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Informed Consent as a Structured Act: A New Framework for Understanding Data Authorization

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Abstract

Informed consent stands as one of the core principles when carrying out research with human subjects. Upon giving consent, research participants engage in an action in which they verbally state, document in writing, or otherwise provide an authorization allowing another party to undertake a specific action. This paper offers a novel interpretation of informed consent, viewing it as a compositional act. Such an approach diverges significantly from the traditional modular view of informed consent processes. This paper conducts a conceptual examination to probe the essence of consent and to determine its actual effects or limitations. It introduces a structured framework for scrutinizing the essential components of consent, dissecting them into their constituent parts. The analysis of the consent act begins by pinpointing its primary elements, which include: a) data subjects or their legal representative who supply the authorization through consent; b) a particular item or activity that receives the consent; and c) specific agent(s) who are the recipients of the consent.

This paper presents a framework that examines the fundamental elements of consent and dissects them into distinct parts. Rather than merely presenting options to prospective research participants, it clarifies the underlying reasons for those options or for the consenting actions that occur when individuals verbally or in writing authorize someone to act. We contend that clearly separating the objectives, the methods of application, and the specific actions performed or reversed through consent enables a more effective response to the difficulties arising in modern data-heavy biomedical research, especially concerning data storage and utilization. Framing consent as a compositional act promotes clearer communication and greater accountability, which, in turn, may facilitate more reliable consent processes within biomedical science.

Keywords: Informed consent, Dynamic consent, Framework, Information technology, Trust

Introduction

Informed consent constitutes one of the essential principles for ethically sound research involving human participants. When research participants provide consent, they authorize another party to carry out a specific task by speaking, writing, or otherwise providing authorization. The objectives, procedural validity, and intentions behind informed consent have been thoroughly examined in bioethics publications [1-3]. Nevertheless, do these objectives and procedures assume an inherent definition of consent? Alternatively, should

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the consenting act be understood in terms of what it achieves or reverses? This paper advances an innovative conception of the informed consent process as a compositional act, shifting away from the standard modular approach to informed consent mechanisms. We suggest a formal model for how the intent behind informed consent is assembled as a compositional act.

This paper provides a conceptual review of consent-related actions, clarifying their nature, functions, and shortcomings. Initially, we distinguish between the aims of informed consent and the procedural stages that are mandatory. Next, we portray informed consent itself as a compositional act. To achieve this, we deconstruct the concept of consent into its foundational components and then introduce a framework that formalizes the composition of the informed consent act. We proceed with a deeper examination of the consent act, starting with the recognition of its core constituents, specifically: (a) designated agents—namely data subjects or their legal representatives—who deliver the consent authorization; (b) a defined matter or procedure to which consent applies; and (c) designated agent(s) receiving the consent. We subsequently investigate the features of each element, their individual objectives, and the way their interplay produces a valid consent act. The discussion concludes with an evaluation of the constraints and potential research directions arising from the outlined framework. We maintain that elucidating what consent accomplishes or negates can strengthen the reliability of consenting acts in biomedical research and clinical practice.

Materials and Methods

In studies involving human participants, informed consent safeguards the rights and responsibilities of those involved [1-3]. Its central objective is to increase participants' authority through meaningful authorization, while reducing the risks of deception and limiting coercive influences [4]. Manson and O'Neil [5] characterize informed consent as the relinquishment of standard normative expectations. Consequently, validating informed consent requires evaluating the surrounding context and prevailing norms of reasonable expectations, while identifying potential violations of those expectations. Informed consent depends on clear and productive dialogue between researchers and participants, ensuring that individuals receive information that is both understandable and pertinent [5]. This perspective aligns with a well-established tradition of theoretical descriptions concerning the ideal structure of informed consent as a procedure, which we summarise briefly below.

Informed consent as a procedure

The influential work of Beauchamp and Childress [3] on framing consent as a philosophical, legal, and policy-based requirement in health research remains a central reference. It is widely considered the conventional perspective on consent. According to their model, informed consent consists of five key components that begin with (a) the disclosure of pertinent information enabling potential participants to evaluate risks and benefits, followed by (b) the research subject's effective understanding of that information; (c) voluntariness, meaning the decision to consent must be made freely; (d) competence, which denotes the capacity to make decisions about the offered choice; and (e) consent itself. When combined, these elements constitute "legally or institutionally effective authorization from a patient or subject" (P. 280). These elements are typically viewed as foundational to the procedure and are sometimes described as preconditions for informed consent [6]. A central aspect of Beauchamp and Childress' [3] framework is its depiction of informed consent procedures as providing the research participant with an opportunity to make a substantially autonomous decision about whether to authorize a medical intervention or participate in research.

Subsequently, Beauchamp refined his initial ideas and advocated for a modular approach to informed consent [7]. He proposed that competence functions as a threshold requirement, separate from the other components, and serves as a prerequisite for informed consent. This view strengthens the idea of informed consent as a distinct process. He further argued that disclosure becomes unnecessary when the individual already possesses the relevant information. In addition, he emphasized that consent represents both a decision to support a proposed action and an act of authorization. Beauchamp also distinguished between two different interpretations of informed consent. The first refers to an individual's autonomous authorization of a medical intervention or research participation. The second refers to an established set of "social rules of consent that determine legally or institutionally valid consent" (Beauchamp, P. 58). Even in this second interpretation, however, informed consent should function as a standard

for assessing the moral acceptability of institutional rules. Our approach aligns more closely with this second understanding of consent.

How informed consent procedures ought to be

Authorization, or consent, is typically regarded as a static act composed of several building blocks — disclosure, comprehension, voluntariness, and competence. If any of these are missing or inadequate, the informed consent is considered invalid. In practice, the implementation of informed consent procedures has frequently fallen short of expectations [8, 9]. Manson and O'Neill [5] remind us that the primary aim of consent is to reduce deception and coercion while increasing participants' or patients' control over the volume of information they receive and their ability to withdraw consent later. In the Beauchamp and Childress model, however, potential research participants or patients do not influence what information is disclosed, and therefore have limited control over the exact scope of what they are consenting to.

Critics of O'Neill highlight an essential issue: the need for control over both the quantity of information provided and the precise boundaries of what is being consented to or withheld. This concern has grown increasingly relevant. Recent scholarly work indicates that traditional conceptions of the consent process and its underlying philosophical foundations are insufficient for the demands of big data environments, particularly in data-intensive fields such as genomic research [10-13].

Biomedical research and its associated informed consent procedures have undergone substantial change due to the integration of information technologies, including pervasive computing, digital health tools, and sophisticated machine learning systems for data analysis. Over the past decade, several alternative consent models have been developed to tackle the unique challenges posed by data-intensive research. These newer models present consent as an ongoing interaction between researchers and participants [14]. One prominent example is broad consent, which invites research participants to select from a range of options concerning the continued storage and future use of their identifiable personal data. This concept has proven especially valuable for biobanks and has been integrated into regulatory frameworks worldwide [15-17]. Nevertheless, broad consent faces difficulties in adequately informing participants about possible future reuses of their data, raising doubts about whether it provides sufficient detail for truly informed consent [18]. Controversies surrounding these models often center on how well they respect participants' personal preferences and autonomy, and whether participants are genuinely well-informed about the research.

Other scholars [14, 19] have therefore recommended shifting away from static, one-time decisions by employing digital communication platforms that link researchers and participants. These approaches support dynamic decision-making and strengthen participants' control over their preferences, allowing them to adjust their choices as often as desired. A similar logic underpins collaborative consent [20], which also relies on an IT-based digital interface but places greater emphasis on the dialogue between the potential participant and the research organization. Collaborative consent frames the process as a joint effort between the individual and the research entity. A third model, portable legal consent [21], specifically targets the difficulties encountered in genomic research. It seeks to establish a shared, open-source data repository that allows participants to customize their preferences through a digital platform. Individuals contribute their data with the assurance that it will be handled ethically and their privacy safeguarded. All of these models deserve further empirical evaluation, and numerous questions remain unresolved. Moreover, these approaches provide mounting evidence that Beauchamp and Childress' [3] emphasis on autonomous choice — the cornerstone of their traditional model — is poorly suited to informed consent delivered through digital interfaces. This mismatch arises for several reasons: first, participants cannot realistically achieve a meaningful understanding of every possible decision they may face due to the sheer volume of information involved, a phenomenon known as "informational overload." Second, individual freedom is restricted by the technical limitations and lack of transparency in the systems themselves [22, 23]. Third, evaluating a person's competence (or lack thereof) is often problematic, potentially discriminatory, and frequently impractical [24].

Beyond the limited compatibility of traditional consent models with interactive online platforms, the expansion of available choices raises another critical question: what specific choices should be offered, and why these rather than others? Which choices actually produce genuine informed consent? Simply increasing the number of options without careful consideration of their significance is unlikely to foster trustworthy consent procedures. Ancker *et al*. [25] observed that offering a

wider array of choices within consent interfaces has minimal impact on individuals unless they trust both the digital tool and the researchers behind it. Trust between potential research participants and research actors is therefore essential for effective informed consent and for the successful development of new consent models [25, 26].

Furthermore, a persistent limitation across these models is the assumption that informed consent must be requested and provided uniformly in all situations and for all individuals. Manson and O'Neill [5] argue that this assumption is ethically flawed, noting that not every participant or patient wishes to be overwhelmed with extensive information. In contrast, others may require more detailed explanations. Although these models highlight the advantages of interactive consent systems — particularly the ability to customize and revise preferences — insufficient attention has been given to the risk of nudging participants' decisions through interface design. Even when individuals have a reasonable opportunity to become informed and to choose voluntarily, their options remain constrained by the information made available and the system's design features [23]. In addition, these models pay little attention to the recipients of the data and their responsibilities toward the data subject regarding the appropriate use of that data.

As a result, the sharing and re-sharing of data has become a defining characteristic of the modern health and research environment. This development raises important questions about data storage and the re-use of information as research objectives and scientific knowledge evolve. Researchers often face uncertainty about whether they hold valid consent to re-use previously archived personal data. Moreover, the role of withdrawing consent within the ongoing informed consent process receives surprisingly little discussion.

To overcome the limitations described above, Manson and O'Neill [5] offer a more practical conceptualization of consent. In their account, consent emerges from rationally assessable social interactions in which it may be requested, granted, or refused. Agents are evaluated on their ability to act competently, reliably, and honestly. Consequently, informed consent is granted to a particular agent to carry out a specific action in a competent, reliable, and honest manner. This act rests upon what they term intelligent trust [27], which arises from active investigation and demonstrated trustworthiness.

Trust is highly context-dependent [28]. In digital consent settings, confidence that an actor will perform a specific task competently, reliably, and honestly is shaped not only by the actor's and the institution's characteristics but also by factors such as the digital platform, legal regulations, and cultural context. Trust and trustworthiness are closely connected but distinct concepts. According to Jones, trustworthiness depends on the expectations and requirements others place on the actor and is not solely determined by the actor [29]. For instance, an AI-based tool may be trustworthy yet still fail to generate trust [28]. O'Neill asserts that "Trust is valuable when placed in trustworthy agents and activities" [27] (p. 293). In the domain of consent, we place trust in an actor — for example, a researcher — to act reliably, honestly, and competently. The authorized action itself must also be trustworthy and remain open to examination.

This understanding of consent as a communicative act can be developed further [30]. Building on this foundation, we propose that concentrating on what consent achieves or reverses offers a more effective route to fulfilling the core purposes of informed consent: reducing deception and coercion while promoting individual self-determination.

Results and Discussion

Following the perspective developed by Manson and O'Neill, consent is an act by which someone authorizes a particular agent to carry out a defined task. We present a structured formalization of the compositional aspects of consent, along with their intended meanings. Consent consists of three core, inseparable components: (a) specific agents — data subjects or legal representatives — who deliver the authorization; (b) a specific matter or activity that is the object of consent; and (c) specific agents who receive the consent. Each component carries its own set of features, which may overlap or differ, and each serves a distinct purpose. None of them is interchangeable. Much as consulting a periodic table allows us to analyze individual elements and their properties, analyzing the elements and their properties enables us to anticipate the types of acts that arise when they are combined. For instance, traits of a data subject — including age, cognitive capacity, ethnicity, legal position, or comparable factors — can require adaptations to the consent process or affect the suitability of the second component. The second component, defined as the "specific thing that is being consented to"

(such as permitting or refusing access to medical records, joining a trial of a novel medication, or contributing DNA for scientific study), is likewise shaped by the third component. The third component — the "specific agent(s)" — generates varying dynamics depending on whether consent is directed toward a public university laboratory, a state institution known to discriminate against groups such as the lesbian, gay, bisexual, transgender, and intersex (LGBTI) community, or a commercially driven organization based in another country. These differences influence the overall consent that results.

Table 1 illustrates the above concepts and introduces further components grouped into blocks or clusters that share related characteristics. The table's rows and columns range from the most concrete details to broader categories. This arrangement allows users to pick one or more elements from each row and column; when combined, they form a tangible outcome — namely, a specific compositional act of consent. For example, data subjects might include typical adults, minors, legal guardians, entire communities, or individuals who need additional safeguards, such as people held in state custody, members of minority populations, or those who experience difficulties interpreting information. Block 2 examines the object of consent. It addresses the various factors that shape the consent process, including the exact scope of what is approved, the circumstances under which profiting from data would be acceptable, and relevant time limits. The final block lists frequent recipients of consent, among them official collective bodies. These bodies may carry different titles depending on the region, appear in several configurations, and, although not universal, are commonly encountered.

For example, an adult might consent to share their health data, along with associated social context information and biological samples, and to participate in current and future studies. This approval would apply only on the condition that no profit is pursued until the person withdraws consent in this or any other jurisdiction. The research must focus on improving health guidance, care, and treatment for the individual and others, thereby contributing to societal gains and scientific advancement. In this case, consent is granted solely to healthcare entities operating under official collective authorities (most often public hospitals). It must not be passed on to other official bodies such as law enforcement, educational institutions, tax authorities, or commercial firms.

Table 1. Elements of informed consent. From: Consent as a compositional act – a framework that provides clarity for the retention and use of data

Category	Subcategory	Aged 18 and above	Below 18 years	Authorized proxy	Group entity	Individuals in state custody	Self-identified ethnic minority	Individuals with information-processing challenges
Consent for	**Purpose**	Contribute to scientific advancement	Enable research across all domains	Enhance healthcare systems	Support research for the public good	Facilitate commercially oriented studies		
	Activities	Provide my medical data	Share socio-contextual information	Contribute biological samples and derived data	Supply supplementary data for current and future clinical studies	Provide additional inputs for ongoing and future qualitative research	Allow full data use for secondary research purposes	
	Advantages	Promote public-interest research	Obtain personalized recommendations	Improve my own healthcare	Support research on conditions I experience	Enhance healthcare for others	Enable research beyond the health sector	Personal financial gain
	Duration	Without time limitation	Throughout my lifetime	Until my next healthcare interaction	Until the withdrawal of consent	While laws remain unchanged	For a period of 5 years	At present (today)
	Risk level	Low	Medium	High				
	Applicable jurisdiction	All jurisdictions	Supranational governing bodies	Country of residence (legal)	Country of nationality	Regions with equal or stronger safeguards	Areas within the country with	This specific country

						equivalent legal frameworks	
Stakeholders	Public health entities under official authority	Entities governed by official collective bodies	Private educational organizations	Any formally recognized public authority	Corporate/private sector organizations	Community-based/shared governance bodies	General public

Data subject

Data subjects or their legal representatives who supply authorization or consent to another party. A data subject is understood as an identifiable living individual [31]. This definition draws directly from contemporary legal standards. It covers cases where a person can be recognized by their name, email address, or digital identifier. The table sets out several wide-ranging categories that determine whether someone is in a position to give consent, for instance, reaching legal adulthood. It also touches on broader categories of social or legal circumstances that may shape a person's capacity to consent. The list remains deliberately non-exhaustive. It focuses on selected categories of vulnerable people who may face built-in or deliberate risks and may require additional protections to safeguard their interests. Keeping the categories broad is advisable, ideally by referencing established laws that safeguard particular populations [32]. Attempting to list every individual trait would add little practical value.

Specific actions

This section specifies the concrete actions the data subject endorses. It does not deal with the provision of information but rather with the actual issues, processes, and deeds being approved. Typical consent templates, such as the example from the Swiss Academy of Medical Sciences, frequently contain general statements along the lines of: "I herewith agree that my health-related data and samples collected during health care (ambulant or as an inpatient) will be available for research purposes" [33]. Such language reveals very little about the precise nature of the approval or the actions that will follow. It also leaves open whether consent has equal weight for routine, everyday activities and for high-stakes research projects. Spelling out the exact matter at hand allows for a clearer definition of the action involved.

Benefits

Researchers bear the central duty of making clear to data subjects the boundary between ordinary clinical care or treatment and involvement in a research study, thereby reducing the chance of therapeutic misconception [3]. Many people assume that participation stems from goodwill and a spirit of altruism [34]. As a result, benefits can take many forms — from receiving customized feedback to earning financial rewards. Whenever financial gain is possible, participants must be explicitly informed of the risks of commercial use of their data, along with any charitable or societal benefits. These elements can fundamentally alter the character of the activity, the conditions of the arrangement, and, ultimately, the consent granted.

Timeframes

Consent operates within a specific timeframe, meaning the validity of the authorization can change over time. Contrary to what is sometimes presumed, consent is not reversible; instead, it is revocable. Revoking consent differs from withdrawing consent in that it halts the authorization rather than nullifying it entirely: the consent remained fully valid and active until the moment of revocation. Consequently, revocation forms an integral part of the ongoing consent continuum and carries several intricate practical consequences. From the moment revocation takes effect, any prior consent ceases to apply. When informed consent is obtained during a face-to-face or other real-time exchange between a researcher and a prospective participant, the individual can initially say "yes" and later revoke their consent; this verbal declaration fully and immediately ends the authorization. The statement that one no longer wishes to take part is generally sufficient to terminate the approval and is commonly regarded as undoing consent. Yet, rather than representing a genuine cancellation, such revocation simply marks the conclusion of the period in which consent was active. It carries no retroactive force; any research performed while consent was in place is not retroactively invalidated by the revocation. However, any continuation of that research or any subsequent projects becomes unauthorized from that point forward. This distinction helps resolve certain complications linked to consent revocation. Some data may already have been processed and cannot be erased, while other datasets might have been completely anonymized, making it impossible to remove individual contributions. In

addition, formal institutional protocols for handling revocation sometimes exist. Even when revocation is clearly expressed, implementing it may take some time. Because both the data and the decisions concerning it can outlast the individual, it is essential to consider the time limits attached to any approvals granted. In the special case of deceptive research permitted by ethics committees and current legislation, consent functions as a retroactive act.

Research goals

Motivations for joining research projects frequently include altruism, goodwill, and the desire to advance the public good. Studies aimed at producing broad societal benefits usually attract stronger support than those primarily focused on generating profit, even when the latter address important scientific gaps [26]. The creation of profit remains a highly debated topic. Profit may be viewed more favorably if the returns are reinvested into public services and ultimately contribute to collective benefit. Legal scholarship draws attention to situations in which a donated sample, owing to its unique properties, results in a major scientific or commercial advance, such as the creation of a new drug or therapy [35]. Such cases are handled differently depending on the legal system involved, yet across all jurisdictions, the principle of data self-determination remains a fundamental right. The stated goals of the research, therefore, modify both the character of participation and the terms under which an individual may reasonably provide consent.

Risk

Determining acceptable levels of risk forms a central aspect of strengthening data subjects' control over meaningful authorization. It is not feasible to describe every possible risk associated with current or future data uses in a clear and comprehensible manner. Nevertheless, risk levels or categories are commonly defined in national legislation, ethical standards, and academic literature. These frameworks help mitigate the subjectivity of risk perception by providing structured categories that can inform future evaluations.

Jurisdictions

Informed consent is safeguarded as a right under numerous national and international instruments [2]. Professional guidelines, laws, and regulatory rules vary considerably from one jurisdiction to another. Data subjects must place substantial trust in those responsible for handling and using their data. An individual may willingly share information with a governance framework they trust and that operates in accordance with rules they consider suitable. However, circumstances can evolve, or data may be transferred to other jurisdictions that could expose the person to new risks. It is therefore vital that data subjects can foresee the degree of protection they require. This process both safeguards the data subject and assigns clear responsibilities to research agents. The chosen jurisdiction guarantees appropriate protective measures and mechanisms for redress or compensation.

Research agents

The following does not constitute an exhaustive catalog of research agents; rather, it highlights those most commonly involved in biomedical research. Rivas Velarde *et al*. [36] observed that individuals are more willing to donate their data when research actors are seen as professionally competent, oriented toward the public good, and subject to robust governance. They note that perceived research competence loses its positive effect — and may even undermine trust — if it fails to produce public benefits or lacks proper oversight, leading to lower willingness to participate. The possibility that data might reside on an open-access platform rather than in highly secure storage, and who will ultimately access and use it, significantly alters consent dynamics. This component enables data subjects or their legal representatives to specify precisely who is being authorized. As a result, moral — and frequently legal — accountability rests clearly with the designated research agent(s), who remain answerable within the relevant jurisdiction.

This periodic table of consent brings together elements already recognized, and we hope it will also serve as a tool for identifying new elements, features, and interactions. Researchers can draw on the information in the table to anticipate how novel elements might function or to determine which existing elements they most closely resemble through systematic comparison.

Summary of the framework

This framework sets out the key components of consent with clear precision. It offers a solid rationale for the options and decisions offered to prospective research participants. We maintain that strengthening disclosure, increasing transparency, and fostering genuine dialogue between research participants and research agents bring clear advantages. Such an approach helps resolve uncertainties in particularly sensitive areas, including situations where research generates financial profit. By making these choices explicit, the framework improves understanding of the terms of agreement. It makes it simpler to detect potentially exploitative arrangements in which the benefits and burdens of research are unfairly

distributed. It also supports the seamless continuation of research projects even when investigators change, shift their focus, or uncover new lines of inquiry within existing datasets. The framework creates a shared platform on which individuals and researchers can jointly determine what outcomes are realistically attainable through participation and what exactly is being consented to. We anticipate that this model can be applied equally to conventional face-to-face or paper-based consent processes and to digital, web-based platforms. In every format, it promotes more open and reliable acts of consent.

Let's look at an example. Traditional informed consent — whether conducted in person or through digital interfaces — requires the party seeking consent to (a) disclose sufficient information so that potential participants can weigh risks and benefits. However, researchers often cannot predict future uses of data or the full consequences of re-use, making full compliance with this step difficult in both in-person and online settings. Next, the data subject is evaluated for (b) effective comprehension of the provided information. This assessment is already challenging during direct interactions and becomes almost impossible in digital environments. The subsequent requirement is (c) voluntariness, whereby the decision to grant or refuse consent must be made freely; yet design elements, nudges, and platform features frequently undermine genuine autonomy. (d) Competence concerns the individual's capacity to make decisions about the offered choice; evaluating competence (or its absence) remains especially difficult, can introduce bias, and is often impractical [24]. Finally, (e) consent itself tends to be treated as a one-off, static event rather than an ongoing process. As previously discussed, this perspective creates problems: when a person decides to end their initial authorization in either a digital or a traditional system, implementing that decision can take time. Consent is inherently dynamic. When consent is revoked, it terminates the authorization going forward but does not erase the period during which it was valid. A significant weakness in conventional consent procedures is therefore the limited consideration given to data re-use, changes in research actors, and evolving timeframes.

Our framework, supported by the accompanying table, is designed to overcome these shortcomings. We contend that a consent process built around this table would allow data subjects to selectively authorize trusted agents while refusing others, both now and in the future. Participants would understand that their data will be shared and reused only for the specific research purposes they have approved, and not for any other purposes. Should they later change their preferences, they can update them with the assurance that any prior legitimate use remains valid. While the framework does not fully resolve challenges related to competence or its absence, it leaves room for supplementary tools, such as non-discrimination laws, to address this area. Ultimately, the choices presented aim not merely to expand options but to promote genuinely transparent and trustworthy consent acts. This method clarifies exactly who may do what with the data, enabling data subjects to assess whether the agents involved are likely to act competently, reliably, and honestly. Without such clarity, meaningful evaluation is not possible. In this way, our approach strengthens the trustworthiness of agents and, by extension, the foundation of trust that effective consent requires.

Limitations of the framework

This framework does not claim to be complete. Certain elements and their interactions may have been missed. We offer it as a starting point for further refinement and empirical testing. Its purpose is to portray informed consent as a compositional act — a collection of actions performed through speaking, writing, or clicking to agree. New uses or previously unknown research agents may emerge in the future; we expect this framework to stimulate ongoing discussion and to evolve. Some observers might criticize it as overly rigid because it renders choices and consent acts explicit and specific. It could also be adapted to support an opt-out system in which participation is assumed unless actively refused. Exploring the implications of such an opt-out model, however, lies outside the scope of this paper.

Our conception of consent as revocable rather than fully retractable may provoke objections, since it suggests that individuals do not retain complete mastery over their personal information and materials, potentially appearing to limit personal autonomy. Nevertheless, this view more accurately reflects the practical realities of data-intensive research than a model that treats consent as instantly cancellable. Once data has been shared, analyzed, and published, or fully anonymized, it cannot be retroactively withdrawn or removed from datasets. Therefore, true retraction is often impossible. Moreover, recognizing consent as revocable actually enhances transparency: researchers are expected to use data only while consent remains active. Without clearly defined timeframes, questions inevitably arise about whether data was used legitimately. For instance, if a person revokes consent, those who accessed the data before revocation can be seen as having respected the original choice, while any use after revocation would not.

Additional objections may arise depending on practical implementation. Healthcare staff conducting consent discussions or data scientists building digital consent platforms and databases might consider our suggestions either too prescriptive or insufficiently detailed. Deployment could also reveal unforeseen burdens associated with the framework. These issues represent the next stage of development, which includes comparing the validity of consent under this model with traditional standards, such as those proposed by Beauchamp and Childress [3], as well as other frameworks. Our central goal remains to make explicit what is achieved or relinquished when consent is given, thereby strengthening the foundations of trust essential to consent acts in biomedical science.

Conclusion

This paper concentrates on the fundamental nature of consent and on what it accomplishes or reverses. We introduce a framework that examines the core elements of consent and decomposes them into their constituent parts. By conceptualizing consent as a composition of these basic elements, we advance a fresh perspective on the informed consent mechanism. This perspective moves beyond debates about what informed consent ideally is or should be, and away from merely validating processes that treat consent as a final endpoint. The model does more than simply present choices to potential research participants; it clarifies the reasoning behind those choices and the consenting acts that occur when someone verbally or in writing authorizes another party to perform a specific action. In addition, it situates consent within the context of contemporary data-intensive biomedical research and provides greater clarity on data retention and re-use. The table is designed to support the discovery of new elements, characteristics, and dynamics related to informed consent. It seeks to encourage substantive conversations between research participants and research agents by clearly defining the precise matters and acts involved in consent. By explicitly identifying the data subjects or legal representatives who provide authorization, the specific issues being consented to, and the particular agents seeking consent, the framework improves the ability to evaluate trustworthiness. It enables data subjects to determine whether a given agent is likely to perform a specific act competently, reliably, and honestly. Those requesting consent bear a moral obligation to be open and truthful about their intentions and planned actions. We conclude that clearly distinguishing between the goals of consent, the procedures used to implement it, and what is actually done or undone when consent is obtained is the most effective way to reinforce the foundations of trust required for consent acts in the biomedical sciences.

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References

1. Berg JW, Appelbaum PS, Lidz CW, Parker LS. Informed consent: framing the questions. In: Informed consent. Oxford: Oxford University Press; 2001.
2. Berg JW, Appelbaum PS, Lidz CW, Parker LS. Informed consent: legal theory and clinical practice. Oxford: Oxford University Press; 2001.
3. Beauchamp T, Childress J. The meaning and justification of informed consent. In: Principles of biomedical ethics. 2001:69–98.
4. O'Neill O. Some limits of informed consent. J Med Ethics. 2003;29(1):4–7.
5. Manson NC, O'Neill O. Rethinking informed consent in bioethics. Cambridge: Cambridge University Press; 2007.
6. Freedman B. A moral theory of informed consent. Hastings Cent Rep. 1975;5(4):32.
7. Beauchamp TL. Autonomy and consent. In: Miller F, Wertheimer A, editors. The ethics of consent: theory and practice. Oxford: Oxford University Press; 2009.
8. Hutton JL, Eccles MP, Grimshaw JM. Ethical issues in implementation research: problems in achieving informed consent. Implement Sci. 2008;3:52.
9. Drazen JM, Solomon CG, Greene MF. Informed consent and SUPPORT. N Engl J Med. 2013;368(20):1929–31.
10. Vayena E, Mastroianni A, Kahn J. Caught in the web: informed consent for online health research. Sci Transl Med. 2013;5(173):173fs6.
11. Vayena E, Tasioulas J. The ethics of participant-led biomedical research. Nat Biotechnol. 2013;31(9):786–7.

12. Cohen IG, Lynch HF, Vayena E, Urs G. Big data, health law, and bioethics: introduction. SSRN. 2018. doi:10.2139/ssrn.3147243.
13. Parra-Calderón CL, Kaye J, Moreno-Conde A, Teare H, Nuñez-Benjumea F. Desiderata for digital consent in genomic research. J Community Genet. 2018;9(2):191–4.
14. Kaye J, Whitley EA, Lund D, Morrison M, Teare H, Melham K. Dynamic consent: a patient interface for twenty-first century research networks. Eur J Hum Genet. 2015;23(2):141–6.
15. Caulfield T, Murdoch B. Genes, cells, and biobanks: yes, there's still a consent problem. PLoS Biol. 2017;15(7):e2002654.
16. Sheehan M. Can broad consent be informed consent? Public Health Ethics. 2011;4(3):226–35.
17. Master Z, Campo-Engelstein L, Caulfield T. Scientists' perspectives on consent in biobanking research. Eur J Hum Genet. 2015;23(5):569–74.
18. Fisher CB, Layman DM. Genomics, big data, and broad consent: a new ethics frontier for prevention science. Prev Sci. 2018;19(7):871–9.
19. Budin-Ljøsne I, Teare HJA, Kaye J, Beck S, Bentzen HB, Caenazzo L, et al. Dynamic consent: a potential solution to challenges of modern biomedical research. BMC Med Ethics. 2017;18(1):4.
20. Bernal P. Collaborative consent: harnessing the internet for online consent. Int Rev Law Comput Technol. 2010;24(3):287–97.
21. Wilbanks J. Portable approaches to informed consent and open data. In: Privacy, big data, and the public good. Cambridge: Cambridge University Press; 2014:234–52.
22. Flick C. Informed consent and the Facebook emotional manipulation study. Res Ethics. 2015;12(1):14–28.
23. Weinmann M, Schneider C, Brocke Jv. Digital nudging. Bus Inf Syst Eng. 2016;58(6):433–6.
24. Scholten M, Gather J, Vollmann J. Equality in the informed consent process. J Med Philos. 2021;46(1):108–36.
25. Ancker JS, Silver M, Miller MC, Kaushal R. Consumer perceptions of electronic health information exchange. Am J Prev Med. 2012;43(1):76–80.
26. Trinidad SB, Fullerton SM, Bares JM, Jarvik GP, Larson EB, Burke W. Genomic research and data sharing: views of participants. Genet Med. 2010;12(8):486–95.
27. O'Neill O. Linking trust to trustworthiness. Int J Philos Stud. 2018;26(2):293–300.
28. Gille F, Jobin A, Ienca M. Trust in AI in healthcare. Intelligence-Based Med. 2020;1–2:100001.
29. Jones K. Trustworthiness. Ethics. 2012;123(1):61–85.
30. Austin JL. How to do things with words. Oxford: Oxford University Press; 1975.
31. European Union. General Data Protection Regulation (GDPR). 2016. Available from: https://eur-lex.europa.eu/EN/legal-content/summary/general-data-protection-regulation-gdpr.html
32. Whatcott J. No selves to consent: women's prisons and informed consent. Signs. 2018;44(1):131–53.
33. Swiss Association of Research Ethics Committees. General consent. 2023. Available from: https://swissethics.ch/en/templates/studieninformationen-und-einwilligungen
34. Williams G, Schroeder D. Human genetic banking: altruism, benefit and consent. New Genet Soc. 2004;23(1):89–103.
35. Moore v. Regents of the University of California. 51 Cal 3d 120; 1990. Harvard Law Rev. 1991;104(3):808.
36. Rivas Velarde MC, Tsantoulis P, Burton-Jeangros C, Aceti M, Chappuis P, Hurst S, et al. Citizens' views on sharing health data. BMC Med Ethics. 2021;22:62. doi:10.1186/s12910-021-00633-3