From consent to authorization: New concepts for solving new problems?

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The turn from traditional paternalism and towards patient autonomy has made informed consent a key concept for medical ethics and health legislation. However, informed consent has been attacked for a wide range of shortcomings, both conceptually and theoretically, as well as practically. Vilhjálmur Árnason has suggested an alternative to informed consent, i.e., to give authorizations. Vilhjálmur[1] has been supported by other researchers, but the authorization approach has not been elaborated in any greater detail or come to widespread use in bioethics. This article describes and discusses Vilhjálmur's and other scholars' approach to authorizations and reflects on why this approach deserves more attention than previously given, especially for addressing the extended challenges emerging from biological sciences generating a wide range of person-related biological entities.

Keywords: Consent, Conditioned authorization, Biobank research, Person-related biological entities (PeRBE), Privacy, Patient autonomy, Data governance, Artificial intelligence (AI), Machine learning (ML)

Introduction

Informed consent is a key rule under the principle of autonomy widely used both in clinical practice and in medical research (Faden & Beauchamp, 1986). While the rule is crucial both in medical ethics and legislation, it has been attacked for a wide range of shortcomings, both conceptually and theoretically, as well as practically. Key challenges are identified amongst each of its key features, i.e., understanding, capacity to consent, and voluntariness: when are we providing sufficient information to ascertain understanding? How can we appropriately assess and ascertain competency to consent? How can we assess and assure voluntariness? Moreover, the relational characteristic of human beings and the many human biases question the premise of human rational decision-making (Kahneman, 2011; Kahneman & Tversky, 2013; Tversky & Kahneman, 1974).

One area where the rule of informed consent has been particularly challenged is biobank research (Solbakk et al., 2009). Large repositories of biological specimens combined with extensive health data information systems provide new opportunities far beyond the initial purpose of the collection. This has raised three

crucial questions: 1) Is informed consent suitable for biobank research at all? (Solbakk et al., 2009), 2) How to apply biological material for future research beyond the scope of the previously given consent (for other or limited purposes)? and 3) How to design procedures for obtaining self-determination and protection for donors of biological material that includes unpredictable future research?

Instead of addressing these crucial questions, informed consent has been introduced and applied for biobank research modelled on traditional clinical research. However, the formal act of signing an informed consent form "meets some administrative requirements but need not entail any of the elements of genuine informed consent" (Li & Cong, 2011). Accordingly, it quickly became clear that it was difficult to satisfy key premises for consent, and that a practice of medicine (and research) that cannot comply with the formal requirements for consent will result in a "systematic hypocrisy" (Manson & O'Neill, 2007, p.112). Then informed consent becomes a device for concealing ethical issues instead of ascertaining ethical research practice. Even more, it can make us ignore the biopolitical and societal aspects of technology (Vilhjálmur 2011). As explicitly stated by Vilhjálmur Árnason: "Bioethics can take on a legitimating role by focusing too narrowly on particular ethical questions at the neglect of the larger social implications" (Vilhjálmur 2005b).

Constructing consent

The basic challenges emerging with biobank research have been addressed by modifying consent procedures or to provide new conceptions of consent, such as broad consent (Hansson et al., 2006; Manson, 2019b; Mikkelsen et al., 2019), wide consent (Vellón & Martin, 2011), open consent (Hallinan & Friedewald, 2015; Lunshof et al., 2008), dynamic consent (Kaye et al., 2015), meta-consent (Ploug & Holm, 2017), presumed consent (Allen & McNamara, 2011), restricted consent, extended consent (Devereux et al., 2016), tiered consent (Nembaware et al., 2019), blanket consent (Brewin, 1997; Caulfield, 2002), waived consent (Veatch, 2007), and trusted consent (Boniolo et al., 2012; Brückner et al., 2023).

Table 1 provides an overview of most referred types of consent with some pros and cons.

Consent type	Characteristics	Pros	Cons
General consent	Consent without restrictions	Open, flexible, low workload	Does not qualify as informed consent
Broad consent	Consent to multiple future studies of which the nature and specificities are yet unknown.	Flexible, Reduces workload of obtaining consent	Unspecific, Violates the premise of understanding and voluntariness
Open consent	Consent open for future use (and changes)	Easy to use and to administer, Permissive	Unspecific, Violates the premise of understanding and voluntariness

Dynamic consent	Consent open for future changes e.g., by digital interaction	Facilitates understanding and voluntariness	Cumbersome to use, workload (tools are available)
Dynamic specific consent	Type of dynamic consent that is based on updated information adapted to consenter's preference	Facilitates understanding and voluntariness	More cumbersome to use
Meta-consent	A type of dynamic consent that allows consenters to choose type of consent	Facilitates understanding and voluntariness	More cumbersome to use
Restricted consent	Consent for restricted use	Facilitates understanding and voluntariness	Limits (future) research
Extended consent	Consent for reuse of information/samples even if the consenter will be re-identifiable	Easy to use and to administer, Permissive	Unspecific, Violates the premise of understanding and voluntariness
Tiered consent	Consent including decisions on the scope and broadness of consent. Also called multi-layered consent.	Facilitates understanding and voluntariness	More cumbersome to use
Presumed consent	Presuming persons would consent	Permissive, easy to use, facilitating application	Presumption can be wrong, No real consent

Table 1 Overview of most referred types of consent with some pros and cons.

As illustrated in Table 1 each of the consent forms seem to solve some of the challenges, but also to introduce new controversies (Bruns & Winkler, 2024 Online first; Manson, 2019a). As stated by Wiertz and Boldt, "[n]one of the consent models satisfies fully both the demands of the individual rights perspective and of the perspective of research as a public good" (Wiertz & Boldt, 2022). Hence, constructing concepts of consent that are applicable to biobank (use and research), future health data analysis, turned out not to be an easy task and no consensus has been reached.

The three basic requirements for consent still seem to be challenging to obtain, i.e., understanding, competency, and voluntariness. Many health services cannot be adequately provided without the gathering of information or biological material (voluntariness) and the services are provided to persons with reduced capacity to consent, e.g., when in pain, unconscious, or vulnerable. However, it is the unavailability of information regarding future use of biological material and

associated data at the time of consent that has gained most attention (Bruns & Winkler, 2024 Online first).

One alternative approach to address these issues suggested by Vilhjálmur Árnason is to apply authorizations for the biobank research.

Authorization

Vilhjalmur Árnason has suggested to apply an explicit written authorization for entering data from health databases into genetic research (Vilhjálmur 2005a; Vilhjálmur 2004): "I … spell out an alternative way to obtain consent for participation in database research. This alternative, which I call an informed authorisation, is to strike a balance between protecting the interests of the participants in the database and paving the way for this new type of genetic research". Even more "I describe an idea of a written authorization based on general information about intended research as an alternative to informed consent and presumed consent for the use of healthcare information. I also propose a more restricted authorization as an alternative to informed consent and open consent to the use of genetic information in database research" (Vilhjálmur 2005a; Vilhjálmur 2004).

This implies that the person must be informed about "the conditions for use of the data, such as how the research will be regulated, how they will be connected to other data, who will have access to the information, how privacy will be secured, and that they will only be used for described health care purposes. Participants would be told that they and/or their proxies will be regularly informed about the research practice and that they can at any time withdraw from particular research projects. In this way, the emphasis on a one time initial consent is rejected in favor of a dynamic dialogical process between researchers and participants" (Vilhjálmur 2011). In particular, the authorization encompasses which information about the person that will be stored; how privacy will be secured; how the information will be connected to other data; who will have access to the information; in what context the information will be used and for what purposes; how consent for genetic research will be obtained; the foreseeable risks and benefits of participation; the regulation of the research on the data; and the right to withdraw at any time (Vilhjálmur 2004).

According to Vilhjálmur the authorization model "enables active scientific citizenship because it emphasizes the creation of conditions or opportunities for citizens to reflect on their participation in scientific research. Contrary to the protective policy of specific informed consent, these conditions for participants' deliberation do not come at the cost of a flexible biobank research." (Vilhjálmur 2009).

With this Vilhjálmur tries to "strike a balance between a researcher's need for flexibility and the ethical demand for protection of participants' interests. The main thrust of these proposals, which have different emphasis, is that participants should be asked to authorize the use of their data for described health care research" (Vilhjálmur 2011).

According to Vilhjálmur authorization requires careful communication, support, and building trust: "Communication does not only convey information, it also provides support and thus meets the needs for counseling and comfort many patients have" (Vilhjálmur 2011). This finds support in Caulfield, arguing that

authorization allows participants "to meaningfully act on their continuing interests in their health information" (Caulfield et al., 2003). According to Vilhjálmur the objective is "to create more informed or educated citizens who do not have to rely exclusively on expert knowledge but can use it in their deliberations about research participation" (Vilhjálmur 2009).

Vilhjálmur is quite clear on the relationship between authorization and consent: "I argue that this demand for informed consent is neither suitable nor desirable" in the case of handling genetic health data and that "authorization is in the spirit of informed consent, but it is far more general and open and should, therefore, not be confused with it" (Vilhjálmur 2004, p.45).

It may be argued that authorization resembles broad consent (or dynamic specific consent) as the content of the authorization is open for future changes. However, there is both a conceptual and didactic difference. Consent requires at least understanding, competency, and voluntariness. For many of the types of research and clinical practice the types of consent listed in Table 1 do not satisfy the understanding and/or the voluntariness clause, and per definition the consent requirements. Hence, they are not consent (Hofmann, 2009). Accordingly, authorization does not give the gaze of being something it is not, i.e., consent. Moreover, by being more specific about its uncertainties (about future use and implications), authorization is more clear on future needs for interaction (updates) and is more educative.

Etymologically, the term authorization stems from Medieval Latin (auctōrizāre) and relates to being an author, and as such highlights (the role of) agency. According to the Oxford English Dictionary, to authorize is "to give official permission for or formal approval to (an action, undertaking, etc.)" and "to give (a person or agent) legal or formal authority (to do something)" (https://www.oed.com/dictionary/authorize_v?tl=true#33136136).

In Faden and Beauchamp's seminal work on informed consent (Faden & Beauchamp, 1986), consent is defined in terms of authorization: "An informed consent is an autonomous action by a subject or a patient that authorizes a professional either to involve the subject in research or to initiate a medical plan for the patient (or both)" (Faden & Beauchamp, 1986, p.278). Hence, authorization is conceptually connected to consent. It is therefore not radically different, but has the potential to cover much of the ethical ground that informed consent is to encompass. Additionally, it does not give the guise of being something it is not, i.e., consent. In authorization you explicitly can address future situations where you do not satisfy conditions that do not qualify as consent.

Moreover, the suggestion to use authorizations is very much in line with other research, e.g., with Henry Greely's proposal to elicit permissions to unforeseen research uses of human tissue samples and health information (Greely, 1999) and can also be related to Tristam Engelhardt's "principle of permission" (Engelhardt Jr, 1996).

While Vilhjálmur suggested using authorizations specific for entering information from the Health Sector Database (HSD) to a central research database, the conception of authorization appears to be applicable in a broader context. Accordingly, others have, inspired by Vilhjálmur suggested to apply "conditioned authorization" for biobank research in general (Hofmann et al., 2009).

Conditioned authorization for biobank research

"Conditional authorization" (CA) contains many of the same requirements as informed consent, such as understanding, competence, and voluntariness (Hofmann et al., 2009). However, they are less strict than for informed consent, particularly with respect to what the person participating in research has to understand in order to participate in research. Moreover, CA is intended to be applied beyond biobanks and health information. Accordingly, conditioned authorization includes specification of five key issues: 1) legal and moral status of the material, 2) potential consequences with respect to risks and benefits, 3) (unsettled) relationship to other sources of information, 4) conditions for initiating further research on basis of existing material, and 5) specification of what happens if any of the parts breach the requirements (Hofmann et al., 2009).With respect to the moral and legal status of the material it is crucial to clarify who has property rights of the material, who has intellectual rights stemming from work with the material, and how remuneration is handled in case of its commercial potential (Liu, 2024; Nwabueze, 2016). Accordingly, it is crucial to clarify who will have access to the material, and under what conditions, including external analysis and export (Hofmann et al., 2009).

The prospective consequences with respect to risks and benefits must be addressed, in particular measures to secure confidentiality and privacy with respect to the material and information that stems from it. Identifiability must be explicitly addressed as well as procedures for recontact and return of research results that are of vital importance for the person (and/or relatives).

Additionally, present and potential future handling of connecting material to other sources of information (coupling), e.g., who would be responsible for handling of information and for possible breaches of confidentiality, as well as who is expected to foresee or regulate future coupling.

Moreover, CA must address the regulation of future research on the basis of existing material, e.g., if IRB/REC assessment, approval of patient organization/ patient representatives, or interaction will be needed.

Additionally, for the CA to be valid, a plan for what happens if the conditions are not fulfilled must be included, e.g., how breaches will be handled, who will be responsible for avoiding breaches, and how the breaches will be compensated. Additionally, withdrawal options must be made explicit. Clearly other ethical issues are relevant as well, depending on the context, however, the points mentioned appear to be relevant for a wide range of research types (Budimir et al., 2011). Table 2 provides an overview of the key issues of CA.

Key issues	**Description**
Legal and moral status of the material	Clarify who has property rights of the material, who has intellectual rights stemming from work with the material, how remuneration is handled in case of its commercial potential, who will have access to the material, and under what conditions, including external analysis and export.

Potential consequences with respect to risks and benefits	In particular assess outcomes for health, confidentiality and privacy with respect to the material and information that stems from it, as well as risk of identifiability
Relationship to other sources of information	Responsibility for present and potential future handling of connecting material to other sources of information (coupling)
Conditions for initiating further research on basis of existing material	Including IRB/REC assessment, approval of patient organization/patient representatives, or interaction
Specification of what happens if any of the parts breach the requirements	Elaborate a plan for what happens if the conditions are not fulfilled, e.g., how breaches will be handled, who will be responsible for avoiding breaches, and how the breaches will be compensated
Contextual issues (from Wiertz and Boldt 2022):	(1) Digital infrastructure and digital literacy are key to content and form of authorization (2) High level of data safety regulation in place reduces need for authorization specification (3) Established standards and safeguards of good scientific and clinical practice reduce need for specification (4) Transparent debates on ethically relevant categories of research can identify issues to specify (5) Social inequalities indicate the needs for specific safeguards against them (6) Anti-discrimination laws and practices reduce need for specific measures (7) Trust in health care institutions reduces needs for specification (8) Consensus on unethical research will foster trust and reduce need for specification

Table 2. Overview of key ethical issues to take into account in designing specific CAs.

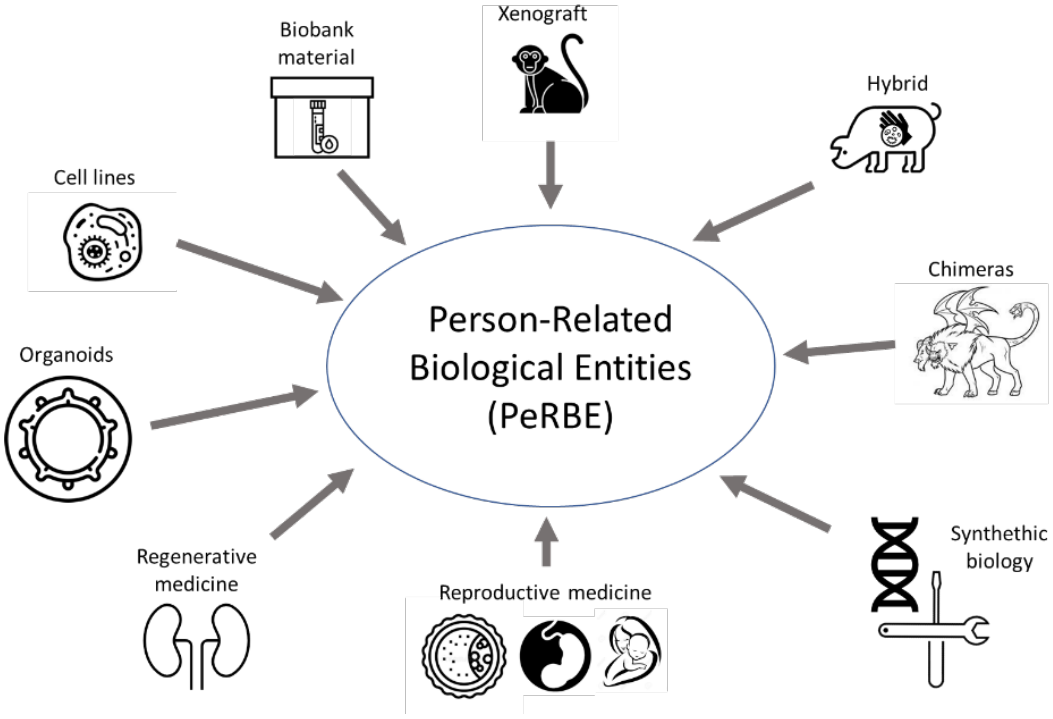
Since Vilhjálmur's suggestion of explicit written authorization in 2005 and the elaboration of conditional consent in 2009, crucial advances have been made both in the field of biological material and health data analysis. Artificial intelligence and machine learning provide vast opportunities for generating crucial health information. However, they also pose challenges for traditional informed consent procedures due to issues of privacy and confidentiality as information is spread and used in previously unprecedently manners and of understanding (of the implications) due to lack of explainability. This relates to downstream epistemic challenges following from the black-box problem, bias, hallucination, and attributability (i.e., decision on ownership).

Advances in the biological sciences have generated a wide range of biological material beyond biobank material that poses challenges to informed consent, for which authorization may be helpful.

From biobanks to person-related biological entities (PeRBE)

Advances in science and technology facilitate a wide range of other types of person-related biological entities (PeRBE), such as cell-lines, organoids, and xenografts (and potentially also xenobots). Additionally, regenerative medicine, reproductive medicine, as well as synthetic biology including gene editing produce PeRBE (Hofmann, 2023) and raise basic issues of informed consent, e.g., consent from future persons for interventions or research before their ability to consent (e.g., before their birth). Hence, PeRBEs extend and enhance the challenges with consent raised by biobank research. Figure 1 provides an overview of various types of PeRBEs.

Figure 1 Overview of types of person-related biological entities (PeRBE) that raise basic issues about informed consent both for clinical practice and research



The challenges with informed consent are becoming ever more topical with this expansion of biological material beyond traditional biobank content. In particular, the issue of addressing the moral status and responsibilities for biological material is enhanced when it comes to organoids, reproductive medicine, and synthetic biology, in particular when PeRBE includes gametes or products or results thereof.

Moreover, openness and transparency with respect to the uncertainty of both risks and benefits is crucial for authorization to various types of PeRBE research (and clinical practices).

PeRBEs also enhance the challenges due to relationships to other biological entities and data sources. For example, biological entities may be genetically

modified, but still strongly related to their source. Relationships as well as potential future connections and related uncertainties must be specified in authorizations.

Clearly, consent retraction will be impossible for a wide range of PeRBE research (as it involves future biological entities with moral status). Hence, authorizations must take restricted authority of biological material into account and be explicit about such issues.

The point here is not to provide a full-fledged framework for authorizations for PeRBEs, but only to indicate that authorizations can be viable for addressing ethical issues beyond health sector databases (HSDs) and biobanks. The same argument can be made for the introduction of artificial intelligence and machine learning (AI/ML).

Discussion

In this article, I have taken Vilhjálmur Árnason's conception of informed written authorization as a point of departure to address ethical challenges with informed consent for biobank research and beyond. In particular, I have indicated how authorizations may be fruitful for addressing the enhanced challenges posed by advances in biological sciences generating a wide range of person-related biological entities and in artificial intelligence and machine learning.

Certainly, there are many limitations to this study. For example, Vilhjálmur is not fully clear on the relationship between consent and authorization, e.g., when he states that authorization is "an alternative way to obtain consent" (Vilhjálmur 2004). Accordingly, it may be argued that there is little difference between authorization and consent, e.g., broad consent or dynamic (specific) consent. With broad consent "[i]nformation about aims, risks and potential benefits thus is provided in rough outline only, for example by naming general objectives of the projects, invoking guidelines all future research projects are obliged to follow, and by informing about risks that are common to all these projects" (Wiertz & Boldt, 2022). This very much resembles authorization. Correspondingly, in dynamic specific consent "online platforms would allow research participants to view information in a format of their choice, adequate to their level of education and interest. An option to pose further questions to researchers could be provided. Information should not only be provided at the onset of a new study, but should be updated regularly to keep participants informed" (Wiertz & Boldt, 2022).

However, as indicated, there are some crucial differences. Authorization does not give the guise of being consent, i.e., to fulfil requirements of understanding, competency, and voluntariness. It is more honest. Clearly, one could alter the concept of consent as to not having to fulfil the standard criteria. However, this is a more challenging task than to apply a different concept that apparently better fits the subject matter. Simply put, it is easier to change the map than the landscape.

However, I think the point is that authorization is an alternative to consent, which is closely enough connected to cover the important ethical issues that informed consent is construed to address, and at the same time provides a flexibility to handle its shortcomings.

Clearly, authorizations may need extensive specifications and raises the question of whether they amount to unmanageable bureaucracy. As with all other types of authorizations, a certain level of specificity is needed to give one's approval, permission, and to give away one's authority and reduce one's agency. Hence, it

may be cumbersome to describe all the details of an authorization and it may be challenging to understand all aspects and details of an authorization, but an authorization may specify what one does not need information about.

Yet another counterargument is that authorizations have exaggerated presumptions of agency. To make a valid authorization, you need to be able to understand and decide more than ordinary people can. This is a valid objection. However, as authorizations can include concessions, their agency requirements may be less than with informed consent.

As pointed out, authorization is included in definitions of informed consent (Faden & Beauchamp, 1986) and the content in conditioned authorization is similar to what is covered by other frameworks (Boniolo et al., 2012), indicating that it addresses crucial issues.

Yet another problem is how to manage withdrawal if you do not have sufficient information. In many ways, this makes withdrawal illusory. Again, this is an important objection, which is not unique to authorization. However, as stated, CA may include statements of reduced withdrawability, which by no means eliminates the problem, but which may at least reduce it and increase transparency and openness.

Future research: moving from PeRBEs to AI/ML

AI/ML is haunted by some of the same challenges as PeRBEs, e.g., in terms of lack of understanding, due to what has been called the black-box problem. Therefore, applying traditional forms of consent is difficult, and authorization may be a relevant alternative. While "explainable AI/ML" has been launched as a solution, it turns out that explainability is more directed to AI experts than lay people (London, 2019). Authorizations therefore must take into account the limited understanding, and especially specify the division of responsibilities resulting from this.

The same goes for bias and hallucination, which tend to distort transparency and understanding of the outcomes from AI/ML. A third issue is the question of who owns the decision, i.e., attributability (Zeiser, 2024 Online first). This enhances the requirements to specify the accountability requirements of the CA.

This only indicates that authorizations for AI/ML in PeRBE research (and practice) is a relevant field of research to investigate whether authorizations can be feasible for addressing ethical issues beyond health sector databases (HSDs) and biobanks.

Conclusion

This article has taken Vilhjálmur Árnason's conception of informed written authorization as a point of departure to address ethical challenges with informed consent for biobank research. Moreover, it has briefly investigated whether authorizations may also be fruitful for addressing the enhanced ethical challenges posed by the many person-related biological entities emerging from vast advances in biological sciences.

While not providing a full-fledged framework for authorizations for research on person-related biological entities and health data, the article indicates why Vilhjálmur's insights and suggestions deserve more attention than previously given.

Additionally, further research may investigate the approach's promising potential in AI/ML.

Note

[1] In Iceland the surname – Árnason – is a patronymic and a description rather than a name. Icelanders use and are known by their given name. This practice is followed throughout this article and Vilhjálmur Árnason will be referred to as Vilhjálmur when citing his works.

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