account for pressing topics including data re-use, data linkage and participant control of their data. In the second part of the report, experiences with current practices and expectations for future developments from over 50 survey respondents are presented.

Rapid review

Methods

A rapid review of the literature was conducted to identify new consent models and their key components. A rapid review can be characterised as an accelerated literature review with components of a systematic review, such as a clearly defined search strategy, that is implemented in a simplified manner (Tricco AC, 2015).

This rapid review was conducted as part of the IMI2 Big Data for Better Outcomes (BD4BO) - DO-IT programme to support the development of data privacy standards for informed consent forms (ICFs). It focuses on novel consent models and approaches tailored to a research environment that has evolved in recent years. Specifically, the review aims to answer the question:

What approaches to informed consent have been proposed since 2010 in response to a research environment requesting access to more and increasingly linked data?

In addition, three sub questions were identified:

- How do recently proposed consent models define the scope of data usage?
- What is the role of novel technologies in administering informed consent forms and in enabling new consent models?
- How is data protection managed in novel consent models?

Search strategy

Commentaries, editorials and reviews were identified through a comprehensive two-tiered search strategy. First, relevant articles were identified through a search with restrictive search terms on a comprehensive online database, MEDLINE (via PubMed). Second, more inclusive search terms and filters were used in targeted searches on the websites of high-impact journals. These journals have a track record of publishing influential editorials and reviews on consent, and provide advanced search masks on their websites. The list of journals included the British Medical Journal; The Lancet; New England Journal of Medicine and the American Journal of Bioethics.

Schematically, our search terms in both steps of our search strategy pertained to “consent” alongside a range of key terms that have been used in the past to describe novel forms of consent. These terms were identified through scoping reviews of the literature as well as discussions with data privacy and informed consent experts. A detailed search strategy is included in the appendix.

Inclusion and exclusion criteria

Articles were included if they discussed new forms of consent against the background of a changing research environment of increasingly big and linked data. The focus was on opinion pieces and reviews with the expectation that authors might have used these formats to share ideas for new models or to comment on consent models proposed elsewhere. Primary studies were excluded.

The following exclusion criteria were applied:

- Article not in English language
- Article published before 2010
- Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)

- Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)
- Article discusses informed consent for treatment rather than for data collection and use

Study selection

Articles were assessed for eligibility through a two-stage screening process. First, one researcher scanned titles and abstracts of articles to identify those potentially eligible for inclusion. Full text for articles deemed eligible at this level were retrieved. Second, two researchers independently assessed full text articles for eligibility and resolved any differences in opinion regarding inclusion by discussion.

Data extraction

One researcher extracted information from the articles. For quality control, data extraction was double checked for one third of included articles, which showed high agreement. The extracted information covered author, publication year, setting, rationale for proposing a new consent model, process for obtaining consent, scope of consent given, approach to re-using data, and approach to participant empowerment.

Data extraction was conducted using a spreadsheet with the pre-specified domains stated above. The data extraction form was piloted for the first five articles that were identified and slight adjustments were made based on our experience after extracting information for these. Data was extracted both in pre-specified categories and in narrative form to allow for the capturing of important information that might not be captured through the standardised data extraction.

PRISMA flow chart

The following PRISMA flow chart depicts the number of articles included and excluded at each stage of the screening process. A total of 1662 articles were identified for inclusion, 160 were included after the first scan, and 50 were included in this review.

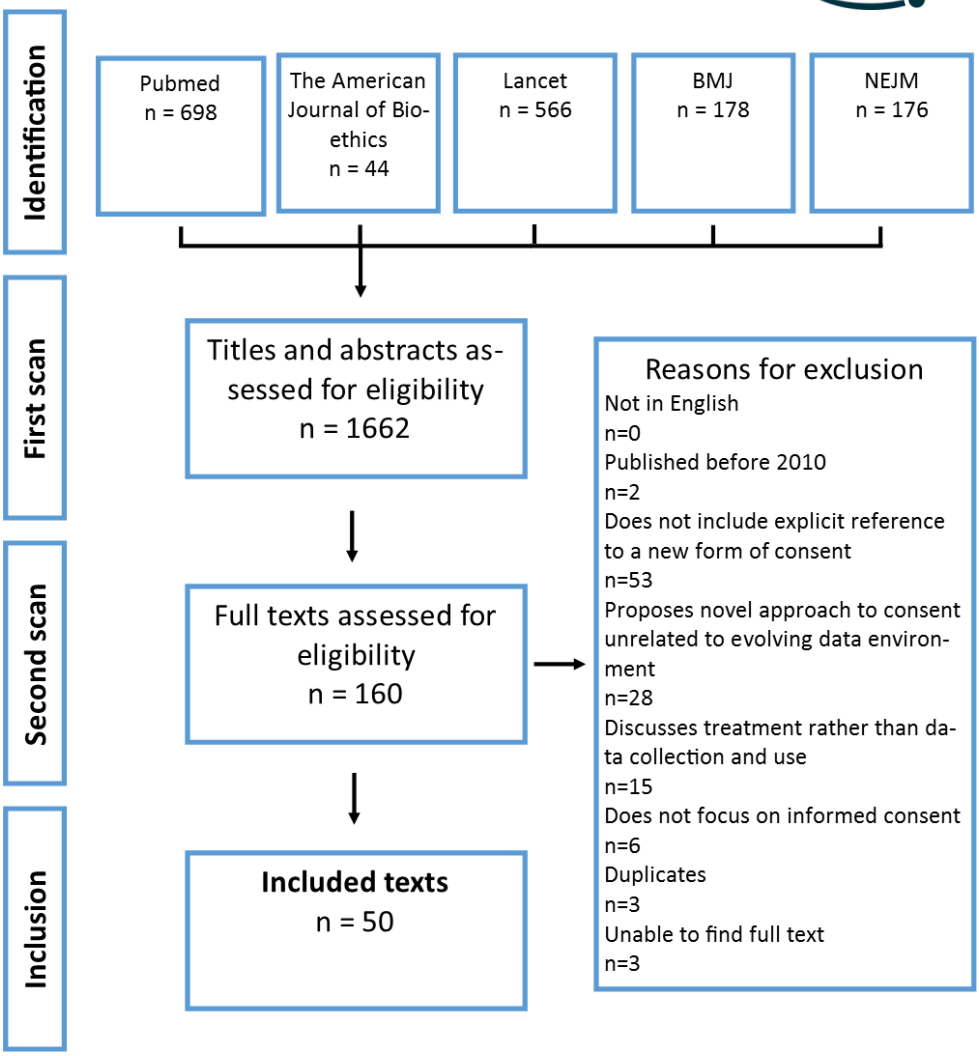

Figure 1: PRISMA flow chart

Overview

The articles included in this review focus on a range of countries and types of information. A full list of articles is provided in the appendix.

Most articles either focus on a range of geographical areas or leave the area unspecified (Figure 2). Of those that do specify a country, the clear majority focus on the United States. The United Kingdom is the focus of a smaller but still substantial number of articles, and a few countries including South Africa (Greenberg, et al., 2013), Australia (Otlowski, 2012), Canada (Groisman, et al., 2014), and the Netherlands (Riegman, 2011) are the focus of one or two articles.

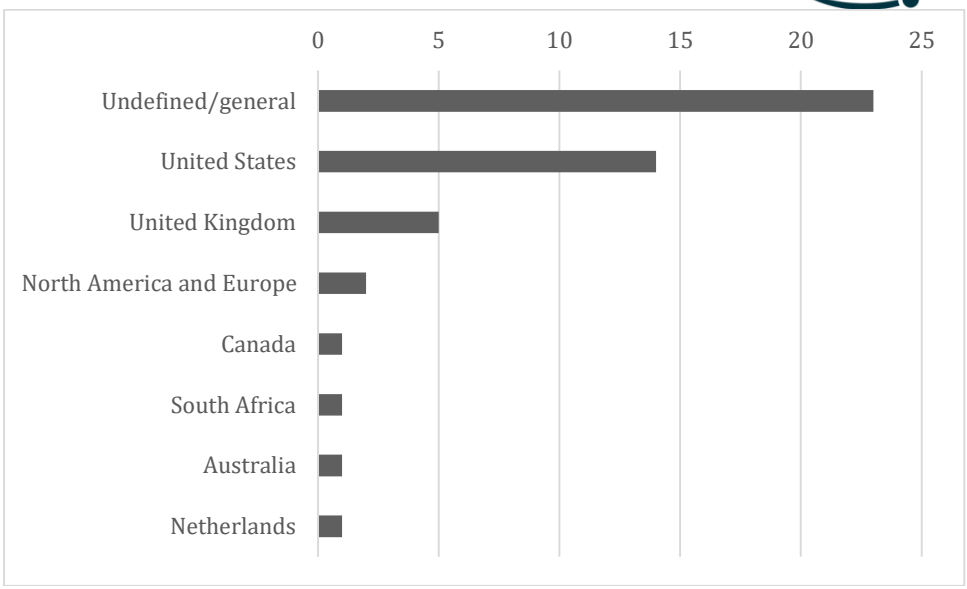

Figure 2: Geographical focus of included articles

A sizeable minority of articles do not focus on a single clinical area. Of those that do focus on a single clinical area, most discuss genetics, genomics, and similar topics. Biomedicine is also a fairly common topic. A small number of articles focus on approaches to health care such as precision medicine, pragmatic trials, and learning health care systems which use research in routine care settings to improve quality of care; or on specific treatment areas such as psychiatry, rare diseases, antihypertension medications, and primary percutaneous coronary intervention.

The data used in the context of the new consent models is most commonly biobank or biomedical data and samples, followed by genetic and genomic data. Less often, the data is from comparative effectiveness research (CER) studies, clinical data or electronic health records, and learning healthcare systems. One article covers internet based research data (Harriman, 2014), and another covers survey data (Whicher & Evans, 2016).

The number of articles that were analysed increases each year from 2010 to 2014, and then decreases each year until part-way through 2017.

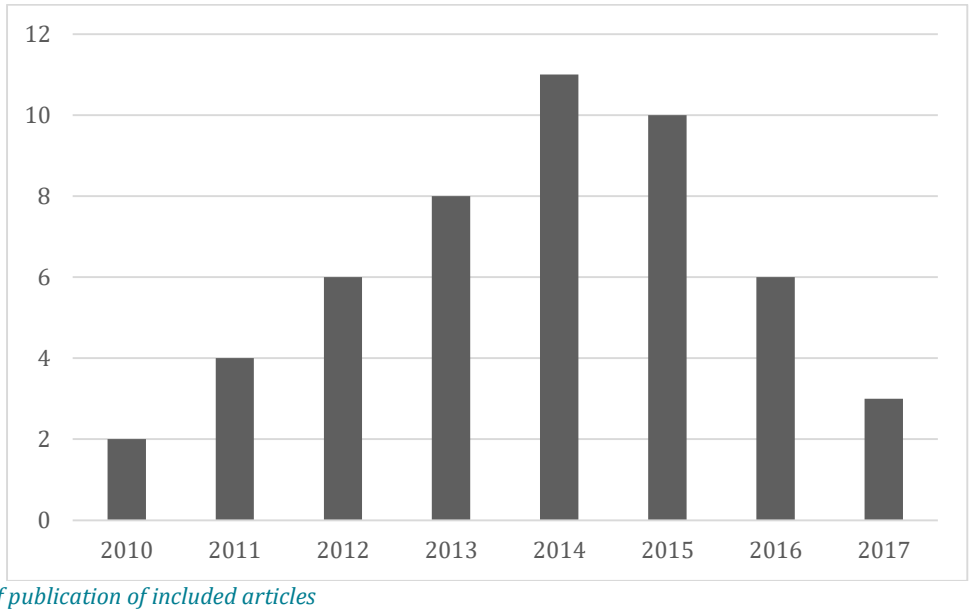

Figure 3: Year of publication of included articles

This review includes articles by many different authors, with a small number of authors appearing more than once.

Rationale

Articles put forward a variety of reasons for implementing new informed consent models and processes (see Box 1 for an overview of key motivations in included articles, and Box 2 for ten of the top arguments for re-thinking informed consent). The most common reasons were the current informed consent process no longer being appropriate, followed closely by ethical considerations and, less frequently, enabling research through novel study designs.

Rationale for new consent models

Outdated existing consent models

- *Progress in research methods and use of new technologies*
- *Changes in type of research (novel study designs)*
- *Pragmatic reasons*

Ethical considerations

- *Ethical imperative to improve health care*
- *Ethical imperative to protect research participants*

Box 1: Summary of rationales for new consent models

Ten arguments for re-thinking informed consent

- Make the most of opportunities provided by **information and communication technology**
- Support **evidence-based** medicine and **learning health care** systems
- Develop new **treatments** and advance medical and health services **research**
- Respond to participants' desires to be **more involved** in decision making
- Adapt to emerging **technologies** especially those related to genetics and genomics
- Respond to the challenge of uncertainty around **future uses** of data and donated material
- Address obstacles to obtaining consent such as **low literacy** about genetics
- Respond to a changing **research environment** which may involve, for example, multiple research sites and a large number of participants
- Adapt to a changing **regulatory environment**
- Minimise the **burden and cost** to researchers

Box 2: List of ten of the main reasons to re-think consent, based on arguments from the articles

Outdated existing consent models

Among reviewed articles, the most popular rationale for a new model or approach to consent is to

change existing outdated consent procedures. Articles using this justification almost exclusively focus on biospecimens and genetics. A small number focus on electronic medical records or on other data types. Most articles cite new technologies or approaches as their justification for changes to informed consent. For example, future use of data and samples might be unknown, and databases like a global rare disease patient registry require guidance. As the number of participants and sites involved in research grows, informed consent approaches could better reflect this changing environment. Similarly, there are questions around how to deal with incidental findings, data increasingly being used for multiple purposes, and the combination of biospecimens with clinical and real-time data. The area of genetics is recognised as posing a particular challenge.

There may, for instance, be a gap between practice and the 'theoretical ideal' in areas like genome sequencing, and questions around how best to limit harm resulting from a shift from discrete to broad genetic testing.

Existing models of consent were also considered to be outdated as a result of novel study designs. Enabling research through novel study designs, such as pragmatic trials and internet-based research, was the least common rationale behind new informed consent approaches. In other articles, these considerations were common as an aspect of the rationale if not the main justification.

Some articles focused on changes in the type of research. For example, the research might have minimal risks but large potential impacts on welfare. Pragmatic trials, for instance, are considered low risk to the patient because therapies are not experimental. In such cases, where two established interventions are compared, existing informed consent procedures could be too strict, resulting in delays in research results and therefore causing indirect harm to patients.

The use of technologies was another focus of these articles. For example, electronic devices and new information and communication technology (ICT) can facilitate new approaches to research such as internet or app-based trials. In this new research environment, informed consent could be used to allow collection of patient-reported outcomes (PROs) for electronic health records which can enable learning health care systems or other forms of research.

In addition, a range of pragmatic reasons are put forward by some of the articles. For example, it may be expensive or impractical to gain consent for all participants for each study (Wendler, 2013), low literacy may affect how well people understand informed consent procedures (Fiore & Goodman, 2016), there is a need to protect participants against harm from data use (Francis, 2013), and participatory models may be more appropriate when participants increasingly expect to be treated as partners in research (Hudson & Collins, 2015).

Ethical considerations

Of the articles that primarily cited ethical considerations, most focused on biomaterials, genetic data and similar types of data. A couple of articles discussed a range of types of data, and there was one article each about internet research and CER (Harriman, 2014; Kass, 2016). The authors tended to base ethical considerations either around an ethical imperative to improve healthcare, or an ethical imperative to protect participants.

In the case of the former, articles cited a desire to, for example, avoid 'regulatory whiplash' or other barriers to sharing data that could limit the potential to use data to improve healthcare. They also mentioned the importance of improving healthcare by learning from the available data, and improving general understanding of the 'moral potential' of emerging technologies and data practices. In order to enable learning healthcare systems procedures that emphasise the need to obtain informed consent from patients for each use of their data have been suggested to be substituted with an opt-out system. In such a system data can be used for non-interventional

research unless the patient objects to it. In healthcare systems that are based on solidarity, patients can also be expected to contribute to a learning healthcare system by making their data available (Riegman, 2011).

In the case of the second category of ethical considerations, articles stressed the importance of improving public trust and confidence including through increased transparency, informing participants as much as possible about implications of research, demonstrating that access to patient data is appropriately managed, and noting uncertainty about future use of data and samples.

There was a desire to involve people more in debate, and encourage a stronger relationship between science and citizens. Protecting the wellbeing of participants, particularly in the context of new technologies, was considered to be crucial. Noting the uncertainty about how data and samples will be used in the future, questioning who can access data especially in the context of reidentification and considering patient competence were considered to be important aspects of an ethical imperative to protect participants. A belief that it is important to balance participant autonomy with the potential improvements through research was evident from many of the articles that focused on ethical considerations.

Informed consent process and scope

A range of approaches to informed consent were proposed. These take a variety of forms including in-person, electronic, written, oral, remote, onsite and combinations of these. Even within the same named models, processes vary and rely on different tools. Many articles did not explicitly state the scope or flexibility of the informed consent model or approach. Of those that do specify the scope of consent, the majority are flexible or open rather than fixed.

Novel consent models

Box 3 at the end of this section lists some of the main forms of consent put forward by the articles in this review while the figure below maps some of these approaches based on their level of openness and participant control.

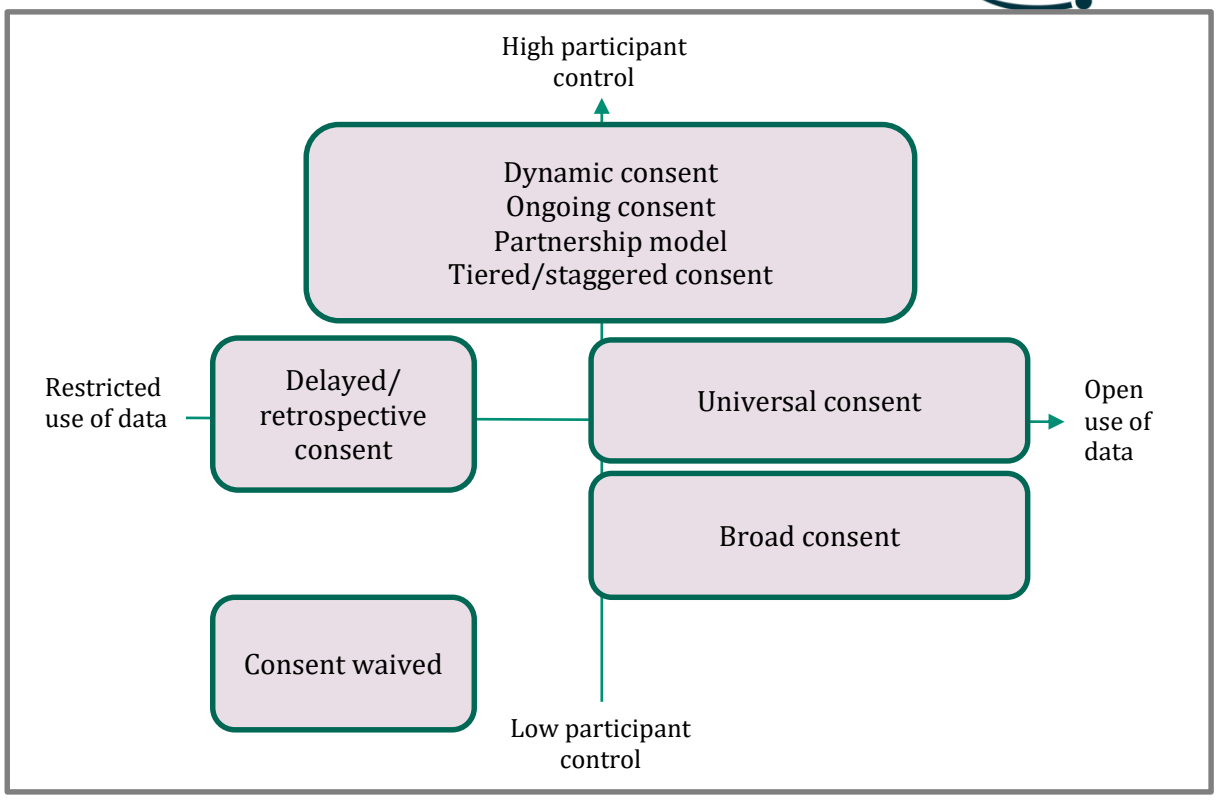

Figure 4: Approaches to informed consent by openness and degree of participant control

There appears to be substantial appetite for patient choice over the forms of consent in use and a range of models have been proposed to enable this. Choice can relate both to the use of the participant's data, and to the process of consent in terms of what is shared with the patient to assist in informed decision-making. One article, for example, proposes that the amount of information provided during the informed consent procedure is tailored to the individual in question. All participants would be provided with 'tier 1' information, while 'tier 2' information is provided only to those who would like further detail (Bradbury, 2015).

There is also significant interest in ongoing opportunities for participants to change their consent preferences over time. Among the most interactive approaches, **dynamic consent** appears to be most frequently put forward by included articles. This form of consent relies on ongoing communication where participants may be able to provide or revoke consent over time, obtain information about how their data is being used, and learn about outcomes of the research.

Electronic systems such as web interfaces are often used to support this form of consent. Ongoing consent is a similar model that was proposed. In this case, consent is a continuing process that is controlled by the participant who is able to withdraw at any time. The **partnership model** is also similar, described as a bidirectional communication process for consent that provides opportunities for researchers and participants to update consent over time.

Tiered consent is another choice-based model. One example allows participants to personalise consent based on a range of factors including preferences for future uses of their data and whether or not they wish to be recontacted before any future use (Hudson, 2011).

Moving away from these more participatory models, **broad consent** is also very frequently discussed in the articles and is a very open form of consent. Occasionally, other relatively open models like **universal consent** are proposed for situations such as quality improvement or quality improvement research which affect the whole organisation. Broad consent proposals often include

other processes working alongside them. For example, one suggestion was to have broad consent with certain limits set on the future use of samples which could be judged by IRBs. Others proposed broad consent in a well-regulated environment with safeguards, and with mechanisms used to monitor communication with donors.

Other suggestions include **opt-out** forms of consent, for example in the case of CER, when the participant is given brief information about the treatment and told they will be part of the research study unless they do not wish to take part (Kass, 2016). Another opt-out model put forward an 8-point model of consent with opt-out based on Fiona Caldicott's recommendations (Perrin, 2016; Caldicott, 2016). These points, aimed at participants, tell participants of the importance of information, the role of law in protecting participants, the right to opt out, and the suggestion that opt out does not apply to anonymised information or exceptional when there is a 'mandatory legal requirement' or 'over-riding public interest' like tackling the Ebola virus.

Conversely, an enhanced **opt-in form** of consent was put forward where consent is sought when patients are most 'competent' and which may use aids like videos and PowerPoint to explain the procedure (van der Baan, 2013). This builds on the premise of traditional opt-in forms of consent when participants are offered an opportunity to express that they want to be involved in data collection or use.

Universal consent was proposed in the case of quality improvement or quality improvement research, as interventions would target the entire health care unit in these cases (e.g. a hospital) (Fiscella, et al., 2015). Another option, **targeted consent**, could be used to disclose extra information during a standard informed consent procedure. One article proposed viewing data as a public good so information about data collection, management and use could be made publicly available (Francis, 2013). Another proposed differentiating between written consent – for example in the case of biospecimens – and oral consent – for example for surveys, focus groups and interviews (Emanuel & Menikoff, 2011).

A small number of articles proposed situations in which obtaining consent was not essential. For example, an ethics committee could grant a **waiver** of informed consent based on specific conditions such as the therapy in question not being experimental in nature thereby posing minimal risk. Authorisation was proposed as an alternative to informed consent in situations such as pragmatic trials based on randomised selection. Others suggested that **delayed or retrospective consent** was thought to be acceptable when therapies are interchangeable and patients were allocated to the therapies randomly.

A number of articles highlighted the role of panels, **institutional review boards (IRBs)** and similar bodies in the consent process. Panels could, for example, decide whether or not studies could be integrated into clinical care without consent, or refer the study to a committee to decide whether or not to grant a waiver of consent. Another idea was that a model of layered consent could involve IRBs that could specifically review studies that intend to link data (Groisman, et al., 2014).

The following box lists some of the forms of consent that appeared in this review, along with some of the articles that discussed them.

Forms of consent		
Dynamic consent	*Ongoing communication allowing participants to provide or revoke consent over time, obtain information about how their data is being used, and learn about outcomes of the research. Electronic systems such as web interfaces are often used to support this form of consent. Similar: ongoing consent, a continuous process controlled by the participant who is able to withdraw at any time.*	(Grady, et al., 2017); (Dixon, et al., 2014); (Kaye, 2012); (McCaughey, et al., 2016); (D'Abramo, 2015)
Partnership model	*Similar to dynamic consent. Bidirectional communication process for consent that provides opportunities for researchers and participants to update consent over time.*	(McGuire & Beskow, 2010); (Driessnack & Gallo, 2011)
Tiered consent	*Allows participants to personalise consent based on a range of factors including preferences for future uses of their data and whether or not they wish to be recontacted before any future use.*	(Bradbury, 2015); (Hudson, 2011)
Layered consent	*Often refers to a form of consent that allows participants to choose between options.*	(Groisman, et al., 2014)
Targeted consent	*Disclose extra information during a standard informed consent procedure.*	(Wendler, 2015)
Broad consent	*Open in terms of data re-use. Broad consent proposals often include other processes working alongside them. For example, one suggestion was to have broad consent with certain limits set on the future use of samples which could be judged by IRBs. Others proposed broad consent in a well-regulated environment with safeguards, and with mechanisms used to monitor communication with donors.*	(Tabor, et al., 2011); (Wendler, 2013); (Otlowski, 2012) *(hybrid model);* (Menikoff, et al., 2017); (Grady, 2015); (Hudson & Collins, 2015); (Lancet, 2014); (Hudson, 2011); (Lo & Barnes, 2016)
Universal consent	*Similar to broad consent. Proposed to be used in situations where the entire healthcare organisation (e.g. a hospital) is affected by an intervention, such as quality improvement or quality improvement research.*	(Fiscella, et al., 2015)

Box 3: List of forms of consent and articles in which they were mentioned

Open consent	*Consists of a notification to the data subject about the use of their data for a new research project. Considered sufficient for deidentified, aggregated data.*	(Grady, et al., 2017)
Integrated consent	*Informed consent process for research in routine care settings is integrated into the standard clinical discussion, which is recorded. Suggested as a pragmatic alternative to a consent waiver for research in routine care.*	(Kim & Miller, 2014)
Opt-in/ opt-out	*Opt-out: suitable for comparative effectiveness research (pragmatic trials in routine care) where the participant is asked to actively express a desire to be involved before any data is collected or used. Opt-out might not apply to anonymised information or when there is a 'mandatory legal requirement' or 'over-riding public interest' like tackling the Ebola virus.* *Enhanced opt-in builds on the premise of traditional opt-in forms of consent when participants are offered an opportunity to express that they do not want to be involved in data collection or use and uses aids like videos and PowerPoint to explain the procedure.*	(Kass, 2016); (van der Baan, 2013); (Riegman, 2011); (Perrin, 2016)
Delayed	*Consent obtained after intervention was done. This can be considered acceptable when therapies are interchangeable (clinical equipoise) and patients were allocated to the therapies randomly (pragmatic trials).*	(MacKay, et al., 2015); (Shaw, 2014)
No consent	*An ethics committee could grant a waiver of informed consent based on specific conditions such as the therapy in question not being experimental in nature thereby posing minimal risk. Authorisation was proposed as an alternative to informed consent in situations such as pragmatic trials based on randomised selection.*	(Crouch, 2015); (Faden, 2014)
IRB review	*Increasingly important role for institutional review boards and similar bodies. Panels could, for example, decide whether or not studies could be integrated into clinical care without consent, or refer the study to a committee to decide whether or not to grant a waiver of consent. A model of layered consent could involve IRBs to review studies that intend to link data retrospectively.*	(Lo & Barnes, 2016); (McGuire & Beskow, 2010); (Hansson, et al., 2013)

Enhanced understanding through novel technologies

ICT is also often introduced as an enabler to improve research participants' understanding of informed consent procedures. For example, video and other multimedia can be used to explain the research study, quizzes can be used to check participants' understanding of the process, and electronic reminders can send summaries of information about the research. These could be linked to mobile devices.

Other tools that could improve informed consent procedures include patient-centric web interfaces, publicly available shared consent tools, e-consent obtained via devices; computer-based analysis techniques to classify the eligibility of proposals coupled with videos and an interactive consent process to check comprehension.

Data re-use

A sizeable proportion of articles explicitly discussed the re-use of data. A number of articles suggested that specific consent for each participant for each re-use of data is not needed in many situations.

Articles discussed a range of challenges regarding data re-use. Biobanks in particular face the difficulty of being unable to specify all future uses of data and samples at the time of consent. Difficulty in anticipating all the future uses of data is a commonly discussed challenge, and one article questioned whether it would be appropriate to approach people for reconsent if they had been told they would never be re-contacted.

Another challenge across a number of articles is achieving appropriate levels of transparency and participant trust. To address this, some articles suggest informing participants of the general ways their data or samples could be used in the future. It was also suggested that there is transparency about where biomaterials might be sent to, in terms of geographical location and so on.

In addition, informed consent was identified as insufficient protection from objectionable uses of data in certain situations. For example, individuals who would have objected to reuse of their data could still be affected by the results of research consented to by their peers, as happened in the case of the Havasupai tribe (Francis, 2013).

Articles discussed a number of options to deal with data re-use which are outlined in Box 4.

Dealing with data re-use

Opt-out approaches
- *Flexible option that leaves participant in control of data use*

Dynamic consent
- *Allows participants to change their opinion*
- *Can be facilitated through ICT*
- *In extended form, a partnership model with ongoing interaction*

Broad consent
- *Facilitate future studies*

Waive re-consent
- *Banking on participant's trust*
- *Option if risks and benefits are similar as in the case of original research*

Role of IRBs
- *Consent waiver appropriateness to be judged by IRB*
- *IRB might not be necessary if other appropriate safeguards are in place*

Box 4: Summary of options to deal with data re-use proposed by articles

In terms of specific models of consent, dynamic consent and partnership models are put forward fairly often in the context of data reuse. The ongoing nature of such models can facilitate taking into account participants' changing opinions and preferences. Broad consent, on the other hand, gives participants less ongoing control over re-use of their data but can be helpful in facilitating yet-to-be-specified research studies.

There were some suggestions to avoid reconsent all together or to draw on support from IRBs or similar bodies. This could happen, for example, when the goals, risks and benefits of a new study

are similar to those described in the original consent documents. Another suggestion was to reuse data as long as specified conditions are met, which is decided by an IRB. A similar suggestion was made in the context of hESC lines, where the proposal was that re-use would be acceptable, even for a different area of research, as long as certain conditions are met. Another similar suggestion in the context of biospecimens was to identify sensitive secondary research projects and target them for heightened scrutiny, possibly including IRB review. Conversely, there was a suggestion to have safeguards in place but no IRB review. Another suggestion was to have a simpler review process for reuse of data for studies related to informational risks.

Other suggestions that were made around consent in the context of data reuse include using the consent document to describe who may access the data and under what circumstances this would be considered acceptable. Another suggestion was, in the case of exome sequencing and whole genome sequencing, to consider obtaining reconsent for studies with an active governance structure where participants have higher expectations of how they are informed about new studies or for studies where researchers have long-term relationships with participants.

Data linkage

The majority of articles did not discuss data linkage in-depth. Of those that did, data linkage was considered to be currently taking place or on the horizon.

Numerous advantages of data linkage were put forward in these articles. In terms of research, data linkage could fast-track disease research, facilitate gene discoveries and play a role in collaborations between international networks like biobanks. Data linkage could also lead to improved care and better-informed commissioning processes. One article mentions registries in Scotland and Scandinavia that have benefited from data linkage in healthcare and research, and suggests the NHS could benefit even more as it is on a larger scale. The main negative aspect of data linkage was considered to be the increased ability to reidentify data. This could result in stigma towards people or groups affected by certain findings.

Articles put forward suggestions of ways to improve informed consent processes in the context of data linkage. For example, informed consent could include information about sharing of data and the risks of identification as well as descriptions of possible harms and the likelihood of them occurring. There could be technical solutions to reidentification such as ensuring confidentiality of the data or using datashield, a technique used to analyse potentially sensitive data without sharing the data (Riegman, 2011). In some cases, a notification approach is sufficient, especially if the goals, risks and benefits of the research are similar to the original study which obtained consent.

Similarly, informing participants about the intention to link data with the opportunity to withdraw, but without obtaining formal consent initially is another option. In some cases, getting consent is useful to boost transparency and trust especially if there is a long-term relationship with participants.

Participant control

It is evident from many articles that participant choice and control over their data is core to the requirements of new models and approaches to informed consent. Largely, the intention is to increase public trust and participant knowledge or research processes.

Articles put forward a number of tools used to facilitate participant control. These include participant-centric systems including IT interfaces that – along with safeguards and strong governance - can help participants to be involved in an on-going way including by being more informed and providing secondary consent. Other tools include communication mechanisms such as newsletters and

websites, as well as app-based trials that allow participants to select which data to make accessible.

Articles vary in the level of participant control they propose. Some propose limited forms including opt-out or broad consent; the right simply to withdraw at any time; the right to opt-in or out of receiving further information about results; and regular contact opportunities when participants can ask questions, withdraw and potentially refresh consent. Other limited forms of participant control include IRBs or similar bodies acting on behalf of patients to judge if research conflicts with participants values, and patients being members of research ethics committees.

On the opposite end of the spectrum exist ongoing highly-participatory consent mechanisms. This might include, for example, participants providing and revoking consent over time; tiered consent; dynamic consent models through which participants can follow the research and revisit consent; partnership models with bidirectional communication alongside ongoing opportunities to update consent perhaps supported using web-based infrastructure; a continuing process of consent supported by a newsletter/website etc.

The middle ground includes proposals such as allowing participants to choose the scope of consent regarding, for example, the sharing of data (D'Abramo, 2015). Another proposal is to heavily consult with patients and other stakeholders firstly by involving them in setting CER priorities and secondly by including them in ethics oversight panels to review CER studies and make decisions about appropriate forms of consent (Faden, 2014). Other suggestions include participants having some power over the amount of information they receive through the informed consent procedure; deciding which specific genes they would not like to have sequenced; and involving current or potential future donors in designing consent forms and process.

Survey

To complement the review of the literature, a survey was sent to members and advisers of the IMI2 BD4BO programme. Based on a larger study being conducted in collaboration with BBMRI-ERIC, COST Action CHIP ME and RD-Connect with contributions from Biobank Norway, the aim of the survey was to learn more about respondents' experiences and opinions of informed consent procedures.

Methods

The survey covered a range of topics including the content of ICFs, procedures surrounding ICFs, data sharing and collaborating with stakeholders, nationally approved ICFs and guidance, and future challenges and developments. These questions were developed with input from DO-IT Work Package 4 members and in collaboration with BBMRI-ERIC, COST Action CHIP ME and RD-Connect with contributions from Biobank Norway. No ethics review was required for this study, as per the London School of Economics and Imperial College London ethics policies, because data collection was anonymous and the questions related to the profession of the respondents.

Qualtrics software was used to administer the survey. The survey was open between 5 September 2017 and 18 October 2017 for most respondents. It closed on 24 September for DO-IT DPEC members to allow this group's results to be analysed earlier. 171 people were sent the survey with an individual link, and an additional number were sent the survey via an anonymous link which was made available so the survey could be distributed further than the initially identified audience. A total of 57 people responded to the survey.

Overview

Respondents work across 16 countries in total. Of these, many respondents work in Germany (11; 23.40%), followed by the United Kingdom (10), Spain (6), Belgium (3), Switzerland, the United States, Netherlands, France, Sweden (2 each), Norway, Canada, Australia, Hungary, Italy, Luxembourg, and Saudi Arabia (1 each).

Respondents work in a range of organisations. Research/academic and industry are represented by the largest proportion of respondents, with 19 (38.3%) and 17 based in each respectively. Patient organisations are much less frequently represented (3), followed by trade associations, ethics review boards, HTA/guidelines, sales, employers' organisation/local government advocate, funders, contract research organisations (CRO) and university hospitals (1 each).

Similarly, job responsibilities were varied. Roles include data management (6; 12.77%), data analysis (5), data collection (3) or all three (2). The largest number of respondents do not fit into these categories (31). Their roles include data privacy and related topics, research, policy, project coordination, technical support, advising, sales, developing guidelines for treatments, clinical trial management and more.

A large proportion of respondents are involved in the BD4BO Coordination and Support Action, DO-IT (18; 33.96%). Members of DO-IT's advisory body, the Data Protection and Ethics Committee (DPEC) are well-represented (11), and colleagues from the disease-specific BD4BO projects, ROADMAP, HARMONY, and BigData@Heart also responded to the survey (7, 7, and 2 respectively). 8 respondents have no relation to the BD4BO projects.

Available guidance for informed consent

Most respondents were aware of nationally approved ICFs or guidance (14; 70%) compared to 6 who were not. In fact, guidance is the main way respondents seek information on designing an informed consent procedure. National guidance is the most popular option (21; 25.30%), followed closely by international guidance (19), searching for information within the working environment including by asking colleagues (17), or seeking ethical-legal guidance by professional information centres (14), and followed more distantly by searching the internet (9). Other sources used by respondents include relevant experts such as those with legal data protection backgrounds (1), and representatives of the patient population through consultation (1).

Unsurprisingly given the number of respondents who would seek advice on informed consent from guidance, almost all respondents would find a nationally approved ICF or guidance for informed consent useful. Of these, the three most popular reasons are that it would be useful for biobanking (25; 33.33%), useful for clinical studies (24), and for pre-clinical studies (21).

Generally, in cases where nationally approved ICF or guidance exist, survey respondents assessed this to be widely used. A third of respondents stated that guidance is widely used because it is mandatory as per the applicable law, while another third believed the reason for its wide use is that it is highly recommended according to the guidance provided by the health authorities or other public bodies. Another respondent believed guidance is widely used because it is considered useful by the research community, but three respondents said it is used in 'some' studies so is not particularly widely used. One respondent was not aware of any studies using the ICF or guidance on informed consent.

When asked about the differences between the ICF used by respondents compared to the nationally approved ICF or guidance, one respondent said there was no difference (14.28%), and two said there were not really any or not many differences. Conversely, one stated the ICF they use

is more elaborate than the guidance. Another said in clinical research studies the consent is written and for inclusion into registries consent is by verbal opt out. One said legal aspects are the same but study-specific procedures and goals may require some differences. One did not know whether there were any differences between the ICs.

The following are the informed consent guidance documents mentioned by respondents:

- Germany: http://www.ak-med-ethik-komm.de/docs/Template-for-informed-consent.docx
- Germany: https://www.berlin.de/lageso/_assets/gesundheit/publikationen/arbeitshilfe_probandeninfo_und_einwilligung_datenverarbeitung.pdf
- Italy: http://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/1671330
- Spain: https://www.msssi.gob.es/profesionales/farmacia/ceic/documentacionEnsayoCli.htm
- Sweden: http://www.epn.se/lund/om-naemnden/
- USA: https://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm
- USA: https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126489.pdf

Content of existing informed consent forms

There is significant crossover between the items included in respondents' ICFs and the items respondents believe should be included in ICFs, as outlined in box 5 below. Of the items examined, none that are included in ICFs appear to be superfluous because for each item a greater number of respondents said it should be included than those saying it is currently included. The greatest differences between what is included and what respondents believe should be included in ICFs appear when discussing returning research results, linking and sharing data, storing data, and having a right to lodge a complaint with a supervisory authority. Breaking these results down further, as outlined in table 2, a greater proportion of researchers compared to industry tended to say items should be included in informed consent.

Item	Yes (is) %	Yes (is) #	Total (is)	Yes (should) %	Yes (should) #	Total (should)		Difference between is and should
General information about the organisation responsible for the IC procedure	78.13%	25	32	92.31%	24	26	-14.18%	-14.18%
Contact details	81.25%	26	32	100.00%	26	26	-18.75%	-18.75%
The purpose and (future) objectives of the associated research	81.25%	26	32	100.00%	25	25	-18.75%	-18.75%
Access to further details about the research conducted	54.84%	17	31	75.00%	18	24	-20.16%	-20.16%
Possibility of re-contact by researchers for additional data	38.71%	12	31	60.00%	15	25	-21.29%	-21.29%
Possibility of returning individual research results	38.71%	12	31	76.00%	19	25	-37.29%	**-37.29%**
Linkage of data with data from other sources (eg registries, national statistics, electronic health records, research	35.48%	11	31	76.92%	20	26	-41.44%	**-41.44%**
Sharing data with other non-commercial research partners	56.25%	18	32	84.00%	21	25	-27.75%	-27.75%
Sharing data with commercial and/or health industry partners	41.94%	13	31	76.00%	19	25	-34.06%	**-34.06%**
Sharing data with parties in other EU countries	51.61%	16	31	72.00%	18	25	-20.39%	-20.39%
Sharing data with parties in other non-EU countries	56.67%	17	30	80.77%	21	26	-24.10%	-24.10%
Expected storage period for data	53.33%	16	30	84.00%	21	25	-30.67%	**-30.67%**
The right to withdraw at any time and what happens to data afterwards	86.67%	26	30	100.00%	25	25	-13.33%	-13.33%
Other rights of participants eg right to access or the right to data portability (ie transfer from one data controller to	41.94%	13	31	70.37%	19	27	-28.43%	-28.43%
The right to lodge a complaint with a supervisory authority (eg an ethics commission or data protection officer)	48.39%	15	31	85.71%	24	28	-37.32%	**-37.32%**
Information about possible future research/areas of research with data	51.61%	16	31	74.07%	20	27	-22.46%	-22.46%

Note: answers differing by more than 30% are coloured red

Box 5: What information is or should be provided to participants in this informed consent procedure?

Item	Research; Yes (is)	Research; Yes (should)	Research; Total	Research; Difference bw is and should	Industry; Yes (is)	Industry; Yes (should)	Industry; Total	Industry; Difference bw is and should
Possibility of returning individual research results	50.00%	90.91%	11	-40.91%	41.67%	50.00%	10	-8.33%
Linkage of data with data from other sources (eg registries, national statistics, electronic health records, research biobanks, non-health care related data etc)	50.00%	90.91%	11	-40.91%	33.33%	54.55%	11	-21.22%
Sharing data with commercial and/or health industry partners	25.00%	81.82%	11	-56.82%	58.33%	70.00%	10	-11.67%
Expected storage period for data	33.33%	81.82%	11	-48.49%	66.67%	80.00%	10	-13.33%
The right to lodge a complaint with a supervisory authority (eg an ethics commission or data protection officer) including contact info	41.67%	90.91%	11	-49.24%	50.00%	81.82%	11	-31.82%

Box 6: Differences between research and industry responses to key items (as defined based on Box 5)

Half of respondents stated that their data was single coded (13; 50%). A much smaller number use anonymized and non re-identifiable data (5), double-code their data (4), or withdraw data of birth and full name (1). Only one respondent uses identifiable data (1).

Given the differences between the items covered by respondents' ICFs and the items respondents think their ICFs should cover, it follows that over two thirds of respondents think their ICF needs some improvements (19; 67.86%). Only one respondent thinks major changes would be necessary, while under a third think their ICF is sufficient as it is (8).

Respondents reported efforts made in the ICF they use to improve the informed consent processes. Summary tables are the most popular additions to ICF (6; 16.67%). Limiting the length of forms (5), and including graphs (4), videos (4), or drawings (4) were also mentioned. Using clearer language was a relatively popular addition, mentioned by 6 respondents. Other suggestions included adjusting the structure of the forms, for example using sub-headings or using an electronic ICF.

Scope of consent

When describing the last ICF they had used, respondents identified a range of scopes of consent that were covered, as illustrated in figure 5 below. A similar number of respondents cited broad consent (11; 28.21%) as those who cited one-time consent (10). Broad consent was usually limited to one disease or disease area, with a smaller number allowing it to cover any research topic. It was also fairly common for participants to choose their consent preferences (8), for ICFs to cover re-consent (7) and, to a lesser extent, for participants to manage their consent preferences including by opting in and out of certain uses (dynamic consent) (3). None of the respondents cited no consent due to a statutory exemption.

Answers to what respondents believe ICFs should cover are similar to their answers about what their ICF presently covers. The main difference was that there was slightly greater appetite for open and participatory forms of consent than currently exist, although one-time consent was also a popular choice. More specifically, many respondents believe their ICF should cover broad consent (14; 40%), followed by one-time consent (6), participants choosing consent preferences (6), re-consent (4), and participants managing their consent preferences including opting in or out of specific purposes (dynamic consent) (2). One respondent specified that participants can choose if

they consent for the study in question or for further studies related to the first study, while if the new project is unrelated the patient should re-consent. Responses were similar between research/academia and industry. The least popular option among both groups was dynamic consent (1 out of 13 respondents for industry, 2 out of 19 respondents for research) and the most common was broad consent (4 industry, 6 research). The main difference was for one time consent, which industry cited as their joint most common option (4) and research cited as their second least common option (3).

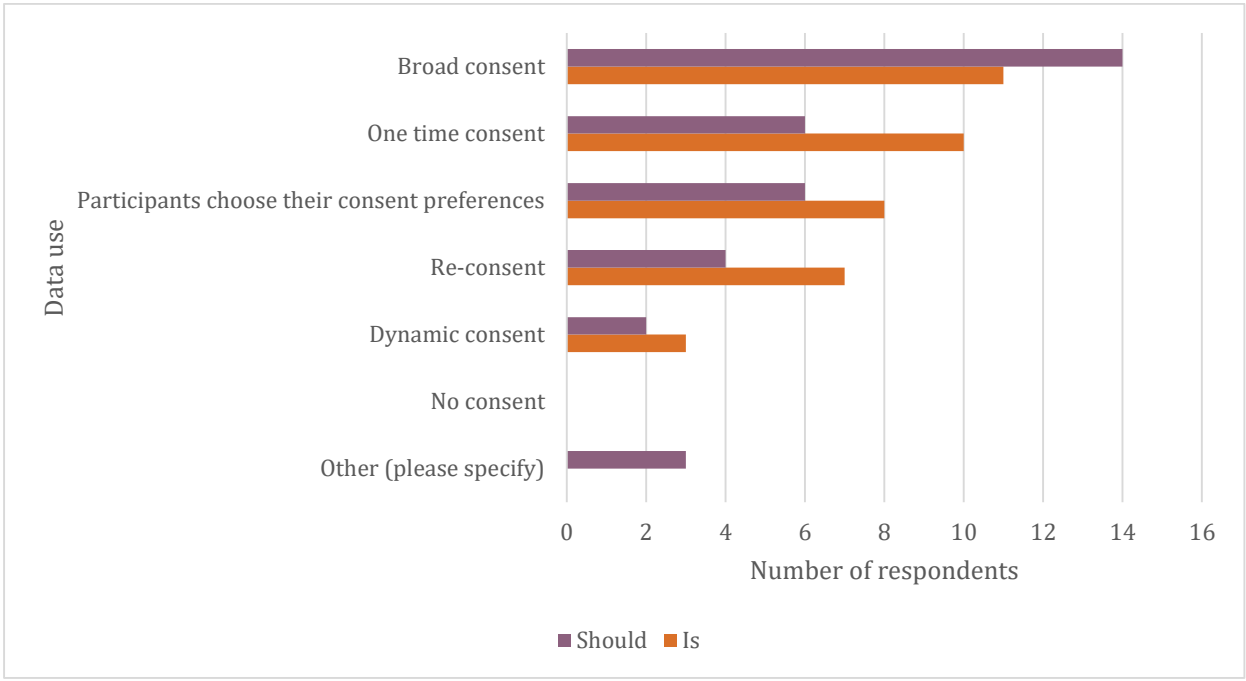

Figure 5: Which data use is/should be covered by the ICF the respondent is referring to?

Informed consent processes

Delving a little deeper into the process surrounding respondents' informed consent procedures, there is a fair amount of agreement between respondents:

- The clear majority of respondents think **reconsent** is required if the research field changes (18; 50%). A smaller number believe it is required if data will be used for a different project in the same field (8). Two respondents think re-consent is needed for research that is not covered in the ICF language. Only three respondents do not think re-consent is necessary (4).
- Most respondents stated that the IC does not cover the possibility to **link** data with data from other sources (17; 62.96%), with a smaller number saying it is (10).
- Many respondents have a standard procedure for **incidental findings** included in the informed consent procedure. Nearly a third do not include incidental findings in the informed consent procedure (8; 31.03%), and a similar number do not know (9).
- Nearly half (11; 47.83%) of respondents provide **results to participants** in cases of the participants' choosing. Seven do not provide results to the participant, and five provide results to the participant in all cases.
- Most respondents do require specific consent to conduct **genetic analysis**. Of these, the majority need consent each time genetic data are used (10; 38.46%), while others do not need it when reusing existing genetic data (4). Another respondent said participants can give

broad consent (1). Of respondents who did not require specific consent to conduct genetic analysis, most merely needed to have genetic analysis as part of the information. Other respondents do not use genetic data (2).

When describing their response to dealing with complete withdrawal of consent, respondents' answers varied substantially. Many respondents would delete all collected and derived data following complete withdrawal of consent (6; 24%), and a similar number would delete all collected data not yet used and archive used and already derived individual data (5), and keep and further use all data but anonymized (5). The majority of respondents, however, chose the response 'other'. These responses varied from 'don't know' to following a procedure according to GCP requirements / nature of study to be considered (eg submission relevant or not), using all data collected so far without collecting more (3), acting depending what the patient or participant requests (2), keeping and using data as per the terms of the original consent, and keeping data which is required for regulatory purposes while deleting other data.

There is some appetite for greater patient involvement in informed consent procedures. Over half (13; 52%) of respondents stated that participants should be informed about research activities performed with data (eg via online information, newsletters or reports). A smaller number of respondents said participants should be able to contact employees on an individual basis for information about what kind of research has been done with their personal data (eg through a helpdesk) (4), and that participants should be able to retrieve individualised information at any time about what kind of research has been done with their data (eg through an online platform or interface) (3). Four respondents saw no need for further information, with one of these stressing the caveat that data should be used as described in the ICF.

Collaboration with industry

Solid contracts describing the responsibilities of the partners are the most commonly cited way to facilitate good collaborations between researchers and stakeholders from the health industry (21; 29.58%). Respondents also cited the importance of making information about the details of the collaboration publicly available (16), ensuring that both parties are aware of the details of the collaboration (12), and having partners sharing data (9), risks (6), and benefits (6) as fairly as possible.

As figure 6 illustrates, nearly three quarters of respondents stated that the data collecting organisation should explicitly ask for participants' broad consent for collaborations with the health industry at the time of recruitment (21; 70%). A far smaller number thought the organisation should ask for participants' consent for each collaboration with the health industry or should inform participants once such collaborations take place (eg through a newsletter or web page). Only one respondent said the data collecting organisation does not need to inform participants about collaborations with the health industry.

Responses between industry and research were somewhat similar. Eight out of ten industry respondents thought the data collecting organization should explicitly ask for participants' broad consent for collaborations with the health industry at the time of recruitment, with the remaining two respondents saying there is no need to inform participants about collaborations (1), and the other saying one needs to define such collaboration and that if data are coded and shared to help develop a drug, it should be covered by the language of the ICF. Similarly, the most common answer among researchers was broad consent (7 out of 12). However, the remaining respondents said participants' consent should be sought for each collaboration (3), participants should be informed once collaborations take place (1) and that a well-considered governance model should be built to safeguard interests (1). Zero researchers said there was no need to inform participants of collaborations.

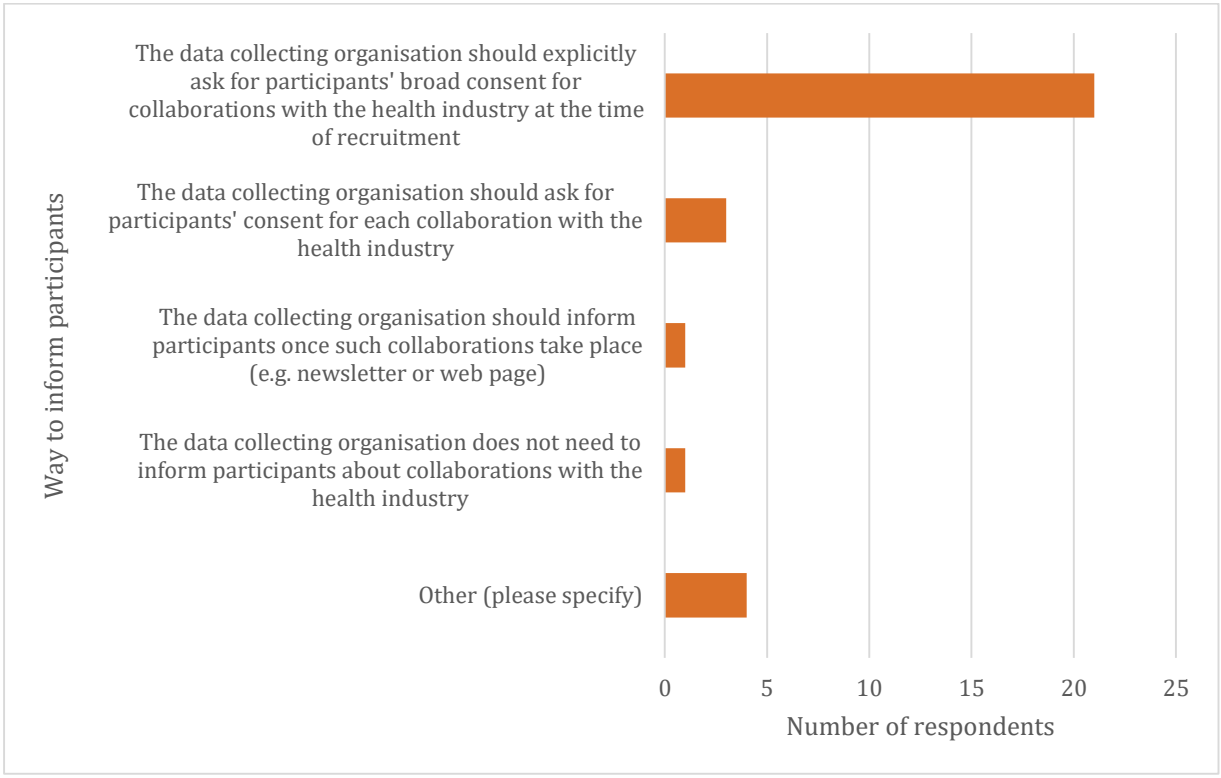

Figure 6: How should research participants be informed about potential or existing collaborations with stakeholders from the health industry?

Future challenges and developments

Respondents raised a number of challenges related to integrating data across organisations that collect data and other databases. These challenges include issues around legislation such as compliance with data protection laws and uncertainty over identifiability of research data and resulting legal obligations. Respondents also mentioned difficulties resulting from the existence of country specific and sponsor specific forms, as well as differences in legal systems, confidentiality, health systems and procedures, definitions, and cultural standards. Inaccurate perceptions were thought to be other challenges, including perceptions of who 'owns' data, and the public's perception of the level of privacy risks. The lack of democratically established guidance on data sharing and (re-)use, plus the potential conflict between confidentiality and business interest were other challenges respondents mentioned.

Despite the challenges, respondents were also aware of a number of promising developments in informed consent and data (re-)use. These include: BD4BO DO-IT, the new EU General Data Protection Regulation, GA4GH, EPAD and AMYPAD guidance, Global Alliance for Genomics and Health Framework for Responsible Sharing of Genomic and Health Related Data; MRCT return of individual results policy; an informed consent based model towards a governance model; social licensing; and new data protection and clinical trials regulations. The use of electronic ICFs was mentioned by a few respondents.

Discussion

There is clear interest in developing new models of informed consent and adapting existing models

to better fit the evolving research context. Some of these new models are already used in several countries and in a variety of settings. Informed consent models have responded to a changing environment both by protecting against potential harm resulting from new technologies and approaches, and by facilitating the opportunities these can offer.

New technological capacity and analytical methods to analyse data increase the range of databases that can be put to use. Linking datasets can provide a richer picture of healthcare treatments and approaches as well as of participants themselves. Informed consent approaches have also used technology to improve participants' understanding of the procedure – perhaps using videos or online quizzes - or by enabling novel forms of consent such as app-based trials. Technology, in the form of web-based interfaces and other tools, has also been used to support the development of more participant-centric informed consent procedures. It will be important for those responsible for managing informed consent to consider accessibility issues around the use of technology among certain population groups.

Data privacy is perhaps the greatest concern associated with the changing research environment. New technologies, data linkage, and data analysis techniques have made reidentifying data easier. When people are concerned about how their data will be used, and by whom, strong governance and transparency between data holders and participants can help to maintain participant satisfaction and confidence.

Despite facing broadly similar challenges and opportunities, informed consent models vary substantially. For instance, they span across a wide range of levels of openness and degrees of participant-control. Some promote broad and other relatively open forms of consent as a way to make the most of the research potential of data. Others endorse more restricted forms of consent. In recent years, participant-centric forms of consent seem to be increasing in popularity – evident from the relatively large number of articles in the rapid review presented above that cite dynamic consent. At the same time, the results of our survey indicate that dynamic consent is still in its early stages and more traditional approaches to informed consent are more common in current practice.

In part, differences in the scope and participant-centric focus of models is likely to reflect differences in the types of data being used. For example, broad consent appears to be particularly popular in the context of biobanks and learning healthcare systems, while more restricted forms of consent might be more prevalent in other contexts such as traditional clinical studies.

This substantial heterogeneity in preferences and practice around informed consent suggests that there is no one-size-fits-all approach. This heterogeneity could be due to the type of data, specific regulations and differing views about the privacy-benefit trade-off. The common thread across most informed consent approaches, however, is an attempt to balance the opportunities and risks presented by a new research context of big and increasingly linked and sensitive data. The feasibility of proposed informed consent approaches varies depending on the legal context so some models will currently only be applicable in some countries or regions. Rather than being immediately applicable, these offer insights into the types of approaches that could be considered in the longer term.

Ethical issues are at the core of discussions about informed consent. However, it is not simply a case of reducing ethical concerns by using stricter forms of informed consent. A number of articles discussed the ethical imperative of designing informed consent to maximise research potential, which should in turn benefit the public. Learning from routine care data involves the re-use of data for previously unforeseen purposes. Given that secondary use of data does not involve direct physical harm to patients, authors have suggested to adopt models that are more open to new research, and reducing the need for obtaining informed consent.

Similarly to routine data, the possibilities for analysing bio-samples meaningfully have increased in

recent years. The rise of new technological developments that allow a wealth of data about individuals to be processed, such as genome-wide association studies, makes traditional informed consent, that specifies the use of collected data, appear outdated. Risks to the data subject in these cases of secondary use of data is related to data privacy, rather than bodily harm. Governance and IRBs have an important role to play in deciding whether additional consent is required for a new study.

Finally, novel developments in ICT have also led to proposals being made to change the informed consent process in a more practical way. The use of quizzes and videos in computer-supported informed consent procedures can enhance the understanding of participants about what they are consenting to, and our survey indicates that some current ICFs are already considering innovative ways of improving the informed consent process. Internet-connected devices, such as smart phones and tablets, can also change the research process in a more fundamental way, including recruitment of participants through the internet, as well as obtaining and updating consent (dynamic consent model) in a more efficient way.

Conclusion

Linkage, re-use and analysis of big data have amplified the scope for medical research in recent years. Alongside these new research opportunities promised by big data, new types of consent models have been suggested, including participatory models that use novel technologies to keep research participants informed about how their data is used and allow consent to be updated. This review has highlighted some of the main novel consent models tailored to a research environment that continues to evolve.

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Appendices

Survey

Big Data for Better Outcomes Survey

Start of Block: Introduction

Big Data for Better Outcomes Survey

Introduction

Thank you for taking the time to complete this survey.

This survey is addressed to members and advisers of the IMI2 BD4BO programme as well as individuals working with relevant stakeholders.

More and more data is being collected by researchers, health care systems and a range of other stakeholders. This collection of data, some of which may be sensitive, offers great opportunities to improve health care systems, but also brings privacy concerns. Given this context, we are interested to learn more about your experiences of and opinions on informed consent procedures. Your responses will be collected anonymously.

This work is part of the Big Data for Better Outcomes programme (BD4BO) which aims to promote the development of value-based, outcomes-focused healthcare systems by using big data. BD4BO is part of the Innovative Medicines Initiative (IMI). As Europe's largest public-private initiative, IMI aims to speed up the development of better medicines and improve pharmaceutical innovation in Europe.

For more information on IMI please see https://www.imi.europa.eu/.

This survey is based on a larger study being conducted in collaboration with BBMRI-ERIC, COST Action CHIP ME and RD-Connect with contributions from Biobank Norway.

The survey consists of about 25 questions and should take you about 15 minutes to complete.

Electronic Consent

- ○ I have read the above information and voluntarily agree to participate in this survey. (1)
- ○ I disagree and do not wish to participate in the research study. (2)

Skip To: End of Survey If Electronic Consent = I disagree and do not wish to participate in the research study.

Page Break


imi
innovative
medicines
initiative

End of Block: Introduction

Start of Block: Your background

Your background

Which country do you work in?
▼ AD - Andorra (1) ... ZW - Zimbabwe (250)

What type of organisation do you work for?

- ○ Patient organisation (1)
- ○ Trade association (2)
- ○ Research/ academia (3)
- ○ Ethics review board (4)
- ○ Disease registry/ biobank (5)
- ○ Industry (6)
- ○ Other (please specify) (7) _____

Are you actively involved as a working member in any of the following IMI2 Big Data for Better Outcomes projects?

- ☐ ROADMAP (Alzheimer's Disease) (1)
- ☐ HARMONY (Hematologic malignancies) (2)
- ☐ BigData@Heart (Cardiovascular diseases) (3)
- ☐ DO-IT (Coordination and Support Action) (4)
- ☐ Data Protection and Ethics Commission from DO-IT (6)
- ☐ None (5)

Which of the following responsibilities does your job mainly involve?

- ○ Data collection (1)
- ○ Data management (2)

- ○ Data use/analysis (3)
- ○ Other (please specify) (4) _____

Page Break

End of Block: Your background

Start of Block: Informed consent (content)

Informed consent (content)

Informed consent (IC) can refer to both a process or dialogue, as well as more narrowly to a formal procedure consisting of information provision and consent options. For the purpose of this survey, please consider both ways of understanding consent when answering the questions and **refer to the most recent IC process you have used** (it might be helpful to have a copy of the IC sheet at hand).

What information is or should be provided to participants in this informed consent procedure? (Please answer questions in both columns)

	Is this included in the informed consent?			Should this be included in the informed consent?		
	Yes (1)	No (2)	Don't know (3)	Yes (1)	No (2)	Don't know (3)
General information about the organisation responsible for the IC procedure (1)	○	○	○	○	○	○
Contact details (2)	○	○	○	○	○	○
The purpose and (future) objectives of the associated research (4)	○	○	○	○	○	○
Access to further details about the research conducted (5)	○	○	○	○	○	○
Possibility of re-contact by researchers for additional data (7)	○	○	○	○	○	○
Possibility of returning individual research results (8)	○	○	○	○	○	○
Linkage of data with data from other sources (eg registries,	○	○	○	○	○	○

national statistics, electronic health records, research biobanks, non-health care related data etc) (10)						
Sharing data with other non-commercial research partners (11)	○	○	○	○	○	○
Sharing data with commercial and/or health industry partners (12)	○	○	○	○	○	○
Sharing data with parties in other EU countries (13)	○	○	○	○	○	○
Sharing data with parties in other non-EU countries (14)	○	○	○	○	○	○
Expected storage period for data (6)	○	○	○	○	○	○
The right to withdraw at any time and what happens to data afterwards (15)	○	○	○	○	○	○
Other rights of participants eg right to access or the right to data portability (ie transfer from one data controller to another) (16)	○	○	○	○	○	○
The right to lodge a complaint with a supervisory authority (eg an ethics commission or	○	○	○	○	○	○

data protection officer) including contact info (17)						
Information about possible future research/areas of research with data (9)	○	○	○	○	○	○

Other items that **should** be included in the informed consent (please specify)
_____

Display This Question:
If What information is or should be provided to participants in this informed consent procedure? (Pl... : Is this included in the informed consent? = Expected storage period for data [Yes]

How long do you currently retain clinical data?

- ○ 25 years (1)
- ○ Other (please specify) (3) _____

Display This Question:
If What information is or should be provided to participants in this informed consent procedure? (Pl... : Is this included in the informed consent? = The right to withdraw at any time and what happens to data afterwards [Yes]

In the case of complete withdrawal of consent, what would you do with the data already collected?

- ○ Delete all collected and derived individual data (1)
- ○ Delete all collected data not yet used and archive used and already derived individual data (2)
- ○ Keep and further use all data but anonymized (3)
- ○ Other (please specify) (4) _____

Have you implemented anything special to improve patients' ability to better understand the content of the IC?

- ☐ IC form length limit with or without a separate "more details" page (1)
- ☐ Drawings (2)

- ☐ Photos (3)
- ☐ Videos (4)
- ☐ Graphs (5)
- ☐ Summary tables (6)
- ☐ Other (please specify) (7) _____

Do you require specific consent to conduct genetic analysis?

- ○ Yes, each time genetic data are used (1)
- ○ Yes but only for whole genome sequencing (2)
- ○ Yes but it is not needed when reusing existing genetic data (3)
- ○ No, it just has to be part of the information (4)
- ○ Other (5) _____
- ○ I don't know (6)

Page Break

End of Block: Informed consent (content)

Start of Block: Informed consent (procedure)

Informed consent (procedure)

Which data use is currently covered by the IC you are referring to?

- ☐ Data will only be used for the study the participant consented for ("one time consent") (1)
- ☐ Data can be used for various purposes after participants re-consent ("re-consent") (2)
- ☐ Data will be used for multiple research projects without re-consent ("broad consent") (3)
- ☐ Participants can choose their consent preferences about what they want to be involved in (online or paper-based) (7)
- ☐ Data can be used without consent because of a statutory exemption (8)
- ☐ Participants are able to manage their consent preferences for the use of their data themselves (e.g. via an online portal), including to opt in or out of specific purposes (such as commercial use and collaboration with the health industry, return of incidental findings, etc.) ("dynamic consent") (4)
- ☐ I don't know (6)

Display This Question:
If Which data use is currently covered by the IC you are referring to? = Data will be used for multiple research projects without re-consent ("broad consent")

What are the prerequisites for broad consent? (please tick all that apply)

- ○ Limited to one disease or disease area (1)
- ○ Can cover any research topic (2)
- ○ Other (please explain) (3) _____

Which data use should be covered by the IC you are referring to?

- ☐ Data will only be used for the study the participant consented for ("one time consent") (1)
- ☐ Data can be used for various purposes after participants re-consent ("re-consent") (2)
- ☐ Data will be used for multiple research projects without re-consent ("broad consent") (3)

- [ ] Participants can choose their consent preferences about what they want to be involved in (online or paper-based) (7)
- [ ] Data can be used without consent because of a statutory exemption (8)
- [ ] Participants are able to manage their consent preferences for the use of their data themselves (e.g. via an online portal), including to opt in or out of specific purposes (such as commercial use and collaboration with the health industry, return of incidental findings, etc.) ("dynamic consent") (4)
- [ ] I don't know (6)
- [ ] Other (please specify) (11) _____

In your opinion, when do you think re-consent is required?

- [ ] If data will be used for a different project in the same field (1)
- [ ] If the research field changes (2)
- [ ] I don't think re-consent is necessary (4)
- [ ] Other (please specify) (3) _____

Does the current IC cover the possibility to link data with data from other sources (databases, registries, national statistics, electronic health records, research biobanks, non-healthcare related data etc)

- ○ Yes (1)
- ○ No (2)

Display This Question:
If Does the current IC cover the possibility to link data with data from other sources (databases, r... = Yes

Please provide details of how data linkage is covered in the IC

_____
_____
_____
_____
_____

In the current IC, how was anonymization or pseudonymization (which is weaker than anonymization as it allows data to be tracked back to its origins) of collected data managed?

- ○ Data was identifiable (1)
- ○ Data was single coded (2)
- ○ Data was double coded (3)
- ○ Data was anonymized and non re-identifiable (4)
- ○ I don't know (5)
- ○ Other (please specify) (6) _____

In the current IC, how were incidental findings managed? (Incidental findings are previously undiagnosed medical or psychiatric conditions that are discovered unintentionally and are unrelated to the current medical or psychiatric condition which is being treated or for which tests are being performed)

- ○ A standard procedure for incidental findings was included in the informed consent procedure (1)
- ○ Incidental findings were not included in the informed consent procedure (2)
- ○ I don't know (3)

What did the IC say about incidental findings?

- ○ Results will be provided to the participant in all cases (2)
- ○ Results will be provided to the participant in cases of the participants' choosing (3)
- ○ Results will not be provided to the participant (4)

Besides the information given at the initial informed consent procedure, how should participants be further informed about data use?

- ○ I see no need for further information (1)
- ○ Participants should be informed about research activities performed with data (eg online information, newsletters or reports) (2)
- ○ Participants should be able to contact employees on an individual basis for information about what kind of research has been done with their personal data (eg helpdesk) (3)
- ○ Participants should be able to retrieve individualized information at any time about what kind of research has been done with their data (eg online platform or interface) (4)
- ○ I don't know (6)
- ○ Other (please specify) (5) _____

Overall, how would you evaluate the IC you are currently practicing?

- ○ I think it is sufficient (1)
- ○ I think it needs some improvements (2)
- ○ I think major changes would be necessary (3)

If you think that improvement/changes are necessary, please let us know which:

_____

Page Break

End of Block: Informed consent (procedure)

Start of Block: Industry collaboration and data sharing

Industry collaboration and data sharing

In your opinion, how should research participants be informed about potential or existing collaborations with stakeholders from the health industry?

- ○ The data collecting organisation should inform participants once such collaborations take place (e.g. newsletter or web page) (2)
- ○ The data collecting organisation should ask for participants' consent for each collaboration with the health industry (3)
- ○ The data collecting organisation should explicitly ask for participants' broad consent for collaborations with the health industry at the time of recruitment (4)
- ○ The data collecting organisation does not need to inform participants about collaborations with the health industry (5)
- ○ Other (please specify) (1) _____

In your opinion, which of the following aspects are important to facilitate good collaborations between researchers and stakeholders from the health industry? Please select a maximum of three options

- ☐ Solid contracts describing the responsibilities of the partners (1)
- ☐ Partners in the collaboration should share risks as fairly as possible (2)
- ☐ Partners in the collaboration should share data as fairly as possible (3)
- ☐ Partners in the collaboration should share benefits as fairly as possible (4)
- ☐ Both parties should be aware of the details of the collaboration (5)
- ☐ Information about the details of the collaboration should be publicly available (6)
- ☐ Other (please specify) (7) _____

Page Break

End of Block: Industry collaboration and data sharing

Start of Block: Nationally approved ICF and guidance

Are you aware of any nationally approved or endorsed ICFs or guidance on informed consent in your country?

- ○ Yes, a nationally approved ICF or guidance on informed consent exists in my country. Please provide a link to it if possible. (1) _____
- ○ No nationally approved ICF or guidance on informed consent exists in my country (2)
- ○ I don't know (3)

Skip To: Q33 If Are you aware of any nationally approved or endorsed ICFs or guidance on informed consent in your... = Yes, a nationally approved ICF or guidance on informed consent exists in my country. Please provide a link to it if possible.
Skip To: Q36 If Are you aware of any nationally approved or endorsed ICFs or guidance on informed consent in your... = No nationally approved ICF or guidance on informed consent exists in my country
Skip To: Q36 If Are you aware of any nationally approved or endorsed ICFs or guidance on informed consent in your... = I don't know

You stated that a nationally approved or endorsed ICF or guidance on informed consent exists in your country. Please indicate the types of data that can be collected on the basis of this informed consent:

- ☐ Clinical data (1)
- ☐ Bio samples (2)
- ☐ Lifestyle data (3)
- ☐ Other (please specify) (4) _____

How widely used is the nationally approved ICF or guidance on informed consent?

- ○ It is widely used, because it is mandatory as per the applicable law (1)
- ○ It is widely used, because it is highly recommended according to the guidance provided by the health authorities / other public bodies (5)
- ○ It is widely used, because it is considered useful by the research community (2)
- ○ It is used in some studies (3)
- ○ I am not aware of any studies using the ICF or guidance on informed consent (4)

Are there any differences between the information included in the nationally approved ICF or guidance on informed consent and the informed consent procedure you use? Please consider the

type of information provided, the possibilities for information and contact, data usage, partcipant rights, and how secondary use of data and re-consent is managed and detail any differences below.

_____
_____
_____
_____
_____

Would you find a nationally approved ICF or guidance for informed consent useful?

- ☐ Yes, a nationally approved ICF or guidance for informed consent would be useful for pre-clinical studies (1)
- ☐ Yes, a nationally approved ICF or guidance for informed consent would be useful for clinical studies (2)
- ☐ Yes, a nationally approved ICF or guidance for informed consent would be useful for biobanking purposes (3)
- ☐ Yes, for another reason (5)
- ☐ No, a nationally approved ICF or guidance for informed consent would not be useful (4)

If you seek information on how to design your IC, where do/would you get it? (Multiple answers possible)

- ☐ Search for information within my working environment or ask colleagues (1)
- ☐ Search the internet (2)
- ☐ Seek ethical-legal guidance by professional information centres such as help desks for ethical and legal issues (3)
- ☐ I use national guidance or standards for IC and/or corresponding templates (4)
- ☐ I use international guidance or standards for IC and/or corresponding templates (5)
- ☐ I don't know (6)
- ☐ Other (please specify) (7) _____

End of Block: Nationally approved ICF and guidance

Start of Block: Future Developments

Future developments

Are you aware of current/future developments in terms of informed consent and re-use of data that

could transform how consent is obtained and how data re-use is being managed? Please provide details.

_____
_____
_____
_____
_____

What are the main challenges to integrating data across organisations that collect data and other databases?

_____
_____
_____
_____
_____

Please indicate some areas of population-level decision-making that you expect to rely increasingly on health data in the future, or briefly explain why you think that health data is unlikely to play a role in population-level decision-making in the future.

_____
_____
_____
_____
_____

End of Block: Future Developments

Search strategy

The search strategy was developed to obtain approximately 1,000 articles to be reviewed for inclusion at the initial screening stage.

We applied a two-tiered search strategy:

1) The primary database search was restricted to one comprehensive online database: MEDLINE via PubMed due to time constraints.
2) To minimise the potential for missing important articles we performed targeted searches on four journals: British Medical Journal, The Lancet, New England Journal of Medicine, and The American Journal of Bioethics. These were chosen based on their track record of published influential editorials and reviews on consent.

The following table outlines the search terms that were used for the primary database search.

Table 1: search terms

#1	(informed[Title/Abstract] OR broad[Title/Abstract] OR dynamic[Title/Abstract] OR enhanced[Title/Abstract] OR integrated[Title/Abstract] OR tiered[Title/Abstract] OR layered[Title/Abstract] OR meta [Title/Abstract])
#2	consent[tw]

#3	“Informed Consent”[Mesh]
#4	Review[ptyp] OR Letter[ptyp] OR Editorial[ptyp] OR Comment[sb] OR systematic[sb]
#5	("2010/01/01"[PDat] : "3000/12/31"[PDat])
#6	English[lang]
#7	#1 AND #2 AND #3 AND #4 AND #5 AND #6

lang... Language
Mesh... Medical Subject Heading
PDat... Publication date
ptyp... Publication type
tw... Text word
sb... Subject filter

The search strategy was adapted for each of the four journals depending on the type of articles they publish and the search features they possess. In all cases, articles were restricted to retrieve opinion pieces and reviews published since 2010 and used the following search terms:

consent AND (informed OR broad OR dynamic OR enhanced OR integrated OR tiered OR layered OR meta)

Study selection

Search results from the database searches were merged into a single database. Articles were assessed for eligibility through a two-stage screening process:

1) One research scanned titles and abstracts of articles to identify articles potentially eligible for inclusion. Full text for articles deemed eligible at this level were retrieved.
2) Two researchers independently assessed full text articles for eligibility and resolved any differences in opinion regarding inclusion by discussion.

Data extraction

One researcher extracted information from the articles, and a second researcher checked one third of articles for quality control. The information was extracted under the following headings:

1) Author
2) Publication year
3) Setting
4) Rationale for proposing a new consent model
5) Process for obtaining consent
6) Scope of consent given
7) Approach to re-using and re-purposing of data
8) Approach to data subject empowerment

List of included studies

List of articles included in analysis

ID	Title	Reference	First author and background

0001	Informed Consent.	Grady, C., Cummings, S.R., Rowbotham, M.C., McConnell, M.V., Ashley, E.A., Kang, G., 2017. Informed Consent. N. Engl. J. Med. 376, 856–867. doi:10.1056/NEJMra1603773	Christine Grady – bioethics
0011	Closing the evidence gap in infectious disease: point-of-care randomization and informed consent.	Huttner, A., Leibovici, L., Theuretzbacher, U., Huttner, B., Paul, M., 2017. Closing the evidence gap in infectious disease: point-of-care randomization and informed consent. Clin. Microbiol. Infect. 23, 73–77. doi:10.1016/j.cmi.2016.07.029	Angela Huttner – infectious diseases
0026	Informed Consent for PROs in EHR Research: Are Additional Requirements Necessary?	Whicher, D., Evans, E., 2016. Informed Consent for PROs in EHR Research: Are Additional Requirements Necessary? Am J Bioeth 16, 63–65. doi:10.1080/15265161.2016.1145300	Danielle Whicher – patient-centred outcomes
0027	An Interactive Multimedia Approach to Improving Informed Consent for Induced Pluripotent Stem Cell Research.	McCaughey, T., Liang, H.H., Chen, C., Fenwick, E., Rees, G., Wong, R.C.B., Vickers, J.C., Summers, M.J., MacGregor, C., Craig, J.E., Munsie, M., Pébay, A., Hewitt, A.W., 2016. An Interactive Multimedia Approach to Improving Informed Consent for Induced Pluripotent Stem Cell Research. Cell Stem Cell 18, 307–308. doi:10.1016/j.stem.2016.02.006	T McCaughey – eye research
0059	Precision medicine ethics: selected issues and developments in next-generation sequencing, clinical oncology, and ethics.	Fiore, R.N., Goodman, K.W., 2016. Precision medicine ethics: selected issues and developments in next-generation sequencing, clinical oncology, and ethics. Curr Opin Oncol 28, 83–87. doi:10.1097/CCO.0000000000000247	RN Fiore - Medicine, bioethics and health policy
0091	Ethical oversight in quality improvement and quality improvement research: new approaches to promote a learning health care system.	Fiscella, K., Tobin, J.N., Carroll, J.K., He, H., Ogedegbe, G., 2015. Ethical oversight in quality improvement and quality improvement research: new approaches to promote a learning health care system. BMC Med Ethics 16, 63. doi:10.1186/s12910-015-0056-2	Kevin Fiscella – family medicine
0095	Research participants' perceptions and views on consent for biobank research: a review of empirical data and ethical analysis.	D'Abramo, F., Schildmann, J., Vollmann, J., 2015. Research participants' perceptions and views on consent for biobank research: a review of empirical data and ethical analysis. BMC Med Ethics 16, 60. doi:10.1186/s12910-015-0053-5	Flavio D'Abramo - medical ethics and history of medicine
0121	UK law on consent: broad consent or authorisation for research?	Crouch, M.A., 2015. UK law on consent: broad consent or authorisation for research? BMJ 350, h3504. doi:https://doi.org/10.1136/bmj.h3504	Mair A Crouch – genetics and law
0132	The Ethics of Big Data: Current and Foreseeable Issues in Biomedical Contexts.	Mittelstadt, B.D., Floridi, L., 2016. The Ethics of Big Data: Current and Foreseeable Issues in Biomedical Contexts. Sci Eng Ethics 22, 303–341. doi:10.1007/s11948-015-9652-2	Brent Mittelstadt – IoT and healthcare
0169	Enduring and emerging challenges of informed consent.	Grady, C., 2015. Enduring and emerging challenges of informed consent. N. Engl. J. Med. 372, 855–862. doi:10.1056/NEJMra1411250	Christine Grady – bioethics

0182	Targeted" consent for pragmatic clinical trials.	Wendler, D., 2015. "Targeted" consent for pragmatic clinical trials. J Gen Intern Med 30, 679–682. doi:10.1007/s11606-014-3169-2	D Wendler - bioethics
0189	Consenting for current genetic research: is Canadian practice adequate?	Jaitovich Groisman, I., Egalite, N., Godard, B., 2014. Consenting for current genetic research: is Canadian practice adequate? BMC Med Ethics 15, 80. doi:10.1186/1472-6939-15-80	Iris Jaitovich Groisman - omics-ethics
0230	Multiplex genetic testing: reconsidering utility and informed consent in the era of next-generation sequencing.	Bradbury, A.R., Patrick-Miller, L., Domchek, S., 2015. Multiplex genetic testing: reconsidering utility and informed consent in the era of next-generation sequencing. Genet. Med. 17, 97–98. doi:10.1038/gim.2014.85	AR Bradbury - hematology-oncology
0231	The ethics and editorial challenges of internet-based research.	Harriman, S., Patel, J., 2014. The ethics and editorial challenges of internet-based research. BMC Med 12, 124. doi:10.1186/s12916-014-0124-3	Stephanie Harriman - medicine
0245	Informed consent for comparative effectiveness trials.	Williams, R.T.W., 2014. Informed consent for comparative effectiveness trials. N. Engl. J. Med. 370, 1959. doi:10.1056/NEJMc1403310#SA5	Robin TW Williams - unknown
0250	Informed consent for comparative effectiveness trials.	Faden, R.R., Beauchamp, T.L., Kass, N.E., 2014b. Informed consent for comparative effectiveness trials. N. Engl. J. Med. 370, 1958–1960. doi:10.1056/NEJMc1403310	Ruth Faden - bioethics
0269	Next-generation sequencing applied to rare diseases genomics.	Danielsson, K., Mun, L.J., Lordemann, A., Mao, J., Lin, C.H., 2014. Next-generation sequencing applied to rare diseases genomics. Expert Rev. Mol. Diagn. 14, 469–487. doi:10.1586/14737159.2014.904749	K Danielsson - genomics
0284	A dynamic model of patient consent to sharing of medical record data.	Dixon, W.G., Spencer, K., Williams, H., Sanders, C., Lund, D., Whitley, E.A., Kaye, J., 2014. A dynamic model of patient consent to sharing of medical record data. BMJ 348, g1294. doi: 10.1136/bmj.g1294	WG Dixon – arthritis and epidemiology
0318	Broad versus blanket consent for research with human biological samples.	Wendler, D., 2013. Broad versus blanket consent for research with human biological samples. Hastings Cent Rep 43, 3–4. doi:10.1002/hast.200	David Wendler - bioethics
0391	Informed consent, big data, and the oxymoron of research that is not research.	Ioannidis, J.P.A., 2013. Informed consent, big data, and the oxymoron of research that is not research. Am J Bioeth 13, 40–42. doi:10.1080/15265161.2013.768864	John PA Ioannidis - medicine
0392	Data citizenship and informed consent.	Francis, L.P., Francis, J.G., 2013. Data citizenship and informed consent. Am J Bioeth 13, 38–39. doi:10.1080/15265161.2013.768862	Leslie P Francis - medicine

0393	Can informed consent go too far? Balancing consent and public benefit in research.	Milner, L.C., Magnus, D., 2013. Can informed consent go too far? Balancing consent and public benefit in research. Am J Bioeth 13, 1–2. doi:10.1080/15265161.2013.778645	Lauren C Milner – health science
0399	Evolving approaches to the ethical management of genomic data.	McEwen, J.E., Boyer, J.T., Sun, K.Y., 2013. Evolving approaches to the ethical management of genomic data. Trends Genet. 29, 375–382. doi:10.1016/j.tig.2013.02.001	JE McEwen - genomics
0413	Stem cells on South African shores: proposed guidelines for comprehensive informed consent.	Greenberg, J., Smith, D., Pope, A., 2013. Stem cells on South African shores: proposed guidelines for comprehensive informed consent. S. Afr. Med. J. 103, 6.	Jacquie Greenberg – human genetics
0444	Ethical considerations in dermatologic photography.	Lakdawala, N., Fontanella, D., Grant-Kels, J.M., 2012. Ethical considerations in dermatologic photography. Clin. Dermatol. 30, 486–491. doi:10.1016/j.clindermatol.2011.06.017	Nikita Lakdawala - dermatology
0470	Consent in psychiatric biobanks for pharmacogenetic research.	van der Baan, F.H., Bernabe, R.D.C., Bredenoord, A.L., Gregoor, J.G., Meynen, G., Knol, M.J., van Thiel, G.J.M.W., 2013. Consent in psychiatric biobanks for pharmacogenetic research. Int. J. Neuropsychopharmacol. 16, 677–682. doi:10.1017/S146114571200048X	FH van der Baan - epidemiology
0492	The tension between data sharing and the protection of privacy in genomics research.	Kaye, J., 2012. The tension between data sharing and the protection of privacy in genomics research. Annu Rev Genomics Hum Genet 13, 415–431. doi:10.1146/annurev-genom-082410-101454	J Kaye – public heath
0493	Informed consent for record linkage: a systematic review.	da Silva, M.E.M., Coeli, C.M., Ventura, M., Palacios, M., Magnanini, M.M.F., Camargo, T.M.C.R., Camargo, K.R., 2012. Informed consent for record linkage: a systematic review. J Med Ethics 38, 639–642. doi:10.1136/medethics-2011-100208	ME da Silva – information systems
0507	Tackling legal challenges posed by population biobanks: reconceptualising consent requirements.	Otlowski, M.F.A., 2012. Tackling legal challenges posed by population biobanks: reconceptualising consent requirements. Med Law Rev 20, 191–226. doi:10.1093/medlaw/fwr035	Margaret Otlowski - law
0541	Genomics really gets personal: how exome and whole genome sequencing challenge the ethical framework of human genetics research.	Tabor, H.K., Berkman, B.E., Hull, S.C., Bamshad, M.J., 2011. Genomics really gets personal: how exome and whole genome sequencing challenge the ethical framework of human genetics research. Am. J. Med. Genet. A 155A, 2916–2924. doi:10.1002/ajmg.a.34357	HK Tabor - paediatrics
0542	Informed consent process for patient participation in rare disease registries linked to biorepositories.	Rubinstein, Y.R., Groft, S.C., Chandros, S.H., Kaneshiro, J., Karp, B., Lockhart, N.C., Marshall, P.A., Moxley, R.T., Pollen, G.B., Miller, V.R., Schwartz, J., 2012. Informed consent process for patient participation in rare disease registries linked to biorepositories. Contemp Clin Trials 33, 5–11. doi:10.1016/j.cct.2011.10.004	YR Rubinstein – rare diseases

0565	Biobanking residual tissues.	Riegman, P.H.J., van Veen, E.-B., 2011. Biobanking residual tissues. Hum. Genet. 130, 357–368. doi:10.1007/s00439-011-1074-x	PHJ Reigman - pathology
0619	Stop, look, and listen: revisiting the involvement of children and adolescents in genomic research.	Driessnack, M., Gallo, A.M., 2011. Stop, look, and listen: revisiting the involvement of children and adolescents in genomic research. Annu Rev Nurs Res 29, 133–149.	M Driessnack - nursing
0672	Informed consent in genomics and genetic research.	McGuire, A.L., Beskow, L.M., 2010. Informed consent in genomics and genetic research. Annu Rev Genomics Hum Genet 11, 361–381. doi:10.1146/annurev-genom-082509-141711	Amy L McGuire – medical ethics
0691	Handling ethical, legal and social issues in birth cohort studies involving genetic research: responses from studies in six countries.	Ries, N.M., LeGrandeur, J., Caulfield, T., 2010. Handling ethical, legal and social issues in birth cohort studies involving genetic research: responses from studies in six countries. BMC Med Ethics 11, 4. doi:10.1186/1472-6939-11-4	NM Ries – health law
1051	Using NHS data to improve health	Perrin, N.M.R., 2016. Using NHS data to improve health. BMJ 354, i3852. doi:10.1136/bmj.i3852	NMR Perrin - policy
1179	Broad Consent for Research With Biological Samples: Workshop Conclusions	Grady, C., Eckstein, L., Berkman, B., Brock, D., Cook-Deegan, R., Fullerton, S.M., Greely, H., Hansson, M.G., Hull, S., Kim, S., Lo, B., Pentz, R., Rodriguez, L., Weil, C., Wilfond, B.S., Wendler, D., 2015. Broad Consent for Research With Biological Samples: Workshop Conclusions. Am J Bioeth 15, 34–42. doi:10.1080/15265161.2015.1062162	Christine Grady – bioethics
1250	Delayed consent: will there be a shift in approach for US primary percutaneous coronary intervention trials?	MacKay, C.R., Torguson, R., Waksman, R., 2015. Delayed consent: will there be a shift in approach for US primary percutaneous coronary intervention trials? The Lancet 386, 714–716. doi:10.1016/S0140-6736(15)60077-0	Charles R MacKay – health research
1276	A step forward on data sharing and consent	The Lancet, 2014. A step forward on data sharing and consent. The Lancet 384, 830. doi:10.1016/S0140-6736(14)61472-0	N/A
1280	HEAT-PPCI sheds light on consent in pragmatic trials	Shaw, D., 2014. HEAT-PPCI sheds light on consent in pragmatic trials. The Lancet 384, 1826–1827. doi:10.1016/S0140-6736(14)61040-0	David Shaw – biomedical ethics
1312	Patients would benefit from simplified ethical review and consent procedure	Hansson, M.G., Ommen, G.J. van, Chadwick, R., Dillner, J., 2013. Patients would benefit from simplified ethical review and consent procedure. The Lancet Oncology 14, 451–453. doi:10.1016/S1470-2045(13)70129-3	MG Hansson – research ethics and bioethics
1724	Alternative consent models for comparative effectiveness studies: Views of patients from two institutions	Kass, N., Faden, R., Fabi, R.E., Morain, S., Hallez, K., Whicher, D., Tunis, S., Moloney, R., Messner, D., Pitcavage, J., 2016. Alternative consent models for comparative effectiveness studies: Views of patients from two institutions.	Nancy Kass - bioethics

		AJOB Empirical Bioethics 7, 92–105. doi:10.1080/23294515.2016.1156188	
1893	23andMe and the FDA	Annas, G.J., Elias, S., 2014. 23andMe and the FDA. New England Journal of Medicine 370, 985–988. doi:10.1056/NEJMp1316367	GJ Annas – health law
1899	Bringing the Common Rule into the 21st Century	Hudson, K.L., Collins, F.S., 2015. Bringing the Common Rule into the 21st Century. New England Journal of Medicine 373, 2293–2296. doi:10.1056/NEJMp1512205	Kathy L Hudson - policy
1909	Federal Research Regulations for the 21st Century	Lo, B., Barnes, M., 2016. Federal Research Regulations for the 21st Century. New England Journal of Medicine 374, 1205–1207. doi:10.1056/NEJMp1600511	Bernard Lo - bioethics
1916	Genomic Medicine: Genomics, Health Care, and Society	Hudson, K.L., 2011. Genomics, Health Care, and Society. New England Journal of Medicine 365, 1033–1041. doi:10.1056/NEJMra1010517	Kathy L Hudson - policy
1922	Informed Consent for Pragmatic Trials — The Integrated Consent Model	Kim, S.Y.H., Miller, F.G., 2014. Informed Consent for Pragmatic Trials — The Integrated Consent Model. New England Journal of Medicine 370, 769–772. doi:10.1056/NEJMhle1312508	SYH Kim - bioethics
1923	Informed Consent, Comparative Effectiveness, and Learning Health Care	Faden, R.R., Beauchamp, T.L., Kass, N.E., 2014a. Informed Consent, Comparative Effectiveness, and Learning Health Care. New England Journal of Medicine 370, 766–768. doi:10.1056/NEJMhle1313674	Ruth R Faden - bioethics
1938	Reforming the Regulations Governing Research with Human Subjects	Emanuel, E.J., Menikoff, J., 2011. Reforming the Regulations Governing Research with Human Subjects. New England Journal of Medicine 365, 1145–1150. doi:10.1056/NEJMsb1106942	Ezekiel J Emanuel - bioethics
1954	The Common Rule, Updated	Menikoff, J., Kaneshiro, J., Pritchard, I., 2017. The Common Rule, Updated. N Engl J Med 376, 613–615. doi:10.1056/NEJMp1700736	Jerry Menikoff – human research protections

List of articles excluded after second scan and reasons for exclusion

ID	Title	Reason for exclusion	
0005	The 'three-legged stool': a system for spinal informed consent.	Article discusses informed consent for treatment rather than for data collection and use	Powell JM, Rai A, Foy M, Casey A, Dabke H, Gibson A, Hutton M.

0012	Surgical innovation: the ethical agenda: A systematic review.	Article discusses informed consent for treatment rather than for data collection and use	Broekman ML, CarriÃ¨re ME, Bredenoord AL.
0018	Informed choice" in a time of too much medicine-no panacea for ethical difficulties.	Article discusses informed consent for treatment rather than for data collection and use	Johansson M, JÃ¸rgensen KJ, Getz L, Moynihan R.
0020	Assent for children's participation in research: why it matters and making it meaningful.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Oulton K, Gibson F, Sell D, Williams A, Pratt L, Wray J.
0040	Key stakeholder perceptions about consent to participate in acute illness research: a rapid, systematic review to inform epi/pandemic research preparedness.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Gobat NH, Gal M, Francis NA, Hood K, Watkins A, Turner J, Moore R, Webb SA, Butler CC, Nichol A.
0043	Letter to the Editor: Medicolegal Sidebar: Informed Consent in the Information Age.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Zagaja A, Patryn RK.
0048	Informed Consent, Libertarian Paternalism, and Nudging: A Response.	Article discusses informed consent for treatment rather than for data collection and use	Ploug T, Holm SR.
0050	Volunteer experiences and perceptions of the informed consent process: Lessons from two HIV clinical trials in Uganda.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Ssali A, Poland F, Seeley J.
0054	Decision aids for people considering taking part in clinical trials.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Gillies K, Cotton SC, Brehaut JC, Politi MC, Skea Z.
0061	Informed consent instead of assent is appropriate in children from the age of twelve: Policy implications of new findings on children's competence to consent to clinical research.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Hein IM, De Vries MC, Troost PW, Meynen G, Van Goudoever JB, Lindauer RJ.
0065	Decision-Making Process Related to Participation in Phase I Clinical Trials: A Nonsystematic Review of the Existing Evidence.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Gorini A, Mazzocco K, Pravettoni G.
0068	Evaluation of interventions for informed consent for randomised controlled trials (ELICIT): protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Gillies K, Entwistle V, Treweek SP, Fraser C, Williamson PR, Campbell MK.
0069	Another look at the informed consent process: The document and the conversation.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Wall LK, Pentz RD.

0076	On Nudging and Informed Consent.	Article discusses informed consent for treatment rather than for data collection and use	Chwang E.
0096	Informed consent in paediatric critical care research--a South African perspective.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Morrow BM, Argent AC, Kling S.
0098	Informed consent: where are we in 2015?	Article discusses informed consent for treatment rather than for data collection and use	Foy MA.
0105	Audio-visual recording of obtaining informed consent: Mandatory for clinical trials.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Gowri S, Kannan S.
0110	Distinctions in Disclosure: Mandated Informed Consent in Abortion and ART.	Article discusses informed consent for treatment rather than for data collection and use	Daar J.
0117	Informed consent in clinical research: Consensus recommendations for reform identified by an expert interview panel.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Lorell BH, Mikita JS, Anderson A, Hallinan ZP, Forrest A.
0124	Informed Consent and the Use of Biospecimens in Research.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Eisenhauer ER.
0131	Enduring and emerging challenges of informed consent.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Grady C.
0170	Advancing informed consent for vulnerable populations.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Heerman WJ, White RO, Barkin SL.
0177	Comprehension of Randomization and Uncertainty in Cancer Clinical Trials Decision Making Among Rural, Appalachian Patients.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Krieger JL, Palmer-Wackerly A, Dailey PM, Krok-Schoen JL, Schoenberg NE, Paskett ED.
0178	Consent: a practical guide.	Article discusses informed consent for treatment rather than for data collection and use	Khoury BS, Khoury JN.
0185	Ethics of research in pediatric emergency medicine.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Neuman G, Shavit I, Matsui D, Koren G.

0193	Ethics of drug research in the pediatric intensive care unit.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Kleiber N, Tromp K, Mooij MG, van de Vathorst S, Tibboel D, de Wildt SN.
0195	Informed consent and ethical re-use of African genomic data.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Wright GE, Adeyemo AA, Tiffin N.
0206	Dementia research and advance consent: it is not about critical interests.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Jongsma KR, van de Vathorst S.
0208	From informed consent to shared decision-making.	Article discusses informed consent for treatment rather than for data collection and use	Manyonga H, Howarth G, Dinwoodie M, Nisselle P, Whitehouse S.
0211	Audio-visual recording of "informed consent" in India: step towards "understood consent".	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Goyal A.
0216	Re: Patients' recollection and understanding of informed consent: a literature review.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Walsh K.
0220	Coming to a consensus on informed consent for case reports.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Neavyn M, Murphy C.
0221	Participant comprehension of research for which they volunteer: a systematic review.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Montalvo W, Larson E.
0236	Consent: Can it be more informed?	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Feld AD.
0246	Informed consent for comparative effectiveness trials.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Modi PK.
0247	Informed consent for comparative effectiveness trials.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Elsayyad A.

0248	Informed consent for comparative effectiveness trials.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Schreiner MS.
0249	Informed consent for comparative effectiveness trials.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Anderson JR, Schonfeld TL.
0254	Audio-visual presentation of information for informed consent for participation in clinical trials.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Synnot A, Ryan R, Prictor M, Fetherstonhaugh D, Parker B.
0258	Disclosure, consent, and the exercise of patient autonomy in surgical innovation: a systematic content analysis of the conceptual literature.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Bracken-Roche D, Bell E, Karpowicz L, Racine E.
0265	Is there an ethical obligation to disclose controversial risk? A question from the ACCORD Trial.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	DeMarco JP, Ford PJ, Patton DJ, Stewart DO.
0267	India puts informed consent on camera.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Kakkar AK.
0282	Practical issues in implementation of WMA's draft Declaration of Helsinki.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Shah P.
0290	Ethical challenges and solutions regarding delirium studies in palliative care.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Sweet L, Adamis D, Meagher DJ, Davis D, Currow DC, Bush SH, Barnes C, Hartwick M, Agar M, Simon J, Breitbart W, MacDonald N, Lawlor PG.
0333	Research methodologies in informed consent studies involving surgical and invasive procedures: time to re-examine?	Article discusses informed consent for treatment rather than for data collection and use	Kim S, Jabori S, O'Connell J, Freeman S, Fung CC, Ekram S, Unawame A, Van Norman G.
0338	Points to consider for informed consent for genome/exome sequencing.	Article does not focus on informed consent	ACMG Board of Directors.
0339	Laws relating to informed consent in clinical trials.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Craig KJ.
0349	Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of	Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, McCormick JB.

		consent, or administration of consent form)	
0351	Social media and community engagement in trials using exception from informed consent.	Article does not focus on informed consent	Chretien KC.
0359	Intensive care unit research and informed consent: still a conundrum.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Matei M, Lemaire F.
0366	Researching the vulnerables: issues of consent and ethical approval.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Afolabi MO.
0370	Should we nudge informed consent?	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Brooks T.
0373	Informed consent in palliative care clinical trials: challenging but possible.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Agar M, Ko DN, Sheehan C, Chapman M, Currow DC.
0384	Navigating the legal and ethical foundations of informed consent and confidentiality in integrated primary care.	Article discusses informed consent for treatment rather than for data collection and use	Hudgins C, Rose S, Fifield PY, Arnault S.
0400	Consent to organ donation: a review.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Siminoff LA, Agyemang AA, Traino HM.
0414	Aspects of vulnerable patients and informed consent in clinical trials.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Kuthning M, Hundt F.
0416	Return of results in translational iPS cell research: considerations for donor informed consent.	Article does not focus on informed consent	Lomax GP, Shepard KA.
0422	IRB decision-making with imperfect knowledge: a framework for evidence-based research ethics review.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Anderson EE, DuBois JM.
0425	Why we should continue to worry about the therapeutic misconception.	No full text found	Churchill LR, King NM, Henderson GE.

0460	Improving the informed consent process for research subjects with low literacy: a systematic review.	Article published before 2010	Tamariz L, Palacio A, Robert M, Marcus EN.
0476	Umbilical cord blood banking and the next generation of human tissue regulation: an agenda for research.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Stewart C, Kerridge I.
0478	Randomization to standard and concise informed consent forms: development of evidence-based consent practices.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Enama ME, Hu Z, Gordon I, Costner P, Ledgerwood JE, Grady C; VRC 306 and 307 Consent Study Teams..
0495	Informed consent for clinical treatment.	Article discusses informed consent for treatment rather than for data collection and use	Hall DE, Prochazka AV, Fink AS.
0501	Comments on protecting clients about whom we write (and speak).	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Fischer CT.
0516	Beyond informed consent.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Sieber JE.
0527	A novel approach to obtaining informed consent from the person responsible: telephone, email and text message.	No full text found	Eastwood GM.
0528	Communication and informed consent in elderly people.	Article discusses informed consent for treatment rather than for data collection and use	Giampieri M.
0535	The use of routinely collected patient data for research: a critical review.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Foster V, Young A; Medicines for Neonates Investigator Group., Modi N, Brocklehurst P, Abbott J, Costeloe K, Field D, Majeed A, Kemp J, Ashby D, Young A, Petrou S.
0540	Broad consent is informed consent.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Sheehan M.
0543	Informed consent and patient registry for the rare disease community: Editorial.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Grady C, Rubinstein YR, Groft SC.
0549	The ethics of obtaining consent in labour for research.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Reid R, Susic D, Pathirana S, Tracy S, Welsh AW.

0564	Is informed consent broken?	No full text found	Henderson GE.
0569	Research enrollment and informed consent.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Labrique AB, Bartlett LA, Merritt MW.
0602	Newborn screening cards: a legal quagmire.	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Bowman DM, Studdert DM.
0616	Informed consent: dissimilar linguistic barriers in different societies.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Momen-Heravi F, Khalilzadeh O, Dorriz H.
0632	Portable video education for informed consent: the shape of things to come?	Article discusses informed consent for treatment rather than for data collection and use	Varma S.
0670	How to improve the informed consent process.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Masera G, D'Angio G
0681	Is emergency research without initial consent justified?: the consent substitute model.	Article proposes novel approach to consent unrelated to evolving data environment (e.g. consent for minors; consent in emergency care settings)	Largent EA, Wendler D, Emanuel E, Miller FG
0690	Informed consent to promote patient-centered care.	Article discusses informed consent for treatment rather than for data collection and use	Krumholz HM
1002	Care.data doesn't care enough about consent	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	McCartney M
1005	Consent forms for clinical trials are too aggressive	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Wassersug RJ
1008	David Oliver: Confidentiality on the wards—regulations and reality	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Oliver D
1063	Patient confidentiality in a time of care.data	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Sheather J, Brannan S

1066	"Personalising" NHS information technology in England	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Greenhalgh T, Keen J
1071	Collecting data on female genital mutilation	Article does not focus on informed consent	Erskine K
1072	Liberating the data from clinical trials	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Henry D, Fitzpatrick T
1076	Confidentiality and sharing health information	Article published before 2010	Sheather J
1078	Revising the Declaration of Helsinki	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Nathanson V
1227	Sharing clinical trial data: a proposal from the International Committee of Medical Journal Editors	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Taichman DB, Backus J, Baethge C, Bauchner H, W de Leeuw P, Drazen JM, et al
1286	Ensuring privacy in the study of pathogen genetics	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Mehta SR, Vinterbo SA, Little SJ
1290	UK funders' framework for health-related findings in research	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Farrar J, Savill J
1320	Our genomic future	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	The Lancet
1386	Data protection: balancing personal privacy and public health	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	The Lancet Respiratory Medicine
1446	A decade into Facebook: where is psychiatry in the digital age?	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Inkster B, Stillwell D, Kosinski M, Jones P
1703	DOCTORS, PATIENTS, AND NUDGING IN THE CLINICAL CONTEXT—FOUR VIEWS ON NUDGING AND INFORMED CONSENT	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of	Ploug T, Holm S

		consent, or administration of consent form)	
1706	NUDGING AND INFORMED CONSENT	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Cohen, S
1710	LAY AND PROFESSIONAL UNDERSTANDINGS OF RESEARCH AND CLINICAL ACTIVITIES IN CANCER GENETICS AND THEIR IMPLICATIONS FOR INFORMED CONSENT	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Hallowell N, Parry S, Cooke S, Crawford G, Lucassen A, Parker M
1726	BROAD CONSENT FOR RESEARCH WITH BIOLOGICAL SAMPLES: WORKSHOP CONCLUSIONS	Duplicate	Grady C, Eckstein L, Berkman B, Brock D, Cook-Deegan R, Fullerton SM, Greely H, Hansson MG, Hull S, Kim S, Lo B, Pentz R, Rodriguez L, Weil C, Wilfond BS, Wendler D
1727	DOES CONSENT BIAS RESEARCH?	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Rothstein MA, Shoben AB
1734	CLARIFYING ETHICAL RESPONSIBILITIES IN PEDIATRIC BIOBANKING	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Spriggs M, Fry CL
1738	ETHICS OF RESEARCH IN USUAL CARE SETTINGS: DATA ON POINT	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Sugarman J
1739	ADRIFT IN THE GRAY ZONE: IRB PERSPECTIVES ON RESEARCH IN THE LEARNING HEALTH SYSTEM	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Lee SS, Kelley M, Cho MK, Kraft SA, James C, Constantine M, Meyer AN, Diekema D, Capron AM, Wilfond BS, Magnus D
1742	PRUDENTIA POPULO: INVOLVING THE COMMUNITY IN BIOBANK GOVERNANCE	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Allyse MA, McCormick JB, Sharp RR
1894	A Global, Neutral Platform for Sharing Trial Data	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Bierer BE, Li R, Barnes M, Sim I
1897	Assessing Participant-Centered Outcomes to Improve Clinical Research	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Kost RG, Lee LM, Yessis J, Wesley RA, Henderson DK, Coller BS

1907	Enduring and Emerging Challenges of Informed Consent	Duplicate	Grady C
1932	Preparing for Responsible Sharing of Clinical Trial Data	Article does not include explicit reference to a new form of consent (in terms of a general approach to consent, scope of consent, or administration of consent form)	Friedman AB
1951	The Changing Face of Clinical Trials: Informed Consent	Duplicate	Grady C, Cummings SR, Rowbotham MC, McConnell MV, Ashley EA, Kang G
1952	The Changing Face of Clinical Trials: Integrating Randomized Comparative Effectiveness Research with Patient Care	Article does not focus on informed consent	Fiore LD, Lavori PW
1953	The Changing Face of Clinical Trials: Pragmatic Trials	Article does not focus on informed consent	Ford I, Norrie J

Full list of articles before first scan

ID	Source	Title
0001	Pubmed	Informed Consent.
0002	Pubmed	Informed consent in the context of research involving acute injuries and emergencies.
0003	Pubmed	Apparent treatment-resistant hypertension - patient-physician relationship and ethical issues.
0004	Pubmed	Court in judgement of informed consent.
0005	Pubmed	The 'three-legged stool': a system for spinal informed consent.
0006	Pubmed	Informed Consent and the Reasonable-Patient Standard-Reply.
0007	Pubmed	Informed Consent and the Reasonable-Patient Standard.
0008	Pubmed	Informed Consent and the Reasonable-Patient Standard.
0009	Pubmed	Obtaining informed consent for delivery room research: the investigators' perspective.
0010	Pubmed	Clinical Trials Without Consent?
0011	Pubmed	Closing the evidence gap in infectious disease: point-of-care randomization and informed consent.
0012	Pubmed	Surgical innovation: the ethical agenda: A systematic review.
0013	Pubmed	Barriers to Change in the Informed Consent Process: A Systematic Literature Review.
0014	Pubmed	How to Avoid and Deal with Pelvic Mesh Litigation.
0015	Pubmed	Contemporary interpretation of informed consent: autonomy and paternalism.

0016	Pubmed	Changes to the law on consent following Montgomery vs Lanarkshire Health Board.
0017	Pubmed	Informed Consent for Vaginal Delivery: Is It Time to Revisit the Shared Decision-Making Process?.
0018	Pubmed	Informed choice" in a time of too much medicine-no panacea for ethical difficulties.
0019	Pubmed	Informed consent in clinical research; Do patients understand what they have signed?
0020	Pubmed	Assent for children's participation in research: why it matters and making it meaningful.
0021	Pubmed	Have the Answers to Common Legal Questions Concerning Nutrition Support Changed Over the Past Decade? 10 Questions for 10 Years.
0022	Pubmed	Factors to consider for informed consent prior to vasectomy reversal.
0023	Pubmed	Motivations of children and their parents to participate in drug research: a systematic review.
0024	Pubmed	Discussion: Breast Implant Informed Consent Should Include the Risk of Anaplastic Large Cell Lymphoma.
0025	Pubmed	Medicolegal Issues in Breast Reduction.
0026	Pubmed	Informed Consent for PROs in EHR Research: Are Additional Requirements Necessary?
0027	Pubmed	An Interactive Multimedia Approach to Improving Informed Consent for Induced Pluripotent Stem Cell Research.
0028	Pubmed	First update of the International Xenotransplantation Association consensus statement on conditions for undertaking clinical trials of porcine islet products in type 1 diabetes--Executive summary.
0029	Pubmed	First update of the International Xenotransplantation Association consensus statement on conditions for undertaking clinical trials of porcine islet products in type 1 diabetes--Chapter 2a: source pigs--preventing xenozoonoses.
0030	Pubmed	It's Nurses' Job to Help Patients and Families Make Informed Decisions.
0031	Pubmed	Informed Consent for Reconstructive Pelvic Surgery.
0032	Pubmed	Exceptions to the rule of informed consent for research with an intervention.
0033	Pubmed	Understanding cognitive processes behind acceptance or refusal of phase I trials.
0034	Pubmed	Reinterpreting Respect for Relationally and Biologically Informed Autonomy.
0035	Pubmed	The right not to know does not apply to HIV testing.
0036	Pubmed	Achieving the Triple Aim Through Informed Consent for Computed Tomography.
0037	Pubmed	Learning to Take Informed Consent: On a Project for German Medical Students: Reply.
0038	Pubmed	Adverse Event and Complication Management in Gastrointestinal Endoscopy.
0039	Pubmed	Medical Liability and Patient Law in Germany: Main Features with Particular Focus on Treatments in the Field of Interventional Radiology.
0040	Pubmed	Key stakeholder perceptions about consent to participate in acute illness research: a rapid, systematic review to inform epi/pandemic research preparedness.
0041	Pubmed	Regulation of Biobanks in South Africa.
0042	Pubmed	Number Unnecessarily Treated in Relation to Harm: A Concept Physicians and Patients Need to Understand.
0043	Pubmed	Letter to the Editor: Medicolegal Sidebar: Informed Consent in the Information Age.

0044	Pubmed	Self-Neglect: Ethical Considerations.
0045	Pubmed	PARP inhibitors in ovarian cancer: Clinical evidence for informed treatment decisions.
0046	Pubmed	Reply to the Letter to the Editor: Medicolegal Sidebar: Informed Consent in the Information Age.
0047	Pubmed	Intravitreal bevacizumab for retinopathy of prematurity: Considerations for informed consent.
0048	Pubmed	Informed Consent, Libertarian Paternalism, and Nudging: A Response.
0049	Pubmed	CRISPR/Cas9 and Germline Modification: New Difficulties in Obtaining Informed Consent.
0050	Pubmed	Volunteer experiences and perceptions of the informed consent process: Lessons from two HIV clinical trials in Uganda.
0052	Pubmed	The 3-I framework: a framework for developing public policies regarding pharmacogenomics (PGx) testing in Canada.
0053	Pubmed	The FGM enhanced dataset: how are we going to discuss this with our patients?
0054	Pubmed	Decision aids for people considering taking part in clinical trials.
0055	Pubmed	Letter to editor: Informed consent in the light of Montgomery.
0056	Pubmed	Umbilical Cord Blood: Counselling, Collection, and Banking.
0057	Pubmed	Informed Consent in Older Medical Inpatients: Assessment of Decision-Making Capacity.
0058	Pubmed	Ethical governance in biobanks linked to electronic health records.
0059	Pubmed	Precision medicine ethics: selected issues and developments in next-generation sequencing, clinical oncology, and ethics.
0060	Pubmed	The issue of consent in medical practice.
0061	Pubmed	Informed consent instead of assent is appropriate in children from the age of twelve: Policy implications of new findings on children's competence to consent to clinical research.
0062	Pubmed	Indeterminacy and the normative basis of the harm threshold for overriding parental decisions: a response to Birchley.
0063	Pubmed	The ethical issues regarding consent to clinical trials with pre-term or sick neonates: a systematic review (framework synthesis) of the empirical research.
0064	Pubmed	Guideline on Informed Consent.
0065	Pubmed	Decision-Making Process Related to Participation in Phase I Clinical Trials: A Nonsystematic Review of the Existing Evidence.
0066	Pubmed	Informed Consent for Research on Medical Practices.
0067	Pubmed	Informed Consent for Research on Medical Practices.
0068	Pubmed	Evaluation of interventions for informed consent for randomised controlled trials (ELICIT): protocol for a systematic review of the literature and identification of a core outcome set using a Delphi survey.
0069	Pubmed	Another look at the informed consent process: The document and the conversation.
0070	Pubmed	Four Principles to Consider Before Advising Women on Screening Mammography.
0071	Pubmed	A framework of ethics for telepsychiatry practice.
0072	Pubmed	Data research on child abuse and neglect without informed consent? Balancing interests under Dutch law.
0073	Pubmed	Involving Medical Students in Informed Consent: A Pilot Study.

0074	Pubmed	Response to Open Peer Commentaries on "Placebo Effects and Informed Consent".
0075	Pubmed	Evidence-Based Nudging: Best Practices in Informed Consent.
0076	Pubmed	On Nudging and Informed Consent.
0077	Pubmed	Clinical Placebo Can Be Defined Positively: Implications for Informed Consent.
0078	Pubmed	Informed Consent: Hints From Placebo and Nocebo Research.
0079	Pubmed	Placebo, Nocebo, Informed Consent, and Moral Technologies.
0080	Pubmed	Mail merge can be used to create personalized questionnaires in complex surveys.
0081	Pubmed	Consent and consensus-ethical perspectives on obtaining bodies for anatomical dissection.
0082	Pubmed	The public display of plastinates as a challenge to the integrity of anatomy.
0083	Pubmed	Ethical issues surrounding the use of images from donated cadavers in the anatomical sciences.
0084	Pubmed	Participant views and experiences of participating in HIV research in sub-Saharan Africa: a qualitative systematic review.
0085	Pubmed	Should consent forms used in clinical trials be translated into the local dialects? A survey among past participants in rural Ghana.
0086	Pubmed	Improving quality of informed consent in clinical research.
0087	Pubmed	The Unbefriended Patient: An Exercise in Ethical Clinical Reasoning.
0088	Pubmed	Addiction, Voluntary Choice, and Informed Consent: A Reply to Uusitalo and Broers.
0089	Pubmed	A systematic review of training programmes for recruiters to randomised controlled trials.
0090	Pubmed	How parents and practitioners experience research without prior consent (deferred consent) for emergency research involving children with life threatening conditions: a mixed method study.
0091	Pubmed	Ethical oversight in quality improvement and quality improvement research: new approaches to promote a learning health care system.
0092	Pubmed	The National Institutes of Health Oversight of Human Gene Transfer Research: Enhancing Science and Safety.
0093	Pubmed	Informed Consent Challenges in Frail, Delirious, Demented, and Do-Not-Resuscitate Adult Patients.
0094	Pubmed	Understanding Informed Consent.
0095	Pubmed	Research participants' perceptions and views on consent for biobank research: a review of empirical data and ethical analysis.
0096	Pubmed	Informed consent in paediatric critical care research--a South African perspective.
0097	Pubmed	Electroconvulsive Therapy Practice in Spain: A National Survey.
0098	Pubmed	Informed consent: where are we in 2015?
0099	Pubmed	Noninvasive Prenatal Genetic Testing: Current and Emerging Ethical, Legal, and Social Issues.
0100	Pubmed	Enmeshed in Controversy: Use of Vaginal Mesh in the Current Medicolegal Environment.
0101	Pubmed	Frailty's Place in Ethics and Law: Some Thoughts on Equality and Autonomy and on Limits and Possibilities for Aging Citizens.
0103	Pubmed	Communicating Potential Radiation-Induced Cancer Risks From Medical Imaging Directly to Patients.

0104	Pubmed	The Psychosocial and Independent Living Donor Advocate Evaluation and Post-surgery Care of Living Donors.
0105	Pubmed	Audio-visual recording of obtaining informed consent: Mandatory for clinical trials.
0106	Pubmed	Living Donor Kidney Transplantation: Improving Efficiencies in Live Kidney Donor Evaluation--Recommendations from a Consensus Conference.
0107	Pubmed	Rhinology and medical malpractice: An update of the medicolegal landscape of the last ten years.
0108	Pubmed	Ethics and the facial plastic surgeon.
0109	Pubmed	Genome-Wide Sequencing for Prenatal Detection of Fetal Single-Gene Disorders.
0110	Pubmed	Distinctions in Disclosure: Mandated Informed Consent in Abortion and ART.
0111	Pubmed	Informed Consent for GI Endoscopy-Do the Time and Place Matter?
0112	Pubmed	Resolving Some, But Not All Informed Consent Issues in DCDD--the Swiss Experiences.
0113	Pubmed	The Impossibility of Obtaining Informed Consent to Donation After Circulatory Determination of Death.
0114	Pubmed	Informed Consent and Communicating Risk and Benefits of Research on Higher-Risk Medications.
0115	Pubmed	Improving the Informed Consent Conversation: A Standardized Checklist that Is Patient Centered, Quality Driven, and Legally Sound.
0116	Pubmed	Giving samples or "getting checked": measuring conflation of observational biospecimen research and clinical care in Latino communities.
0117	Pubmed	Informed consent in clinical research: Consensus recommendations for reform identified by an expert interview panel.
0118	Pubmed	Podoconiosis treatment in northern Ethiopia (GoLBet): study protocol for a randomised controlled trial.
0119	Pubmed	Patients' Attitudes Toward Medical Student Participation Across Specialties: A Systematic Review.
0120	Pubmed	Points to Consider: Ethical, Legal, and Psychosocial Implications of Genetic Testing in Children and Adolescents.
0121	Pubmed	UK law on consent: broad consent or authorisation for research?
0122	Pubmed	Medicolegal Implications of Common Rhinologic Medications.
0123	Pubmed	Assent as an ethical imperative in the treatment of ADHD.
0124	Pubmed	Informed Consent and the Use of Biospecimens in Research.
0125	Pubmed	The ethics of placebo treatments in clinical practice: a reply to Glackin.
0126	Pubmed	Living kidney donation: outcomes, ethics, and uncertainty.
0127	Pubmed	Direct to consumer testing in reproductive contexts--should health professionals be concerned?
0128	Pubmed	Use of contrast media in diagnostic imaging: medico-legal considerations.
0129	Pubmed	Enduring and emerging challenges of informed consent.
0130	Pubmed	Enduring and emerging challenges of informed consent.
0131	Pubmed	Enduring and emerging challenges of informed consent.
0132	Pubmed	The Ethics of Big Data: Current and Foreseeable Issues in Biomedical Contexts.

0133	Pubmed	Patients as partners in innovation.
0134	Pubmed	Informed screening.
0135	Pubmed	The Belmont Report. Ethical principles and guidelines for the protection of human subjects of research.
0136	Pubmed	Informed Consent for Electroconvulsive Therapy--Finding Balance.
0137	Pubmed	Research without informed patient consent in incompetent patients.
0138	Pubmed	Intensive care unit research ethics and trials on unconscious patients.
0139	Pubmed	Informed consent: the dawning of a new era.
0140	Pubmed	Patients or volunteers? The impact of motivation for trial participation on the efficacy of patient decision Aids: a secondary analysis of a Cochrane systematic review.
0141	Pubmed	HIV pre-test information, discussion or counselling? A review of guidance relevant to the WHO European Region.
0142	Pubmed	Can shared decision-making reduce medical malpractice litigation? A systematic review.
0143	Pubmed	Living Donor Kidney Transplantation: Facilitating Education about Live Kidney Donation--Recommendations from a Consensus Conference.
0144	Pubmed	Informed Consent for Radiation Risk from CT Is Unjustified Based on the Current Scientific Evidence.
0145	Pubmed	Response to commentaries by Karin Rolanda Jongsma and Suzanne van de Vathorst, and Oliver Hallich.
0146	Pubmed	Participants' understanding of informed consent in clinical trials over three decades: systematic review and meta-analysis.
0147	Pubmed	Coronary angiography and bronchoscopy on brain-dead donors: is informed consent required?
0148	Pubmed	Open-access endoscopy.
0149	Pubmed	Elements of informed consent and decision quality were poorly correlated in informed consent documents.
0150	Pubmed	Informed consent and parental permission for research: rules, roles, and relationships.
0151	Pubmed	Parental live liver donation: psychosocial considerations in the decision to donate.
0152	Pubmed	Openness and honesty in gaining fully informed consent will benefit both patients and doctors.
0154	Pubmed	Ethical issues in gastroenterology research.
0155	Pubmed	Advance directives, living wills, and futility in perioperative care.
0156	Pubmed	E-recruitment based clinical research: notes for Research Ethics Committees/Institutional Review Boards.
0157	Pubmed	Questionable informed consent of vulnerable pregnant research participants in South India - what a staff reminder poster does not say.
0158	Pubmed	Evolution of European Union legislation on emergency research.
0159	Pubmed	Pragmatic randomized trials in drug development pose new ethical questions: a systematic review.
0160	Pubmed	Re-evaluating ethical concerns in planned emergency research involving critically ill patients: an interpretation of the guidance document from the United States Food and Drug Administration.
0161	Pubmed	Ethics of genetic and biomarker test disclosures in neurodegenerative disease prevention trials.
0162	Pubmed	Medico-legal aspects of dental treatment of the ageing and aged patient.

0163	Pubmed	Informed consent procedures with cognitively impaired patients: A review of ethics and best practices.
0164	Pubmed	Measuring voluntariness of consent to research: an instrument review.
0165	Pubmed	Ethical issues when using social media for health outside professional relationships.
0166	Pubmed	Stakeholders' perspectives on biobank-based genomic research: systematic review of the literature.
0167	Pubmed	Exception from informed consent: ethics and logistics.
0168	Pubmed	The association of health status and providing consent to continued participation in an out-of-hospital cardiac arrest trial performed under exception from informed consent.
0169	Pubmed	Enduring and emerging challenges of informed consent.
0170	Pubmed	Advancing informed consent for vulnerable populations.
0171	Pubmed	Medical photography: current technology, evolving issues and legal perspectives.
0172	Pubmed	Reconsidering the ethics of sham interventions in an era of emerging technologies.
0173	Pubmed	Ethical and regulatory considerations in the design of traumatic brain injury clinical studies.
0174	Pubmed	Seeking consent from those who cannot answer: new light on emergency research conducted under the exception from informed consent.
0175	Pubmed	Pastoral power and gynaecological examinations: a Foucauldian critique of clinician accounts of patient-centred consent.
0176	Pubmed	The independent living donor advocate: a guidance document from the American Society of Transplantation's Living Donor Community of Practice (AST LDCOP).
0177	Pubmed	Comprehension of Randomization and Uncertainty in Cancer Clinical Trials Decision Making Among Rural, Appalachian Patients.
0178	Pubmed	Consent: a practical guide.
0179	Pubmed	Establishing code status: are people's decisions truly informed?
0180	Pubmed	Ethical considerations in stem cell research on neurologic and orthopedic conditions.
0181	Pubmed	A comparative study of patients' attitudes toward clinical research in the United States and urban and rural China.
0182	Pubmed	Targeted" consent for pragmatic clinical trials.
0183	Pubmed	The complexity of consenting to clinical research in phase I pediatric cancer studies.
0184	Pubmed	Features and ethical considerations associated with living kidney and liver transplantations in South Korea.
0185	Pubmed	Ethics of research in pediatric emergency medicine.
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0187	Pubmed	The need for a standardized informed consent procedure in live donor nephrectomy: a systematic review.
0188	Pubmed	Informed consent in pediatric research.
0189	Pubmed	Consenting for current genetic research: is Canadian practice adequate?
0190	Pubmed	Informed consent in the psychosis prodrome: ethical, procedural and cultural considerations.
0191	Pubmed	Stratified reproduction, family planning care and the double edge of history.

0192	Pubmed	Commentary--Informed consent for a life-saving operation in Albania and in India.
0193	Pubmed	Ethics of drug research in the pediatric intensive care unit.
0194	Pubmed	Medicolegal pitfalls of cataract surgery.
0195	Pubmed	Informed consent and ethical re-use of African genomic data.
0196	Pubmed	Placebo treatments, informed consent and 'the grip of a false picture'.
0197	Pubmed	The reporting of research ethics committee approval and informed consent in otolaryngology journals.
0198	Pubmed	The communication of the radiation risk from CT in relation to its clinical benefit in the era of personalized medicine: part 2: benefits versus risk of CT.
0199	Pubmed	From 'Image Gently' to image intelligently: a personalized perspective on diagnostic radiation risk.
0200	Pubmed	Biorepository regulatory frameworks: building parallel resources that both promote scientific investigation and protect human subjects.
0201	Pubmed	Musculoskeletal health disparities: health literacy, cultural competency, informed consent, and shared decision making.
0202	Pubmed	Is "your only hope" medical treatment choice really a choice?
0203	Pubmed	Is 'informed consent' an 'understood consent' in hematopoietic cell transplantation?
0205	Pubmed	Legal issues in child maltreatment.
0206	Pubmed	Dementia research and advance consent: it is not about critical interests.
0207	Pubmed	Dense breast notification: anatomy, imaging, and patient awareness.
0208	Pubmed	From informed consent to shared decision-making.
0209	Pubmed	Evaluation of patient education materials: the example of circulating cell free DNA testing for aneuploidy.
0210	Pubmed	Comparative effectiveness trials: generic misassumptions underlying the SUPPORT controversy.
0211	Pubmed	Audio-visual recording of "informed consent" in India: step towards "understood consent".
0212	Pubmed	Why is informed consent important?
0213	Pubmed	Seeking worldwide professional consensus on the principles of end-of-life care for the critically ill. The Consensus for Worldwide End-of-Life Practice for Patients in Intensive Care Units (WELPICUS) study.
0214	Pubmed	Informed consent for procedures in the intensive care unit: ethical and practical considerations.
0215	Pubmed	Minimally legally invasive dentistry.
0216	Pubmed	Re: Patients' recollection and understanding of informed consent: a literature review.
0217	Pubmed	Response to Re: Patients' recollection and understanding of informed consent: a literature review.
0218	Pubmed	Externalization of consciousness. Scientific possibilities and clinical implications.
0219	Pubmed	Should informed consent be required for routine newborn screening and for the storage of blood samples?
0220	Pubmed	Coming to a consensus on informed consent for case reports.
0221	Pubmed	Participant comprehension of research for which they volunteer: a systematic review.

0222	Pubmed	Quality criteria for health checks: development of a European consensus agreement.
0223	Pubmed	Neuro-oncology: Under-recognized mental incapacity in brain tumour patients.
0224	Pubmed	Sympathetic ophthalmia after diode laser cyclophotocoagulation: now an issue in informed consent.
0225	Pubmed	Learning from experience: a systematic review of community consultation acceptance data.
0226	Pubmed	The right to information.
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0229	Pubmed	Volume-outcome disparities and informed consent: what should surgeons disclose?
0230	Pubmed	Multiplex genetic testing: reconsidering utility and informed consent in the era of next-generation sequencing.
0231	Pubmed	The ethics and editorial challenges of internet-based research.
0232	Pubmed	Application of legal principles and medical ethics: multifetal pregnancy and fetal reduction.
0233	Pubmed	Treatment decisions and changing selves.
0234	Pubmed	An ethical framework for global psychiatry.
0235	Pubmed	Psychosocial predictors, assessment, and outcomes of cosmetic procedures: a systematic rapid evidence assessment.
0236	Pubmed	Consent: Can it be more informed?
0237	Pubmed	A review of contemporary work on the ethics of ambient assisted living technologies for people with dementia.
0238	Pubmed	Informed consent and ECT: how much information should be provided?
0239	Pubmed	Informed consent in Italy-traditional versus the law: a gordian knot.
0240	Pubmed	Informed consent for anesthesia: a review of practice and strategies for optimizing the consent process.
0241	Pubmed	Methodological and ethical challenges in studying patients' perceptions of coercion: a systematic mixed studies review.
0242	Pubmed	Ethical issues in the management of thyroid disease.
0243	Pubmed	Informed consent for procedures in the intensive care unit: ethical and practical considerations.
0244	Pubmed	Commentary on: why was there no mention of informed consent and ethics committee approval in a prospective trial?
0245	Pubmed	Informed consent for comparative effectiveness trials.
0246	Pubmed	Informed consent for comparative effectiveness trials.
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0250	Pubmed	Informed consent for comparative effectiveness trials.

0251	Pubmed	Patients' recollection and understanding of informed consent: a literature review.
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0254	Pubmed	Audio-visual presentation of information for informed consent for participation in clinical trials.
0256	Pubmed	Commentary on: why was there no mention of informed consent and ethics committee approval in a prospective trial?
0257	Pubmed	Informed consent in surgery.
0258	Pubmed	Disclosure, consent, and the exercise of patient autonomy in surgical innovation: a systematic content analysis of the conceptual literature.
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0260	Pubmed	Counseling women with a previous cesarean birth: toward a shared decision-making partnership.
0261	Pubmed	A narrative review of the empirical evidence on public attitudes on brain death and vital organ transplantation: the need for better data to inform policy.
0262	Pubmed	Understanding, interests and informed consent: a reply to Sreenivasan.
0263	Pubmed	Using and respecting the dead human body: an anatomist's perspective.
0264	Pubmed	Disclosing controversial risk in informed consent: how serious is serious?
0265	Pubmed	Is there an ethical obligation to disclose controversial risk? A question from the ACCORD Trial.
0266	Pubmed	Ethical challenges in biobanking: moving the agenda forward in India.
0267	Pubmed	India puts informed consent on camera.
0268	Pubmed	The extent of surgical patients' understanding.
0269	Pubmed	Next-generation sequencing applied to rare diseases genomics.
0270	Pubmed	Making the cut: evidence-based lessons for improving the informed consent process for voluntary medical male circumcision in Swaziland and Zambia.
0271	Pubmed	How informed is informed consent?
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0273	Pubmed	Strengths and weaknesses of guideline approaches to safeguard voluntary informed consent of patients within a dependent relationship.
0274	Pubmed	Informed consent for human genetic and genomic studies: a systematic review.
0275	Pubmed	The best of all possible paternalisms?
0276	Pubmed	Overcoming language barriers in the informed consent process: regulatory and compliance issues with the use of the "short form".
0277	Pubmed	Communicating the benefits and harms of cancer screening.
0278	Pubmed	Medical research in emergency research in the European Union member states: tensions between theory and practice.
0279	Pubmed	Ethics of facial transplantation revisited.
0280	Pubmed	Ethical review of health systems research in low- and middle-income countries: a conceptual exploration.

0281	Pubmed	Current policies on informed consent in Japan constitute a formidable barrier to emergency research.
0282	Pubmed	Practical issues in implementation of WMA's draft Declaration of Helsinki.
0283	Pubmed	From informed consent to informed request: strengthening shared decisionmaking.
0284	Pubmed	A dynamic model of patient consent to sharing of medical record data.
0285	Pubmed	Psychiatric disorders impacting critical illness.
0286	Pubmed	Informed consent and the new EU regulation on data protection.
0287	Pubmed	Deliberation and the life cycle of informed consent.
0288	Pubmed	Mnemonic that corroborates informed consent in oculoplastic surgery.
0289	Pubmed	Parental permission for pilot newborn screening research: guidelines from the NBSTRN.
0290	Pubmed	Ethical challenges and solutions regarding delirium studies in palliative care.
0291	Pubmed	Medical malpractice in hand surgery.
0292	Pubmed	Navigating the institutional review board approval process in a multicenter observational critical care study.
0293	Pubmed	Participation in biobanks for research by incapacitated adults: review and discussion of current guidelines.
0294	Pubmed	Family voice with informed choice: coordinating wraparound with research-based treatment for children and adolescents.
0295	Pubmed	Comment on Levy's 'Forced to be free? Increasing patient autonomy by constraining it'.
0296	Pubmed	Informed consent and the use of gametes and embryos for research: a committee opinion.
0297	Pubmed	Who is the patient? Disclosure of information and consent in anesthesia and intensive care (informed consent).
0298	Pubmed	Risk management in radiology.
0299	Pubmed	Pearls and pitfalls: medico-legal considerations for sinus surgery.
0300	Pubmed	Prognostic value of sentinel lymph node biopsy compared with that of Breslow thickness: implications for informed consent in patients with invasive melanoma.
0301	Pubmed	Informed consent: essential legal and ethical principles for nurses.
0302	Pubmed	Stakeholder views on returning research results.
0303	Pubmed	Risk, respect for persons, and informed consent in comparative effectiveness research.
0304	Pubmed	The weird divergence of ethics and regulation with regard to informed consent.
0305	Pubmed	Informed consent is not the major ethical issue in clinical research.
0307	Pubmed	An opportunity to improve informed consent and shared decision making: the role of the ACS NSQIP Surgical Risk Calculator in oncology.
0308	Pubmed	Informed consent: what the patient heard.
0309	Pubmed	The ethics of clinical research in low- and middle-income countries.
0310	Pubmed	Legal process, litigation, and judicial decisions.

0311	Pubmed	Nudging in context: response to open peer commentaries on "nudging and informed consent".
0312	Pubmed	ACOG CommitteeOpinion No. 578: Elective surgery and patient choice.
0313	Pubmed	Does patient-centered care mean that informed consent is necessary for clinical performance measures?
0314	Pubmed	Shared decision making and informed consent for hysterectomy.
0315	Pubmed	And there we go again: the ethics of placebo-controlled RCT in case of catastrophic illness.
0316	Pubmed	Reply to letter to the editor: "are there moral obligations to cosmetic dermatology patients beyond informed consent?".
0317	Pubmed	Comments on: "are there moral obligations to cosmetic dermatology patients beyond informed consent?".
0318	Pubmed	Broad versus blanket consent for research with human biological samples.
0319	Pubmed	Mind the gap: are NHS trusts falling short of recommended standards for consent to autopsy?
0320	Pubmed	Parental permission and child assent in research on children.
0321	Pubmed	Ethical considerations in deep brain stimulation for psychiatric illness.
0322	Pubmed	Decision aids for breast cancer chemoprevention.
0323	Pubmed	Systematic review and meta-analysis of audio-visual information aids for informed consent for invasive healthcare procedures in clinical practice.
0324	Pubmed	Evolution of biomedical research during combat operations.
0325	Pubmed	Doing no harm and getting it right: guidelines for ethical research with immigrant communities.
0326	Pubmed	Waiver of informed consent in pediatric resuscitation research: a systematic review.
0327	Pubmed	Informed consent, the value of trust, and hedons.
0328	Pubmed	Moral challenges with surgical treatment of type 2 diabetes.
0329	Pubmed	Challenges in biobank governance in Sub-Saharan Africa.
0330	Pubmed	Ethical issues in research involving minority populations: the process and outcomes of protocol review by the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, Thailand.
0331	Pubmed	Experimental human exposure to air pollutants is essential to understand adverse health effects.
0332	Pubmed	International standards on informed patient consent are available.
0333	Pubmed	Research methodologies in informed consent studies involving surgical and invasive procedures: time to re-examine?
0334	Pubmed	Ethical considerations in consenting critically ill patients for bedside clinical care and research.
0335	Pubmed	Potential harms of computed tomography: the role of informed consent.
0336	Pubmed	Informed consent.
0337	Pubmed	Audit of the informed consent process as a part of a clinical research quality assurance program.
0338	Pubmed	Points to consider for informed consent for genome/exome sequencing.
0339	Pubmed	Laws relating to informed consent in clinical trials.

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0341	Pubmed	When should women be recruited to intrapartum research projects? A retrospective review.
0342	Pubmed	Patient information ahead of thyroid surgery. Guidelines of the French Society of Oto-Rhino-Laryngology and Head and Neck Surgery (SFORL).
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0345	Pubmed	Knowledge of state-level abortion laws and regulations among reproductive health care providers.
0346	Pubmed	The standard of care and conflicts at the end of life in critical care: lessons from medical-legal crossroads and the role of a quasi-judicial tribunal in decision-making.
0347	Pubmed	Re: is 'informed consent' a deceptive notion with negligible protection value for doctors?
0348	Pubmed	Response to re: is 'informed consent' a deceptive notion with negligible protection value for doctors?
0349	Pubmed	Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials.
0350	Pubmed	Management of bloodless surgery in a trauma setting. Balancing patient wishes with safety.
0351	Pubmed	Social media and community engagement in trials using exception from informed consent.
0352	Pubmed	Informed consent and shared decision-making in cases of futility.
0353	Pubmed	Informed consent in Italian Intensive Care Units: a moral tenet or just a formal legal requirement?
0354	Pubmed	Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures.
0355	Pubmed	Reflecting on earlier experiences with unsolicited findings: points to consider for next-generation sequencing and informed consent in diagnostics.
0356	Pubmed	Let's get the best quality research we can": public awareness and acceptance of consent to use existing data in health research: a systematic review and qualitative study.
0358	Pubmed	Basic principles for conducting human research in orthopaedic medicine.
0359	Pubmed	Intensive care unit research and informed consent: still a conundrum.
0360	Pubmed	Social work in a digital age: ethical and risk management challenges.
0361	Pubmed	Informed consent for blood transfusion and the Joint Commission: the authors' reply.
0362	Pubmed	Obtaining informed consent from a 45-year-old woman with dissociative identity disorder.
0363	Pubmed	There are (STILL) no coercive offers.
0364	Pubmed	Legal aspects of administrating antipsychotic medications to jail and prison inmates.
0365	Pubmed	Ethical and regulatory guidelines in clinical trials of xenocorneal transplantation in Korea; the Korean xenocorneal transplantation consensus statement.
0366	Pubmed	Researching the vulnerables: issues of consent and ethical approval.
0367	Pubmed	Systematic review and metasummary of attitudes toward research in emergency medical conditions.
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0369	Pubmed	Nudging" and informed consent revisited: why "nudging" fails in the clinical context.

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0373	Pubmed	Informed consent in palliative care clinical trials: challenging but possible.
0374	Pubmed	Bariatric surgery for obese children and adolescents: a review of the moral challenges.
0375	Pubmed	Authors' reply: Comment on authors' reply: Patients' perception of risk: informed choice in prenatal testing for foetal aneuploidy.
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0377	Pubmed	Informed consent for imaging studies.
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0380	Pubmed	Informed consent and SUPPORT.
0381	Pubmed	Consent to eventual treatment in the intensive care unit expressed within the consent form for elective anaesthesia and surgery.
0382	Pubmed	Primary care provider reflections on common themes from special issue on ethical quandaries when delivering integrated primary care.
0383	Pubmed	Patient and provider relationships: consent, confidentiality, and managing mistakes in integrated primary care settings.
0384	Pubmed	Navigating the legal and ethical foundations of informed consent and confidentiality in integrated primary care.
0385	Pubmed	Medicolegal issues surrounding devices and mesh for surgical treatment of prolapse and incontinence.
0386	Pubmed	Consideration of the gestational carrier: a committee opinion.
0387	Pubmed	Health outcomes among non-Caucasian living kidney donors: knowns and unknowns.
0388	Pubmed	The legal authority of mature minors to consent to general medical treatment.
0389	Pubmed	Optimal global value of information trials: better aligning manufacturer and decision maker interests and enabling feasible risk sharing.
0390	Pubmed	Health-care professionals' knowledge, attitudes and behaviours relating to patient capacity to consent to treatment: an integrative review.
0391	Pubmed	Informed consent, big data, and the oxymoron of research that is not research.
0392	Pubmed	Data citizenship and informed consent.
0393	Pubmed	Can informed consent go too far? Balancing consent and public benefit in research.
0394	Pubmed	Informed consent and research subject understanding of clinical trials.
0395	Pubmed	Incapacity in Canada: review of laws and policies on research involving decisionallyÂ impaired adults.
0396	Pubmed	Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis.
0397	Pubmed	Chronic back pain with possible prescription opioid misuse.
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0399	Pubmed	Evolving approaches to the ethical management of genomic data.
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0402	Pubmed	Bioethics in popular science: evaluating the media impact of The Immortal Life of Henrietta Lacks on the biobank debate.
0403	Pubmed	Common causes of injury and legal action in laser surgery.
0404	Pubmed	Medico-legal issues in cardiology.
0405	Pubmed	An ethical analysis of proxy and waiver of consent in critical care research.
0406	Pubmed	Hematopoietic stem cell donation.
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0409	Pubmed	Informed consent for special procedures: electroconvulsive therapy and psychosurgery.
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0411	Pubmed	Evidence-based information on mammography screening in Austria--reality or more pie in the sky?
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0415	Pubmed	HIV testing and care in Burkina Faso, Kenya, Malawi and Uganda: ethics on the ground.
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0418	Pubmed	Informed consent for whole-genome sequencing studies in the clinical setting. Proposed recommendations on essential content and process.
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0422	Pubmed	IRB decision-making with imperfect knowledge: a framework for evidence-based research ethics review.
0423	Pubmed	Clinical evidence versus patients' perception of coronary revascularization.
0424	Pubmed	Problems with the consensus definition of the therapeutic misconception.
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0428	Pubmed	Electroconvulsive therapy: the importance of informed consent and 'placebo literacy'.

0429	Pubmed	Review of national research ethics regulations and guidelines in Middle Eastern Arab countries.
0430	Pubmed	Re-visiting consent for clinical research on acute myocardial infarction and other emergent conditions.
0431	Pubmed	Informed consent in 2012.
0432	Pubmed	Retention and research use of residual newborn screening bloodspots.
0433	Pubmed	Electroconvulsive therapy (ECT) from the patient's perspective.
0434	Pubmed	Effective dose of PET/CT in informed consent forms.
0435	Pubmed	Communicating the risk of side effects to rheumatic patients.
0436	Pubmed	Patients' perception of risk: informed choice in prenatal testing for foetal aneuploidy.
0437	Pubmed	Vaginal birth after cesarean delivery: comparison of ACOG practice bulletin with other national guidelines.
0438	Pubmed	Ethical aspects of clinical research with minors.
0439	Pubmed	The professional responsibility model of obstetric ethics and caesarean delivery.
0440	Pubmed	Ethical issues in neonatal and pediatric clinical trials.
0441	Pubmed	Problems of capacity, consent and confidentiality.
0442	Pubmed	Therapeutic management of uterine fibroid tumors: updated French guidelines.
0443	Pubmed	Patient safety in plastic surgery.
0444	Pubmed	Ethical considerations in dermatologic photography.
0445	Pubmed	Preimplantation genetic diagnosis: a systematic review of litigation in the face of new technology.
0446	Pubmed	Off-label medication use.
0447	Pubmed	Ethics in sports medicine.
0448	Pubmed	Reconciling informed consent with prescription drug requirements.
0449	Pubmed	Terminal cancer patients' informed consent for palliative care admission and their quality of life.
0450	Pubmed	Ethical issues in umbilical cord blood banking: a comparative analysis of documents from national and international institutions.
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0453	Pubmed	The pharmacists' role in patient-provider pain management treatment agreements.
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0455	Pubmed	Therapy in virtual environments--clinical and ethical issues.
0456	Pubmed	Informed deferral: a moral requirement for entry into the hepatitis C virus treatment warehouse.
0457	Pubmed	The French bioethics debate: norms, values and practices.

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0460	Pubmed	Improving the informed consent process for research subjects with low literacy: a systematic review.
0461	Pubmed	Informed consent in clinical practice and literature overview.
0462	Pubmed	Psychosocial and socioeconomic issues facing the living kidney donor.
0463	Pubmed	Risks and outcomes of living donation.
0464	Pubmed	Informed consent and AUC: bare it all....
0465	Pubmed	Cardiac imaging modalities with ionizing radiation: the role of informed consent.
0466	Pubmed	Should mortality be informed for cesarean hysterectomy for placenta accreta?
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0485	Pubmed	Informed consent in opioid therapy: a potential obligation and opportunity.
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0488	Pubmed	Bioethical considerations in developing a biorepository for the Pneumonia Etiology Research for Child Health project.
0489	Pubmed	Saying things the "right" way: avoiding "nocebo" effects and providing full informed consent.
0490	Pubmed	Nocebo and informed consent in the internet era.
0491	Pubmed	Shared decision making through informed consent in chiropractic management of low back pain.
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0506	Pubmed	Multimedia patient education to assist the informed consent process for knee arthroscopy (Re: ANZ J. Surg. 2011; 81: 176â€“80).
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0514	Pubmed	What rhinologists and allergists should know about the medico-legal implications of corticosteroid use: a review of the literature.
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0534	Pubmed	A systematic review of early postpartum medroxyprogesterone receipt and early breastfeeding cessation: evaluating the methodological rigor of the evidence.
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0550	Pubmed	The bioethics of separating conjoined twins in plastic surgery.
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0563	Pubmed	What do "triage" and "informed consent" really mean in practice?
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0619	Pubmed	Stop, look, and listen: revisiting the involvement of children and adolescents in genomic research.
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0630	Pubmed	Ethical issues surrounding fertility preservation in cancer patients.
0631	Pubmed	Covert administration of medication to older adults: a review of the literature and published studies.
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0634	Pubmed	RE: faculty of radiation oncology endorsed guidelines for informed consent: risk description.
0635	Pubmed	Communication between patients and providers and informed decision making.
0636	Pubmed	Ethics in systematic reviews.
0637	Pubmed	An approach to selected legal issues: confidentiality, mandatory reporting, abuse and neglect, informed consent, capacity decisions, boundary issues, and malpractice claims.
0638	Pubmed	Ethical guidelines in psychiatric research.
0639	Pubmed	Informed consent for interventions in stable coronary artery disease: problems, etiologies, and solutions.
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0644	Pubmed	Anesthesia for the patient with dementia.
0645	Pubmed	Human tissue ownership and use in research: what laboratorians and researchers should know.
0646	Pubmed	Survey cover pages: to take or not to take.
0647	Pubmed	Screening and brief intervention for substance misuse among patients with traumatic brain injury.
0648	Pubmed	Ethical issues in penile transplantation.
0649	Pubmed	Candidate hepatitis C vaccine trials and people who inject drugs: challenges and opportunities.
0650	Pubmed	Ethical aspects on rare diseases.
0651	Pubmed	Improving the quality of informed consent: it is not all about the risks.
0652	Pubmed	Oncofertility and informed consent: addressing beliefs, values, and future decision making.
0653	Pubmed	Informed consent needs information.
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1273	Lancet (full text)	Regulatory obstacles affecting ecological studies in the ICU
1274	Lancet (full text)	Mental health interventions in schools in high-income countries
1275	Lancet (full text)	Emergency preservation and resuscitation: a Lazarus trial?
1276	Lancet (full text)	A step forward on data sharing and consent
1277	Lancet (full text)	Chromosomal microarray analysis—a routine clinical genetic test for patients with schizophrenia
1278	Lancet (full text)	EANO guideline for the diagnosis and treatment of anaplastic gliomas and glioblastoma
1279	Lancet (full text)	The use of bedaquiline in regimens to treat drug-resistant and drug-susceptible tuberculosis: a perspective from tuberculosis-affected communities
1280	Lancet (full text)	HEAT-PPCI sheds light on consent in pragmatic trials
1281	Lancet (full text)	A needed Convention against trafficking in human organs
1282	Lancet (full text)	The epidemic of chronic kidney disease in Central America
1283	Lancet (full text)	Research into a functional cure for HIV in neonates: the need for ethical foresight
1284	Lancet (full text)	Facial transplantation: the first 9 years
1285	Lancet (full text)	Cancer research in India: national priorities, global results
1286	Lancet (full text)	Ensuring privacy in the study of pathogen genetics
1287	Lancet (full text)	Embolic strokes of undetermined source: the case for a new clinical construct
1288	Lancet (full text)	Current concepts and clinical applications of stroke genetics
1289	Lancet (full text)	A risk-management approach for effective integration of biomarkers in clinical trials: perspectives of an NCI, NCRI, and EORTC working group
1290	Lancet (full text)	UK funders' framework for health-related findings in research
1291	Lancet (full text)	Strengthening the Reporting of Molecular Epidemiology for Infectious Diseases (STROME-ID): an extension of the STROBE statement

1292	Lancet (full text)	Health-related quality of life in small-cell lung cancer: a systematic review on reporting of methods and clinical issues in randomised controlled trials
1293	Lancet (full text)	Patient safety must be a priority in all aspects of care
1294	Lancet (full text)	Increasing value and reducing waste in biomedical research regulation and management
1295	Lancet (full text)	Perinatally acquired HIV infection in adolescents from sub-Saharan Africa: a review of emerging challenges
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1297	Lancet (full text)	Sex, health, and society: ensuring an integrated response
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1301	Lancet (full text)	Secure use of individual patient data from clinical trials
1302	Lancet (full text)	The right to participate in high-risk research
1303	Lancet (full text)	Can we predict diabetes remission after weight-loss surgery?
1304	Lancet (full text)	Point-of-care testing for community-acquired pneumonia
1305	Lancet (full text)	Vertebral compression fracture after stereotactic body radiotherapy for spinal metastases
1306	Lancet (full text)	Universal health coverage in Turkey: enhancement of equity
1307	Lancet (full text)	Streamlining of prehospital stroke management: the golden hour
1308	Lancet (full text)	Concepts of blood transfusion in adults
1309	Lancet (full text)	Blood management: transfusion medicine comes of age
1310	Lancet (full text)	Expression of concern—Effect of tesofensine on bodyweight loss, body composition, and quality of life in obese patients: a randomised, double-blind, placebo-controlled trial
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1322	Lancet (full text)	Disorders of consciousness: responding to requests for novel diagnostic and therapeutic interventions
1323	Lancet (full text)	A call to action for comprehensive HIV services for men who have sex with men
1324	Lancet (full text)	Use of human rights to meet the unmet need for family planning
1325	Lancet (full text)	Sham neurosurgical procedures in clinical trials for neurodegenerative diseases: scientific and ethical considerations
1326	Lancet (full text)	Androgen insensitivity syndrome
1327	Lancet (full text)	Engineered whole organs and complex tissues
1328	Lancet (full text)	Moral science and the Presidential Commission for the Study of Bioethical Issues
1329	Lancet (full text)	Nocebo side-effects in cancer treatment
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1335	Lancet (full text)	The tubal hypothesis of ovarian cancer: caution needed
1336	Lancet (full text)	The rights of people with mental disorders: WPA perspective
1337	Lancet (full text)	Truth telling in clinical practice
1338	Lancet (full text)	Ethical behaviour in clinical research—a lesson from the past
1339	Lancet (full text)	Telemedicine and remote management of patients with heart failure
1340	Lancet (full text)	Systemic therapy in the management of metastatic or locally recurrent adenoid cystic carcinoma of the salivary glands: a systematic review
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1346	Lancet (full text)	School: a place for children to learn their HIV status?
1347	Lancet (full text)	Fertility-sparing surgery in patients with cervical cancer

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1402	Lancet (full text)	Outcomes and endpoints in cancer trials: bridging the divide
1403	Lancet (full text)	Sexual and reproductive health in cystic fibrosis: a life-course perspective

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1410	Lancet (full text)	Disrespect and abuse of women in childbirth: challenging the global quality and accountability agendas
1411	Lancet (full text)	Cardiovascular outcome trials of glucose-lowering drugs or strategies in type 2 diabetes
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1452	Lancet (full text)	Strengthening the Reporting of Observational Studies in Epidemiology for Newborn Infection (STROBE-NI): an extension of the STROBE statement for neonatal infection research
1453	Lancet (full text)	Interpretation of the evidence for the efficacy and safety of statin therapy
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1457	Lancet (full text)	Diabetes in rural Africa: what can Kenya show us?
1458	Lancet (full text)	Serving transgender people: clinical care considerations and service delivery models in transgender health
1459	Lancet (full text)	New ISSCR guidelines: clinical translation of stem cell research

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1461	Lancet (full text)	Ethical issues of clinical trials in paediatric oncology from 2003 to 2013: a systematic review
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1464	Lancet (full text)	Recent advances in the pharmacological management of hypercholesterolaemia
1465	Lancet (full text)	Non-insulin drugs to treat hyperglycaemia in type 1 diabetes mellitus
1466	Lancet (full text)	Sharing clinical trial data: a proposal from the International Committee of Medical Journal Editors
1467	Lancet (full text)	BMPR2 revisited: are bigger data better?
1468	Lancet (full text)	Mental distress and potentially modifiable social factors in post-conflict Sri Lanka
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1472	Lancet (full text)	A risk management approach for imaging biomarker-driven clinical trials in oncology
1473	Lancet (full text)	Classification of treatment-related mortality in children with cancer: a systematic assessment
1474	Lancet (full text)	Distinguishing activity from progress
1475	Lancet (full text)	Will Ebola change the game? Ten essential reforms before the next pandemic. The report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola
1476	Lancet (full text)	Offline: 13/11—The flames of war
1477	Lancet (full text)	The Ebola Vaccine Team B: a model for promoting the rapid development of medical countermeasures for emerging infectious disease threats
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1479	Lancet (full text)	Prevention of sporadic Alzheimer's disease: lessons learned from clinical trials and future directions
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1485	Lancet (full text)	Genetics in medicine—progress and pitfalls
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1790	NEJM (full text. Perspective, commentary, review)	200th Anniversary Article: Doctors, Patients, and Lawyers — Two Centuries of Health Law
1791	NEJM (full text. Perspective, commentary, review)	200th Anniversary Article: Patients and Doctors — The Evolution of a Relationship
1792	NEJM (full text. Perspective, commentary, review)	A Request for Abortion

1793	NEJM (full text. Perspective, commentary, review)	Assisted Reproduction — Canada's Supreme Court and the “Global Baby”
1794	NEJM (full text. Perspective, commentary, review)	Becoming a Physician: Breaking the Silence of the Switch — Increasing Transparency about Trainee Participation in Surgery
1795	NEJM (full text. Perspective, commentary, review)	Bending the Cost Curve in Cancer Care
1796	NEJM (full text. Perspective, commentary, review)	Beyond Repeal — A Republican Proposal for Health Care Reform
1797	NEJM (full text. Perspective, commentary, review)	Care of the Adult Patient after Sexual Assault
1798	NEJM (full text. Perspective, commentary, review)	Chronic Pain, Addiction, and Zohydro
1799	NEJM (full text. Perspective, commentary, review)	Closing the Mortality Gap — Mental Illness and Medical Care
1800	NEJM (full text. Perspective, commentary, review)	Clostridium difficile Infection
1801	NEJM (full text. Perspective, commentary, review)	Collaboration in Response to Disaster — Typhoon Yolanda and an Integrative Model
1802	NEJM (full text. Perspective, commentary, review)	Cost Consciousness in Patient Care — What Is Medical Education's Responsibility?
1803	NEJM (full text. Perspective, commentary, review)	Court-Ordered Care — A Complication of Pregnancy to Avoid
1804	NEJM (full text. Perspective, commentary, review)	Cryopreservation of Oocytes

1805	NEJM (full text. Perspective, commentary, review)	Curating the Way to Better Determinants of Genetic Risk
1806	NEJM (full text. Perspective, commentary, review)	Current Concepts: Myocardial Infarction Due to Percutaneous Coronary Intervention
1807	NEJM (full text. Perspective, commentary, review)	Current Concepts: Percutaneous Coronary Interventions without On-Site Cardiac Surgical Backup
1808	NEJM (full text. Perspective, commentary, review)	Cutting Family Planning in Texas
1809	NEJM (full text. Perspective, commentary, review)	Dealing with Racist Patients
1810	NEJM (full text. Perspective, commentary, review)	Decriminalizing Mental Illness — The Miami Model
1811	NEJM (full text. Perspective, commentary, review)	Don't Learn on Me — Are Teaching Hospitals Patient-Centered?
1812	NEJM (full text. Perspective, commentary, review)	Drug Therapy: Oral Phosphate Binders in Patients with Kidney Failure
1813	NEJM (full text. Perspective, commentary, review)	Ebola 2014 — New Challenges, New Global Response and Responsibility
1814	NEJM (full text. Perspective, commentary, review)	ECG — Still the Best for Selecting Patients for CRT
1815	NEJM (full text. Perspective, commentary, review)	Electroconvulsive Therapy in the Spotlight
1816	NEJM (full text. Perspective, commentary, review)	Epidural Analgesia for Labor and Delivery

1817	NEJM (full text. Perspective, commentary, review)	Ethical Considerations in Studying Drug Safety — The Institute of Medicine Report
1818	NEJM (full text. Perspective, commentary, review)	Evaluating Rivaroxaban for Nonvalvular Atrial Fibrillation — Regulatory Considerations
1819	NEJM (full text. Perspective, commentary, review)	Evidence, Preferences, Recommendations — Finding the Right Balance in Patient Care
1820	NEJM (full text. Perspective, commentary, review)	First-in-Human Clinical Trials — What We Can Learn from Tragic Failures
1821	NEJM (full text. Perspective, commentary, review)	Forbidden and Permitted Statements about Medications — Loosening the Rules
1822	NEJM (full text. Perspective, commentary, review)	Force-Feeding, Autonomy, and the Public Interest
1823	NEJM (full text. Perspective, commentary, review)	Groin Hernias in Adults
1824	NEJM (full text. Perspective, commentary, review)	Guantanamo Bay: A Medical Ethics–free Zone?
1825	NEJM (full text. Perspective, commentary, review)	Hand Eczema
1826	NEJM (full text. Perspective, commentary, review)	Hemicraniectomy — To Halve or Halve Not
1827	NEJM (full text. Perspective, commentary, review)	History of Medicine: “An Uncommonly Silly Law” — Contraception and Disparities in the United States
1828	NEJM (full text. Perspective, commentary, review)	History of Medicine: The Challenges of Challenge Experiments

1829	NEJM (full text. Perspective, commentary, review)	History of Medicine: The DNR Order after 40 Years
1830	NEJM (full text. Perspective, commentary, review)	Hoarding Disorder
1831	NEJM (full text. Perspective, commentary, review)	How AIDS Invented Global Health
1832	NEJM (full text. Perspective, commentary, review)	Improving the Allocation System for Deceased-Donor Kidneys
1833	NEJM (full text. Perspective, commentary, review)	In Support of SUPPORT — A View from the NIH
1834	NEJM (full text. Perspective, commentary, review)	Incidentalomas in Genomics and Radiology
1835	NEJM (full text. Perspective, commentary, review)	International Health Care Systems: Transforming Turkey's Health System — Lessons for Universal Coverage
1836	NEJM (full text. Perspective, commentary, review)	Intramuscular versus Intravenous Benzodiazepines for Prehospital Treatment of Status Epilepticus
1837	NEJM (full text. Perspective, commentary, review)	Intravenous Thrombolytic Therapy for Acute Ischemic Stroke
1838	NEJM (full text. Perspective, commentary, review)	Justice for Injured Research Subjects
1839	NEJM (full text. Perspective, commentary, review)	Leaping without Looking — Duty Hours, Autonomy, and the Risks of Research and Practice
1840	NEJM (full text. Perspective, commentary, review)	Legislative Interference with the Patient–Physician Relationship

1841	NEJM (full text. Perspective, commentary, review)	Life or Death for the Dead-Donor Rule?
1842	NEJM (full text. Perspective, commentary, review)	Medicaid Policy on Sterilization — Anachronistic or Still Relevant?
1843	NEJM (full text. Perspective, commentary, review)	Medical Malpractice in the Military
1844	NEJM (full text. Perspective, commentary, review)	Medical Malpractice Liability in the Age of Electronic Health Records
1845	NEJM (full text. Perspective, commentary, review)	Medical Marijuana and the Law
1846	NEJM (full text. Perspective, commentary, review)	Medicare's Chronic Care Management Payment — Payment Reform for Primary Care
1847	NEJM (full text. Perspective, commentary, review)	Moving Boundaries — The Nightingale Twins and Transplantation Science
1848	NEJM (full text. Perspective, commentary, review)	Multiple-System Atrophy
1849	NEJM (full text. Perspective, commentary, review)	N-of-1 Policymaking — Tragedy, Trade-offs, and the Demise of Morcellation
1850	NEJM (full text. Perspective, commentary, review)	Neonatal Abstinence Syndrome
1851	NEJM (full text. Perspective, commentary, review)	New FDA Breakthrough-Drug Category — Implications for Patients
1852	NEJM (full text. Perspective, commentary, review)	NIH Policy on Single-IRB Review — A New Era in Multicenter Studies

1853	NEJM (full text. Perspective, commentary, review)	No Appointment Necessary? Ethical Challenges in Treating Friends and Family
1854	NEJM (full text. Perspective, commentary, review)	OHRP and Standard-of-Care Research
1855	NEJM (full text. Perspective, commentary, review)	Opioid Prescribing for Chronic Pain — Achieving the Right Balance through Education
1856	NEJM (full text. Perspective, commentary, review)	Oxygen-Saturation Targets in Preterm Infants
1857	NEJM (full text. Perspective, commentary, review)	Pancreatic Adenocarcinoma
1858	NEJM (full text. Perspective, commentary, review)	Physicians and the (Woman's) Body Politic
1859	NEJM (full text. Perspective, commentary, review)	Placebo Effects in Medicine
1860	NEJM (full text. Perspective, commentary, review)	Placebo-Controlled Trials in Osteoporosis — Proceeding with Caution
1861	NEJM (full text. Perspective, commentary, review)	Post-9/11 Torture at CIA “Black Sites” — Physicians and Lawyers Working Together
1862	NEJM (full text. Perspective, commentary, review)	Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs
1863	NEJM (full text. Perspective, commentary, review)	Putting Parity into Practice — Integrating Opioid-Use Disorder Treatment into the Hospital Setting
1864	NEJM (full text. Perspective, commentary, review)	Ranibizumab Therapy for Neovascular Age-Related Macular Degeneration

1865	NEJM (full text. Perspective, commentary, review)	Red Cells — Aging Gracefully in the Blood Bank
1866	NEJM (full text. Perspective, commentary, review)	Regulatory Action on Rosiglitazone by the U.S. Food and Drug Administration
1867	NEJM (full text. Perspective, commentary, review)	Removing Legal Barriers to High-Quality Care for HIV-Infected Patients
1868	NEJM (full text. Perspective, commentary, review)	Resurrection of a Stem-Cell Funding Barrier — Dickey–Wicker in Court
1869	NEJM (full text. Perspective, commentary, review)	Revisiting the Rosiglitazone Story — Lessons Learned
1870	NEJM (full text. Perspective, commentary, review)	Rural Health Care: Out of Sight, Out of Mind — Behavioral and Developmental Care for Rural Children
1871	NEJM (full text. Perspective, commentary, review)	Standard of Care — In Sickness and in Health and in Emergencies
1872	NEJM (full text. Perspective, commentary, review)	Studying “Secret Serums” — Toward Safe, Effective Ebola Treatments
1873	NEJM (full text. Perspective, commentary, review)	Tackling the Unknowns in HIV-Related Kidney Diseases
1874	NEJM (full text. Perspective, commentary, review)	Taxane-Based Chemotherapy for Node-Positive Breast Cancer — Take-Home Lessons
1875	NEJM (full text. Perspective, commentary, review)	The 21st Century Cures Act — Will It Take Us Back in Time?
1876	NEJM (full text. Perspective, commentary, review)	The Axes of Access — Improving Care for Patients with Disabilities

1877	NEJM (full text. Perspective, commentary, review)	The Changing Face of Clinical Trials: Lessons in Uncertainty and Humility — Clinical Trials Involving Hypertension
1878	NEJM (full text. Perspective, commentary, review)	The Concept of Risk in Comparative-Effectiveness Research
1879	NEJM (full text. Perspective, commentary, review)	The Dead-Donor Rule and the Future of Organ Donation
1880	NEJM (full text. Perspective, commentary, review)	The Ebola Emergency — Immediate Action, Ongoing Strategy
1881	NEJM (full text. Perspective, commentary, review)	The Ethics of Placebo in Studies with Fracture End Points in Osteoporosis
1882	NEJM (full text. Perspective, commentary, review)	The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples
1883	NEJM (full text. Perspective, commentary, review)	The Palliative Care Information Act in Real Life
1884	NEJM (full text. Perspective, commentary, review)	The Paradoxical Problem with Multiple-IRB Review
1885	NEJM (full text. Perspective, commentary, review)	The United States and Cuba — Turning Enemies into Partners for Health
1886	NEJM (full text. Perspective, commentary, review)	Transplanting Hepatitis C–Positive Kidneys
1887	NEJM (full text. Perspective, commentary, review)	Unanimity on Death with Dignity — Legalizing Physician-Assisted Dying in Canada
1888	NEJM (full text. Perspective, commentary, review)	Underestimating Medical Therapy for Coronary Disease . . . Again

1889	NEJM (full text. Perspective, commentary, review)	Undocumented Injustice? Medical Repatriation and the Ends of Health Care
1890	NEJM (full text. Perspective, commentary, review)	When Religious Freedom Clashes with Access to Care
1891	NEJM (full text. Perspective, commentary, review)	"Ethics and Clinical Research" — The 50th Anniversary of Beecher's Bombshell
1892	NEJM (full text. Perspective, commentary, review)	"If I Had Only Known" — On Choice and Uncertainty in the ICU
1893	NEJM (full text. Perspective, commentary, review)	23andMe and the FDA
1894	NEJM (full text. Perspective, commentary, review)	A Global, Neutral Platform for Sharing Trial Data
1895	NEJM (full text. Perspective, commentary, review)	A New Initiative on Precision Medicine
1896	NEJM (full text. Perspective, commentary, review)	Advantages of a Truly Open-Access Data-Sharing Model
1897	NEJM (full text. Perspective, commentary, review)	Assessing Participant-Centered Outcomes to Improve Clinical Research
1898	NEJM (full text. Perspective, commentary, review)	Brave New Genome
1899	NEJM (full text. Perspective, commentary, review)	Bringing the Common Rule into the 21st Century
1900	NEJM (full text. Perspective, commentary, review)	Cardiac Arrest and the Limitations of Clinical Trials

1901	NEJM (full text. Perspective, commentary, review)	Challenges to Data Monitoring Committees When Regulatory Authorities Intervene
1902	NEJM (full text. Perspective, commentary, review)	Clinical Implications of Genomic Discoveries in Lung Cancer
1903	NEJM (full text. Perspective, commentary, review)	Data Sharing at a Crossroads
1904	NEJM (full text. Perspective, commentary, review)	Developing the Nation's Biosimilars Program
1905	NEJM (full text. Perspective, commentary, review)	Diagnostic Clinical Genome and Exome Sequencing
1906	NEJM (full text. Perspective, commentary, review)	Disheartening Disparities
1907	NEJM (full text. Perspective, commentary, review)	Enduring and Emerging Challenges of Informed Consent
1908	NEJM (full text. Perspective, commentary, review)	FDA Regulation of Mobile Health Technologies
1909	NEJM (full text. Perspective, commentary, review)	Federal Research Regulations for the 21st Century
1910	NEJM (full text. Perspective, commentary, review)	Foreseeable Risks? Informed Consent for Studies within the Standard of Care
1911	NEJM (full text. Perspective, commentary, review)	Fostering Responsible Data Sharing through Standards
1912	NEJM (full text. Perspective, commentary, review)	From Patient to Patient — Sharing the Data from Clinical Trials

1913	NEJM (full text. Perspective, commentary, review)	From Trial to Target Populations — Calibrating Real-World Data
1914	NEJM (full text. Perspective, commentary, review)	Genomic Medicine: Genomic Medicine — An Updated Primer
1915	NEJM (full text. Perspective, commentary, review)	Genomic Medicine: Genomics and Perinatal Care
1916	Genomic Medicine: Genomics, Health Care, and Society	
1917	NEJM (full text. Perspective, commentary, review)	GINA, Genetic Discrimination, and Genomic Medicine
1918	NEJM (full text. Perspective, commentary, review)	Global Health: Natural Disasters, Armed Conflict, and Public Health
1919	NEJM (full text. Perspective, commentary, review)	History of Clinical Trials: Clinical Trials, Healthy Controls, and the Birth of the IRB
1920	NEJM (full text. Perspective, commentary, review)	Informed Consent and SUPPORT
1921	NEJM (full text. Perspective, commentary, review)	Informed Consent and the First Amendment
1922	NEJM (full text. Perspective, commentary, review)	Informed Consent for Pragmatic Trials — The Integrated Consent Model
1923	NEJM (full text. Perspective, commentary, review)	Informed Consent, Comparative Effectiveness, and Learning Health Care
1924	NEJM (full text. Perspective, commentary, review)	Looking beyond Translation — Integrating Clinical Research with Medical Practice
1925	NEJM (full text. Perspective,	Lost in Translation

	commentary, review)	
1926	NEJM (full text. Perspective, commentary, review)	Missing Data
1927	NEJM (full text. Perspective, commentary, review)	New Data on Prostate-Cancer Mortality after PSA Screening
1928	NEJM (full text. Perspective, commentary, review)	Overbilling and Informed Financial Consent — A Contractual Solution
1929	NEJM (full text. Perspective, commentary, review)	Participant-Level Data and the New Frontier in Trial Transparency
1930	NEJM (full text. Perspective, commentary, review)	Patients in Context — EHR Capture of Social and Behavioral Determinants of Health
1931	NEJM (full text. Perspective, commentary, review)	Pharmaceutical Marketing and the New Social Media
1932	NEJM (full text. Perspective, commentary, review)	Preparing for Responsible Sharing of Clinical Trial Data
1933	NEJM (full text. Perspective, commentary, review)	Prescriptions, Privacy, and the First Amendment
1934	NEJM (full text. Perspective, commentary, review)	Protection or Harm? Suppressing Substance-Use Data
1935	NEJM (full text. Perspective, commentary, review)	Randomized Clinical Trials — Removing Unnecessary Obstacles
1936	NEJM (full text. Perspective, commentary, review)	Realizing Genomic Medicine
1937	NEJM (full text. Perspective,	Reform of Clinical Research Regulations, Finally

	commentary, review)	
1938	NEJM (full text. Perspective, commentary, review)	Reforming the Regulations Governing Research with Human Subjects
1939	NEJM (full text. Perspective, commentary, review)	Restrictions on the Use of Prescribing Data for Drug Promotion
1940	NEJM (full text. Perspective, commentary, review)	Risk, Consent, and SUPPORT
1941	NEJM (full text. Perspective, commentary, review)	Risks (and Benefits) in Comparative Effectiveness Research Trials
1942	NEJM (full text. Perspective, commentary, review)	Safeguarding Children — Pediatric Research on Medical Countermeasures
1943	NEJM (full text. Perspective, commentary, review)	Seamless Oncology-Drug Development
1944	NEJM (full text. Perspective, commentary, review)	Sham Controls in Medical Device Trials
1945	NEJM (full text. Perspective, commentary, review)	Sharing Clinical Trial Data — A Proposal from the International Committee of Medical Journal Editors
1946	NEJM (full text. Perspective, commentary, review)	Sharing Individual Patient Data from Clinical Trials
1947	NEJM (full text. Perspective, commentary, review)	Sleep Deprivation, Elective Surgical Procedures, and Informed Consent
1948	NEJM (full text. Perspective, commentary, review)	Support for SUPPORT
1949	NEJM (full text. Perspective,	The Calculus of National Medical Research Policy — The United States versus Asia

	commentary, review)	
1950	NEJM (full text. Perspective, commentary, review)	The Changing Face of Clinical Trials: An FDA Viewpoint on Unique Considerations for Medical-Device Clinical Trials
1951	NEJM (full text. Perspective, commentary, review)	The Changing Face of Clinical Trials: Informed Consent
1952	NEJM (full text. Perspective, commentary, review)	The Changing Face of Clinical Trials: Integrating Randomized Comparative Effectiveness Research with Patient Care
1953	NEJM (full text. Perspective, commentary, review)	The Changing Face of Clinical Trials: Pragmatic Trials
1954	NEJM (full text. Perspective, commentary, review)	The Common Rule, Updated
1955	NEJM (full text. Perspective, commentary, review)	The Paternalism Preference — Choosing Unshared Decision Making
1956	NEJM (full text. Perspective, commentary, review)	The Power Proxy
1957	NEJM (full text. Perspective, commentary, review)	The Randomized Registry Trial — The Next Disruptive Technology in Clinical Research?
1958	NEJM (full text. Perspective, commentary, review)	The Yale Open Data Access (YODA) Project — A Mechanism for Data Sharing
1959	NEJM (full text. Perspective, commentary, review)	Time for a Patient-Driven Health Information Economy?
1960	NEJM (full text. Perspective, commentary, review)	Time to Treatment in Patients with STEMI
1961	NEJM (full text. Perspective,	Toward a Shared Vision for Cancer Genomic Data

	commentary, review)	
1962	NEJM (full text. Perspective, commentary, review)	Transforming Evidence Generation to Support Health and Health Care Decisions
1963	NEJM (full text. Perspective, commentary, review)	Transparency for Clinical Trials — The TEST Act
1964	NEJM (full text. Perspective, commentary, review)	Vindication for SUPPORT