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| 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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Contents

[Summary 3](#_Toc10812425)

[List of abbreviations 3](#_Toc10812426)

[Introduction 4](#_Toc10812427)

[Rapid review 5](#_Toc10812428)

[Methods 5](#_Toc10812429)

[Overview 7](#_Toc10812430)

[Rationale 9](#_Toc10812431)

[Informed consent process and scope 11](#_Toc10812432)

[Data re-use 16](#_Toc10812433)

[Data linkage 17](#_Toc10812434)

[Participant control 17](#_Toc10812435)

[Survey 18](#_Toc10812436)

[Methods 18](#_Toc10812437)

[Overview 19](#_Toc10812438)

[Available guidance for informed consent 19](#_Toc10812439)

[Content of existing informed consent forms 20](#_Toc10812440)

[Scope of consent 22](#_Toc10812441)

[Informed consent processes 23](#_Toc10812442)

[Collaboration with industry 24](#_Toc10812443)

[Future challenges and developments 25](#_Toc10812444)

[Discussion 25](#_Toc10812445)

[Conclusion 27](#_Toc10812446)

[References 27](#_Toc10812447)

[Appendices 30](#_Toc10812448)

[Survey 30](#_Toc10812449)

[Search strategy 45](#_Toc10812450)

[List of included studies 46](#_Toc10812451)

[Full list of articles before first scan 61](#_Toc10812452)

**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.

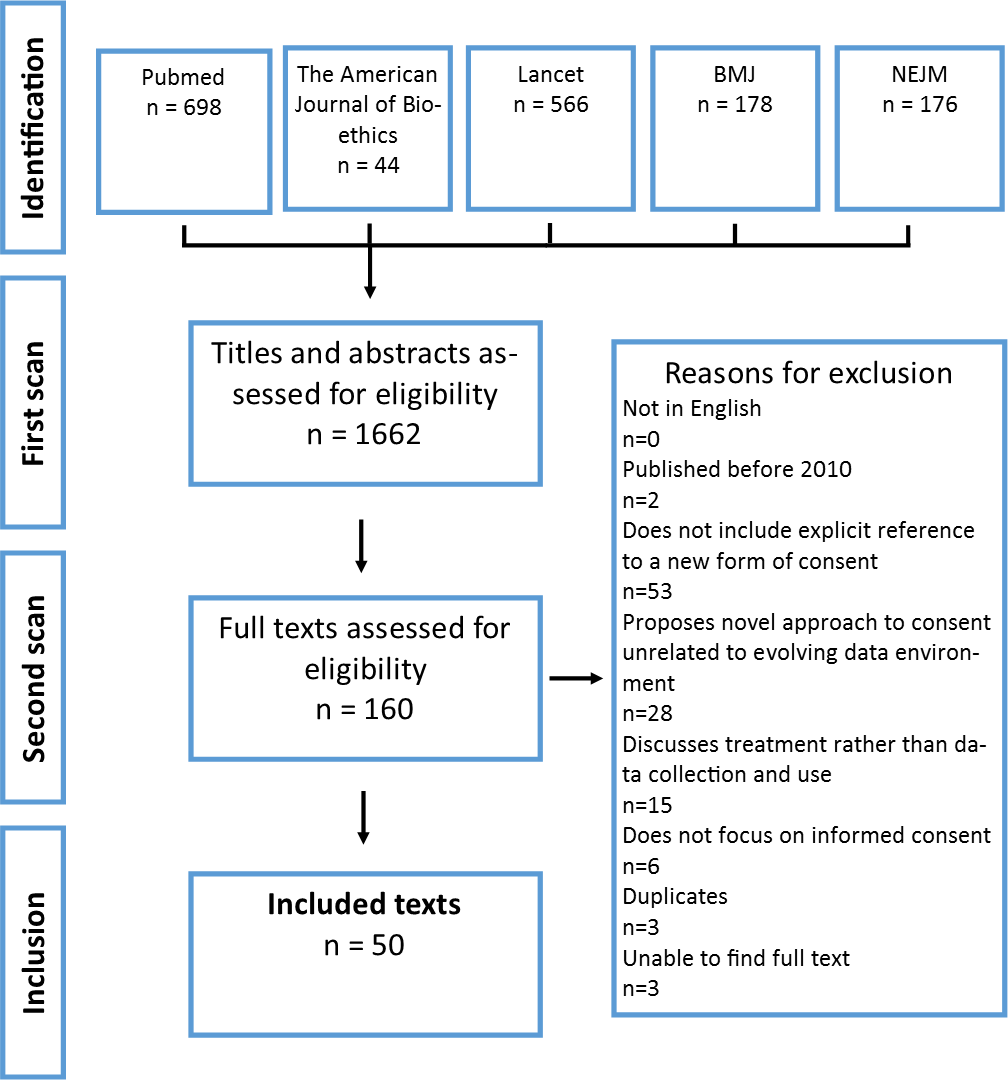


Figure 1: PRISMA flow chart

## 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.

Restricted use of data

Open use of data

Low participant control

High participant control

Dynamic consent

Ongoing consent

Partnership model

Tiered/staggered consent

Consent waived

Delayed/

retrospective consent

Universal consent

Broad consent

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) |
| **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) |
|  |  |  |

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

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.



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?



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.*

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**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) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**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)

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*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)

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**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

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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:

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**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) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**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.

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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.

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

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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.

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**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 |
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| 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. AJOB Empirical Bioethics 7, 92–105. doi:10.1080/23294515.2016.1156188 | Nancy Kass - bioethics |
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List of articles excluded after second scan and reasons for exclusion

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| **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 consent, or administration of consent form) | Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, McCormick JB. |
| 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](http://www.bioethics.net/articles/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 consent, or administration of consent form) | Ploug T, Holm S |
| 1706 | [NUDGING AND INFORMED CONSENT](http://www.bioethics.net/articles/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](http://www.bioethics.net/articles/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](http://www.bioethics.net/articles/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?](http://www.bioethics.net/articles/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](http://www.bioethics.net/articles/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](http://www.bioethics.net/articles/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](http://www.bioethics.net/articles/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](http://www.bioethics.net/articles/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

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| **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. | |
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| 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. | |
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| 0050 | Pubmed | Volunteer experiences and perceptions of the informed consent process: Lessons from two HIV clinical trials in Uganda. | |
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| 0076 | Pubmed | On Nudging and Informed Consent. | |
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| 0091 | Pubmed | Ethical oversight in quality improvement and quality improvement research: new approaches to promote a learning health care system. | |
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| 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 | |
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| 1804 | NEJM (full text. Perspective, commentary, review) | Cryopreservation of Oocytes | |
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| 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 | |
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| 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 | |
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| 1817 | NEJM (full text. Perspective, commentary, review) | Ethical Considerations in Studying Drug Safety — The Institute of Medicine Report | |
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| 1838 | NEJM (full text. Perspective, commentary, review) | Justice for Injured Research Subjects | |
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| 1884 | NEJM (full text. Perspective, commentary, review) | The Paradoxical Problem with Multiple-IRB Review | |
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| 1916 | Genomic Medicine: Genomics, Health Care, and Society | |
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| 1953 | NEJM (full text. Perspective, commentary, review) | The Changing Face of Clinical Trials: Pragmatic Trials | |
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