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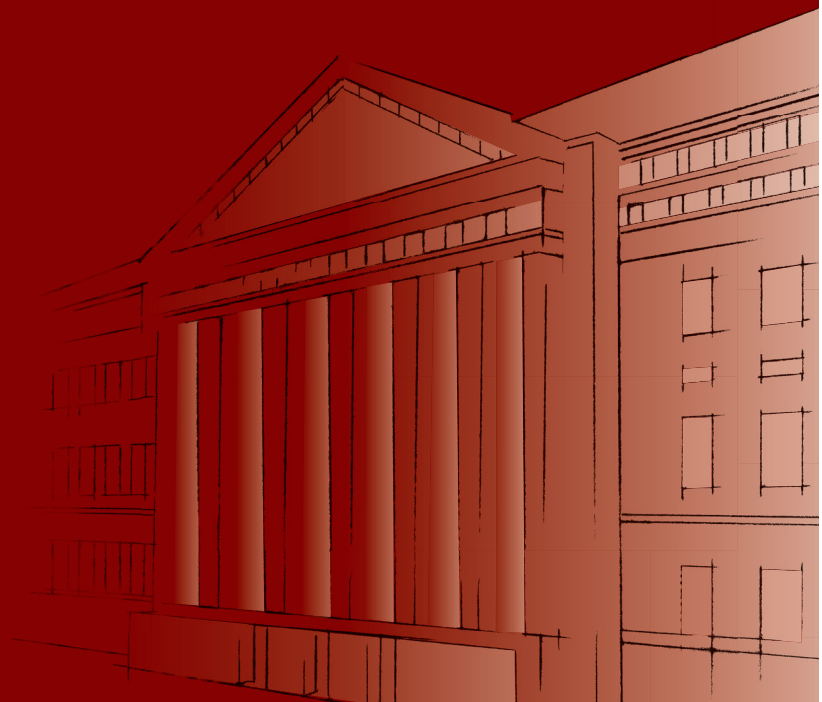
EMMI KAAYA

The Ethics of Informed Consent in Open Science: From Autonomy to Fairness



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The Ethics of Informed Consent in Open Science: From Autonomy to Fairness

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Faculty of Arts and Humanities, Institute of Philosophy and Semiotics

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INTRODUCTION TO THE THESIS

Open science has transformed the way research data circulate. Whereas data were once collected, stored, and used for a single project – sometimes erased after a fixed period – they can now be shared across institutions, borders, and disciplines, often for purposes not foreseeable at the time of collection. In human research, this creates a fundamental challenge for informed consent: participants cannot be fully informed about every possible future use of their data. The central question of this thesis is whether, and under what conditions, informed consent in such contexts can still have moral force. Answering this question requires examining when consent can be morally[1] transformative – that is, when it morally authorises the consent-receiver to act. The aim is not to redefine informed consent itself – already well-established in bioethics – but to assess when it retains moral force in situations where relevant information cannot be provided.

A widely held view in bioethics locates the moral force of consent in the internal state of the consent-giver. Ruth Faden and Tom Beauchamp (1986) define informed consent as autonomous authorisation, which they hold to require three conditions: intentionality, substantial understanding, and substantial freedom from controlling influences. They further argue that it is the fulfilment of these autonomy conditions that makes consent morally transformative[2]. Because this view grounds moral force in the fulfilment of autonomy conditions that refer to the individual's internal, subjective mental states, it is referred to in this thesis as the *autonomy-based*, or *internalist*, model of moral transformation. Although highly influential, this model proves too narrow – not only in open science but in other contexts as well. In open science, it implies that morally transformative consent is strictly impossible, since participants cannot substantially understand unknown future uses. In other domains, it produces counterintuitive results by ruling impermissible practices that often seem morally acceptable.

In response, Franklin Miller and Alan Wertheimer (2010) develop what this thesis refers to as the *transactional*, or *externalist*, model of moral transformation. This view ties the moral force of consent directly to the external features of the consent procedure: moral transformation depends on whether the process is fair – for example, whether disclosures are accurate, accessible, and not misleading,

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[1] In this thesis, terms *ethical* and *moral* are used with different meanings, consistent with the usage in Faden & Beauchamp's (1986) work. *Ethical* refers to a property of practices that are institutionally justified, typically within the framework of professional codes, regulations, or disciplinary norms. *Moral* refers to a property of practices that can be considered right in a broader normative sense, independent of institutional endorsement.

[2] Faden and Beauchamp do not themselves use the term *morally transformative*. For them, the very conditions that define informed consent also serve as the threshold for moral transformation: if these are not fulfilled, there is no informed consent, even if institutional rules would still authorise research to proceed. In this thesis, the term *morally transformative* is applied also to Faden and Beauchamp's account, to emphasise that it is precisely the fulfilment of these conditions that gives consent its normative force to permit action.

and whether both parties are positioned fairly – rather than on the internal states of the consent-giver. This thesis shows that the transactional model offers a more intuitive framework across diverse contexts and provides a plausible way of addressing the difficulties posed by informed consent in open science.

In practice, the challenge of obtaining consent for unknown future uses has been met through the adoption of *broad consent*. Research biobanks – one of the earliest implementations of open science, owing to their reliance on broad-scale data sharing – have implemented this approach (Kaye, 2004, p. 104). Under broad consent, participants agree in advance to unspecified future research uses of their data and samples. This consent solution operationalises the logic of consent in open science, where data are shared for purposes not yet determined, and provides a workable solution to the otherwise impossible task of securing specific consent for unforeseeable uses. Broad consent has come to be regarded as an ethically acceptable compromise, particularly when recontacting participants for renewed consent is impractical or impossible (Hansson et al., 2006). Examining this consent model, and the scholarly debate surrounding it, offers a valuable lens for understanding the evolving ethical and moral challenges of informed consent in open science.

Despite its practical utility, broad consent has been criticised, among other things, for undermining participants' autonomy due to the lack of relevant information (Árnason, 2004; Caulfield, 2007; Caulfield & Kaye, 2009; Hofmann, 2009; Salvaterra et al., 2008). In response, proposals for more flexible consent models, such as dynamic consent, have been put forth with the aim of providing participants with more granular, ongoing oversight (Budin-Ljøsne et al., 2017; Kaye et al., 2015; Ploug & Holm, 2016; Ram, 2008). Yet in practice, these models may not empower individuals much more than broad consent, largely because research data that qualify as personal data are subject to the rules of the General Data Protection Regulation (GDPR) in the European Union (EU) and European Economic Area (EEA). Together with research-ethical and institutional guidelines, the GDPR shapes the scope of consent and includes provisions that prioritise scientific research, even at the expense of individual data control. As a result, dynamic consent and other flexible models may create only the *appearance* of greater autonomy while, in practice, yielding outcomes similar to broad consent. In this light, broad consent may be the more transparent model – not because it offers more control, but because it does not promise what it cannot deliver.

Emphasising this possibility does not imply that broad consent is morally unproblematic. Rather, it recognises that, under certain conditions, it may still justify action. Building on this perspective, this thesis shifts focus from abstract standards of moral transformation to how consent operates in practice as a form of communication. Judged against the autonomy-based model, broad consent appears incapable of being morally transformative. But as already noted, this model is too rigid and yields counterintuitive results when applied in different consent situations. By contrast, the transactional model offers a more flexible and intuitively appealing framework: even where autonomy is incomplete, consent may still morally transform if the procedure is fair.

The original contribution of this thesis lies in analysing the intersection of ethical principles and the legal realities of data governance under the GDPR, and how these shape the conditions of consent in open science. Unlike most treatments, it adopts the standpoint of the ordinary person – someone unfamiliar with the regulatory landscape – and asks how the implications of research participation are actually communicated to participants. This perspective reveals how the moral significance of consent emerges from the interplay between ethical principles, legal frameworks, and communicative practice, as well as from the social roles, responsibilities, and power relations that structure consent interactions.

From this vantage point, the thesis pursues three aims: (1) to explore the implications of research participation under the GDPR, focusing on how it structures consent; (2) to consider what information should be disclosed for a fair procedure in open science; and (3) to investigate actual consent practices, analysing how the implications of participation are communicated to participants.

These aims are pursued through three articles: Article I, "*Facilitating a fair consent procedure in open science – recommendations for information disclosure*," adopts a doctrinal analysis of the GDPR and proposes recommendations for transparent disclosure; Article II, "*Biobank consent under the GDPR: are potential sample donors informed about all lawful uses of biobank data?"*, applies a Gricean content analysis to examine how lawful uses are communicated; and Article III, "*Right to withdraw consent from biobank research – a weak right wrapped in empty promises?"*, analyses how the right to withdraw consent and its consequences are communicated. Articles II and III together form the empirical part of the thesis, focusing on how information about research participation in an open science setting is conveyed to participants.

The analysis of biobank consent documents highlights two central issues that threaten the fairness of the consent process. First, although most of the information provided is consistent with applicable laws and regulations, it also risks communicating falsehoods that can lead participants to form mistaken beliefs about the scope of consent, the potential uses of their data, and the consequences of exercising the right to withdraw. Second, certain statements convey information that is plainly inconsistent with the legal or practical realities of participation. These findings raise doubts about the moral legitimacy of actions taken on the basis of such consent. They emphasise the need to move beyond formal legal compliance and engage more seriously with how information is communicated, both as a regulatory requirement and as a moral practice.

Although the analysis focuses on biobank consent documents, its scope is broader: it examines these documents not with the aim of evaluating biobank practices in isolation, but to draw more general lessons about the structure and communicative function of informed consent in open science. The central conclusion of this thesis is that consent to research in open science can be morally transformative, provided that participants are given accurate and accessible information about the scope of consent, the lawful range of data uses, and the implications of withdrawal – communicated in a manner that accounts for the fact that participants are not legal experts. While not an exhaustive list, these disclosures

are essential for facilitating a fair consent process and upholding the moral function of consent beyond mere regulatory compliance.

This conclusion also challenges the widely accepted view in bioethics that the purpose of informed consent is to safeguard individual autonomy. While safeguarding autonomy remains an important aim, this thesis refines that claim by highlighting that informed consent also serves a critical social function: legitimising action within interpersonal relationships, particularly in contexts where otherwise impermissible conduct is rendered morally acceptable through consent. This transactional view shifts attention from assessing whether fixed conditions are met to examining what the parties involved, especially researchers and participants, morally owe each other. It foregrounds the social norms of consent as a communicative and moral practice, thus expanding our understanding of what informed consent is for and why it matters.

The remainder of this introductory chapter is structured as follows. Section 1 examines the ethical challenges of informed consent in open science, showing how uncertainty about future data use, especially in biobank research, has led from purpose-specific to broad and adaptive consent, yet remains constrained by the GDPR. It argues that the key issue is not simply missing information but how participants are treated as moral agents, laying the groundwork for a relational account of morally transformative consent. Section 2 contrasts the autonomy-based model, which grounds legitimacy in the individual's internal states, with the transactional model, which ties it to the fairness of the procedure; it contends that the latter offers a more context-sensitive account of how broad consent can still carry moral force. Section 3 presents the three articles comprising the thesis, which collectively demonstrate that the moral force of consent rests less on strict autonomy-based criteria and more on communicative fairness – ensuring information is both accurate and meaningful to ordinary participants.

1 INFORMED CONSENT

This thesis examines how informed consent functions not only as an ethical requirement but also as a moral and communicative practice situated within specific legal and institutional contexts. A central concern is the difficulty of securing morally meaningful consent in open science environments, where data are collected for one purpose but often reused for many others, frequently in ways that cannot be specified at the time of consent. This structural uncertainty places pressure on the autonomy-based model of informed consent articulated by Ruth Faden and Tom Beauchamp (1986). On this view, consent is understood as an act of autonomous authorisation (discussed further in Section 2).

While this framework has shaped bioethical thinking for decades, its reliance on substantial understanding of *material facts at the time of consent* makes it difficult to apply in data-intensive research contexts. The problem is not that participants would need God-like foresight, but that many material facts about future data uses do not yet exist when consent is sought; the proposition to which one is asked to consent is therefore under-specified. On the internalist view, this under-specification blocks the autonomy condition from being met, and thus blocks moral transformation.

Building on this observation, this section explores how the principle of informed consent is challenged by data-sharing practices in open science. It considers the ethical, moral, practical and legal tensions that arise when participants are asked to consent to research without being fully informed about future uses of their data. Using biobank research as a focal point, the section surveys both the criticisms of current consent practices and the alternative models proposed to address them. In doing so, it lays the foundation for a broader inquiry into how informed consent can remain morally robust in a research landscape defined by long-term data storage and use, institutional complexity, and evolving regulatory frameworks.

To guide the discussion, the section begins by situating informed consent within the framework of open science (Section 1.1), then considers its operation in biobank research (Section 1.2). It next turns to consent as a legal basis for data processing under the GDPR (Section 1.3), and, finally, places these debates in historical perspective by examining disclosure failures and their implications for the moral force of consent, thereby preparing the ground for the normative analysis developed in Section 2 (Section 1.4).

1.1 Informed consent in open science

The following subsections situate informed consent within the broader movement of open science, highlighting its normative foundations, the ethical and moral tensions it creates, and the practical responses developed to address them.

1.1.1 Open science – normative framework

Open science is an umbrella term referring to a range of practices aimed at making scientific research more accessible, collaborative, and transparent – in short, better science. These practices include but are not limited to making research articles freely available to readers, sharing raw data for reanalysis and reuse, increasing transparency in the peer review process, involving non-professionals (such as citizens or patients) in the research process (e.g., data collection), and evaluating scientific impact using alternative metrics beyond the journal impact factor (e.g., downloads, social media attention) (Fecher & Friesike, 2014, pp. 17, 25; Simm & Eigi-Watkin, 2024). While open science encompasses a broad set of goals and tools, this thesis focuses specifically on the practice of data sharing – particularly the reuse of personal data collected for one research purpose in future studies – as a key site for examining the ethical and moral challenges of informed consent.

Importantly, open science is not only a normative ideal – it can entail concrete legal obligations. In the EU, *open science* can refer to a binding set of requirements for researchers and research institutions. The legal basis for these obligations lies in the Horizon Europe Regulation (2021/695), which considers open science as *an approach to the scientific process based on cooperative work and diffusing knowledge*, ensuring open access to research data (Art. 14(1)(b)). Under this Regulation, open access to research data is a general rule, subject to the terms and conditions in the grant agreement. At the same time, the GDPR provides the overarching legal framework for the governance of personal data within the EU/EEA, meaning that the collection, storage, use, and sharing of research data classified as personal data must comply with its requirements. When ethical or legal mandates to share research data intersect with data protection rules, collisions with the ethical duties of disclosure that underpin informed consent will arise – creating a structural tension this section now examines.

1.1.2 The core tension: compromised autonomy

Against this backdrop, the sharing of research data for future reuse presents a significant challenge to one of the field's most foundational doctrines: informed consent, particularly as articulated by Ruth Faden and Tom Beauchamp (1986, pp. 274, 281–283). Their account remains a widely regarded standard in bioethics, according to which *institutionally effective*[3] informed consent requires that

[3] Faden and Beauchamp (1986, pp. 277–280) distinguish between informed consent as autonomous authorisation and institutionally effective informed consent. The latter refers to consent that is considered valid because it follows formal rules, such as ethical codes or legal regulations, even if the participant's understanding may be insufficient. While autonomous consent emphasises personal agency and comprehension, institutional effectiveness focuses on procedural compliance.

the consent-seeker informs the potential research participant about the proposed research before the participant makes a decision about research participation.

In the context of open science, potential research participants can be informed about the specific research project for which their data is initially collected, but not about future research projects in which the data may later be reused. Nevertheless, participation in a single research project can entail acceptance that the collected data may be used in future studies, the details of which are unknown at the time of consent. In other words, by consenting to one research project, participants effectively agree to the use of their data in multiple, undefined future studies. This practice of data sharing stands in tension with the ethical requirement that participants should receive relevant information about the proposed research before deciding whether to take part.

It is relatively straightforward to see why the absence of specific information about particular uses of data poses an ethical concern: researchers and research institutions cannot meet their disclosure obligations. However, this alone does not fully explain why such an absence raises deeper *moral* concerns. In bioethics, informed consent has been regarded not only as an ethical practice but, more fundamentally, as the central means of operationalising the principle of respect for autonomy (Beauchamp & Childress, 2019, p. 118). Crucially, Faden and Beauchamp (1986, p. 238) ground informed consent in a specific conception of autonomy. According to their account, consent is morally transformative only when an authorisation of an action satisfies the conditions that define autonomous action: it must be intentional, based on substantial understanding of material facts, and carried out in the substantial absence of controlling influences.

Open science's commitment to future data reuse makes it impossible to provide participants with material information about how their data will be used. This means that, at the moment of consent, individuals cannot achieve the substantial understanding that autonomy requires. The core concern is therefore not limited to incomplete disclosure: it is that individuals are asked to consent under conditions that systematically frustrate their capacity to act autonomously. If Faden and Beauchamp's account is correct, the absence of information is problematic precisely because it undermines the autonomy of the consenting individual. In other words, informed consent inevitably fails to achieve its fundamental purpose: safeguarding individual autonomy.

1.1.3 Practical workarounds and their limits

In light of these considerations, data sharing for reuse places researchers and research institutions in a difficult position. On the one hand, they are encouraged, or even obligated, to promote open science by making research data available for future use. On the other hand, they remain bound by ethical and moral obligations to ensure adequate disclosure during the consent process. Since participants cannot be informed about what they are being asked to consent to, informed consent in the ethical and moral sense seems impossible.

A technical response to this dilemma is to narrow the *legal* scope of informed consent so that participants only agree to participation in the current study, but their consent is not requested for the subsequent use of their data. In practice, this means that by agreeing to participate, individuals effectively accept the sharing and reuse of their data for unforeseen purposes, even though they do not, in a legal sense, provide consent for such future uses.

While this solution may offer a practical workaround, it fails to address the core moral issue: participants remain uninformed about the future uses of their data, which may be accessed and reused without their knowledge, thereby undermining their autonomy. These considerations prompt broader questions about whether consent processes in open science should be reconsidered to meet the ethical requirements for information disclosure, or whether the ethical requirements for informed consent should be re-evaluated in a research context which relies on reuse of data. These questions have been extensively examined in the context of biobank research, which involves collecting human biological samples and associated data for an open-ended range of future purposes. The following section provides an overview of the debate and the proposed solutions.

1.2 Informed consent in biobank research

The tension between the practice of sharing research data for purposes that are unknown at the time of consent and the ethical and moral requirement to provide adequate information to prospective research participants is a widely discussed issue in the context of biobank research. This section provides a brief overview of the debate as a prelude to introducing proposed solutions to this moral challenge: the difficulty of securing morally significant informed consent when future uses of data cannot be specified in advance.

1.2.1 The emergence of broad consent

Population-based research biobanks are repositories of human biological samples and associated data established to function as a resource for scientific research. When individuals give consent to providing biological samples to biobanks for research purposes, future research projects are not specified. If the requirement for information disclosure were interpreted strictly, each sample donor's consent would need to be sought for every new research project. This approach would not only be very costly, but it would also risk losing part of research participants due to consent fatigue or difficulties in reaching them, thereby endangering the scientific value of research and rendering genetic databases unworkable. (Elger & Caplan, 2006; Kaye, 2004, p. 104).

In light of these practical considerations, several ethical guidelines in the late 1990s and early 2000s took the view that it is acceptable to obtain participants' consent for the use of biological samples for a range of unspecified future research, provided that research projects are approved by a research ethics committee and

the participants have the right to withdraw consent at any time. This acceptance marked the emergence of a new consent regime in human research: *broad consent*, also known as *general consent* or *open consent*. (Boggio et al., 2005; Elger & Caplan, 2006.).

The endorsement of broad consent as an ethically acceptable method for obtaining sample donors' consent in biobank research exemplifies what Solomon Cargill (2016) identifies as one of two principal responses to the problem of absent information at the time of consent. She refers to the proponents of this approach as r*eplacers*, as they argue for the substitution of traditional, project-specific informed consent with alternative models, such as broad (i.e., non-specific) consent. This position reflects a re-assessment of the ethical requirements governing informed consent in light of the distinctive demands and interests posed by a new research context.

Hansson et al. (2006) view the acceptance of broad consent as a balanced solution, as it supports important research while upholding sample donors' autonomy by allowing them to withdraw consent. Kaye (2004, pp. 104–105), while critical of broad consent, outlines the institutional rationale for its adoption. She notes that the relatively low risk profile associated with biobank research is often cited as justification for broad consent. Unlike clinical trials and other forms of human experimentation, biobank research poses minimal physical risk to participants, the primary concern being privacy, which can be managed to some extent. Since one of the key purposes of informed consent is to enable participants to protect themselves against research-related risks, the demand for detailed information disclosure has been regarded as less pressing in the context of biobank research. Nevertheless, the limitations of broad consent were recognised from the outset.

Already during the early debates on its adoption, broad consent attracted sustained criticism. Scholars such as Árnason (2004), Caulfield (2007), Caulfield & Kaye (2009), Hofmann (2009), Kaye (2004), and Salvaterra et al. (2008) argued that broad consent does not genuinely safeguard participants' autonomy. Because future research uses remain undefined, participants cannot achieve the substantial understanding required for autonomous decision-making. As Hofmann (2009) noted, this reduces autonomy to mere liberty of choice, while Salvaterra et al. (2008) described broad consent as a *generic authorisation* that sacrifices self-determination in favour of research efficiency. These concerns highlight that broad consent risks diluting the ethical and protective functions of informed consent. It is precisely this recognition of its limitations that motivated the search for alternative models of consent – an endeavour reflected in the development of adaptive consent approaches.

1.2.2 Adaptive consent

Although broad consent has been widely accepted in biobank practice, its limitations have been the subject of sustained criticism. In particular, its perceived failure to safeguard participants' autonomy has motivated the development of alternative consent models. This second type of response comes from what Solomon

Cargill (2016) calls the *adapters* – those who seek to modify the consent process in order to satisfy the ethical and moral standards of informed consent, while maintaining intact the existing normative framework regarding information disclosure.

This approach seeks to address two specific concerns about the use of broad consent identified by Kaye (2004, p. 104). The first is the problem of unclear boundaries. One purpose of information disclosure to potential research participants is to help define the boundaries within which researchers are authorised by the participants to operate. When participants are provided with specific information about a research project, and they agree to take part in it in light of this information, researchers are better positioned to respect participants' autonomy by staying within the boundaries of consent. With broad consent, however, these boundaries are unclear because participants consent to a range of unspecified research projects whose aims, methods, and implications are not yet known. The second concern is the problem of vagueness: stating the aim of research in very broad terms (e.g., *increasing knowledge in order to improve health and health services*), broad consent runs the risk of being so vague that consent becomes essentially meaningless or, as Greely (2007) puts it, "*watered-down version of informed consent"*.

These considerations have led to the development of various adaptive consent models, including *tiered consent*, *meta consent*, *GDPR-compliant broad consent* and *dynamic consent*. Tiered consent allows sample donors to provide consent for categories of research (Ram, 2008). While this solution does not constitute specific consent in the strict sense, it offers a more fine-grained alternative to broad consent. Meta consent enables individuals to choose how they would like to provide consent for the research use of various different types of data, such as patient records data and genomic data (Ploug & Holm, 2020). GDPR-compliant broad consent seeks consent for a broadly defined purpose while simultaneously offering access to detailed information about upcoming research projects. In response to this information, participants have the opportunity to withdraw consent (Zenker et al., 2022). Dynamic consent refers to an online consent management platform that allows donors to give or withhold consent for each individual research purpose (Kaye et al., 2015). Of these models, dynamic consent aligns most closely with the ethical requirements for information disclosure, particularly regarding information disclosure. Yet even before adaptive consent models were developed, some commentators had already questioned whether the very notion of informed consent was suited to data-intensive research contexts such as biobanking.

1.2.3 Should informed consent be abandoned?

Although not central to the focus of this thesis, a third response is worth brief mention: the abandonment of informed consent altogether. This stance, in this thesis referred to as the view of the *abandoners*, questions whether informed consent should be retained in biobank research at all. Exemplified by Solomon

Cargill (2016) herself, this group argues for the complete abandonment of informed consent in data-intensive research contexts such as biobanking. Her position represents a radical extension of a view previously articulated by Árnason (2004) and Hofmann (2009), who are critical of relying on broad consent as the ethical foundation for biobank research. While they maintain that it remains important to seek participants' permission, they argue that this act should no longer be described as *informed consent*. According to them, the more general consent becomes, the less informed it is. In the context of biobank research, consent is, at best, a form of authorisation – a delegation of decision-making power to trusted, ethically governed institutions.

A difficulty with Árnason's (2004) and Hofmann's (2009) position is that it is unclear what practical difference such a semantic shift makes from the participant's perspective. Whether termed *consent* or *authorisation*, the participant still faces the same situation: agreeing to something whose future scope is unknown. As such, changing the terminology may clarify matters conceptually for ethicists and institutions, but it does nothing to enhance the participant's position.

It is at this point that Solomon Cargill (2016) takes the critique a step further. Building on Árnason's and Hofmann's concerns, she argues that when it is impossible to inform participants meaningfully about the future uses of their data, consent becomes a bureaucratic ritual, offering only the illusion of ethical legitimacy. In such cases, she contends, continuing to rely on informed consent undermines rather than protects participant autonomy and interests. Instead, she proposes replacing it with alternative mechanisms, such as strong governance, transparency, accountability, and public engagement, as more ethically viable means of respecting individuals.

Although Solomon Cargill's (2016) critique raises important questions about the coherence and viability of informed consent in data-intensive research, this thesis does not take a normative position on whether biobank research should or should not be based on consent. Since consent remains a central feature of biobank practice, both institutionally and legally, this thesis focuses on the two other main responses to the problem of absent information: the redefinition of informed consent through broad consent and adaptive consent models (e.g., dynamic consent). These two approaches aim to preserve consent as the primary source of justification for research, while modifying its practical implementation.

A key problem with Solomon Cargill's argument is that it builds on a particular conception of informed consent – namely, informed consent as autonomous authorisation, as articulated by Faden and Beauchamp (1986). If this conception is taken as definitive, then the conclusion to abandon informed consent in biobank research may indeed appear justified, even ethically compelling. However, as Section 2 will demonstrate, when these underlying assumptions about the nature and function of informed consent are revisited, Solomon Cargill's conclusion no longer appears self-evident. The next section thus returns to adaptive consent, which, although designed to preserve informed consent, also faces important limitations.

1.2.4 The limits of adaptive consent

While adaptive consent solutions share the laudable aim of enhancing sample donors' autonomy by offering greater control over the research use of their samples and associated data, these solutions are based on the assumption that donors can exert meaningful control over the use of the data derived from those samples, such as genomic information. In other words, these models presuppose that participants are in the position to regulate the flows of their personal information in a way that aligns with their preferences.

Central to this approach is the idea that the legitimacy of data use is grounded in the participant's consent, understood here primarily as a mechanism of individual control rather than as a legal basis for processing personal data (i.e., one of the lawful grounds for data processing recognised under EU data protection law, discussed in more detail in Section 1.3). However, even if consent were to function as such a legal basis, as dynamic consent would allow, it would not guarantee greater individual control, given the complexities inherent in the data protection framework that can impede participants' ability to effectively regulate the uses of their personal information.

Against this backdrop, this thesis aligns with the position of the *replacers*, who advocate revising the normative framework of informed consent to better fit the realities of data-intensive research. However, it does not treat broad consent as a simple or morally unproblematic solution. Rather, it argues that the use of broad consent imposes stringent obligations on researchers and institutions to communicate clearly and openly what participation entails.

The following section sheds light on informed consent as a legal basis for processing personal data in the EU in order to show that adaptive consent solutions, as such, would not solve the problem of absent information about future uses of data at the time of consent. Consequently, these solutions may not effectively fulfil their intended purpose – namely, to increase participants' control over their personal information and thereby enhance their autonomy.

1.3 Informed consent as a legal basis

Beyond its ethical meaning, consent also operates as a legal construct under the GDPR. This dual role and its implications are the focus of the following subsections.

1.3.1 Framing the dual role of consent (ethical vs. legal)

In the context of research involving personal data, the concept of consent has a dual meaning that is important to distinguish. First, consent functions as an ethical requirement, signalling an individual's voluntary agreement to participate in a specific research project. Second, under the GDPR, consent may also serve as one of several possible legal bases that legitimise the processing of personal data.

These two meanings are not interchangeable: one may ethically consent to participate in a study, while the data controller may legally rely on a different basis, such as public interest, to process the participant's data.

This distinction is particularly relevant when evaluating adaptive consent models. Dynamic consent and related approaches are often presented as ethical innovations in the governance of research involving personal data. They promise increased transparency, granular control, and enhanced participant autonomy by enabling individuals to update, refine, or withdraw their consent over time (Budin-Ljøsne et al., 2017; Kaye et al., 2015; Ploug & Holm, 2016). However, when examined within the regulatory framework governing personal data and its use, these promises prove more symbolic than substantive when assessed against the requirements of the GDPR and related national frameworks. Although dynamic consent can satisfy the formal legal requirements for valid consent, it does not necessarily translate into substantive control over personal data in practice. This section explores the structural and legal reasons for that disconnect. It focuses on the limitations embedded in both the GDPR and national legal frameworks, showing how these constraints significantly weaken the ability of adaptive consent mechanisms to meaningfully empower research participants. Further discussion of these challenges can be found in Articles I–III.

1.3.2 Limitations within the GDPR framework

Consent to participate in research always operates within a broader legal architecture. Under the GDPR, personal data processing must rest on a predetermined legal basis. While consent is one such basis, it is not the only one. Where controllers, such as biobanks, rely on another ground, such as public interest, participant consent becomes legally irrelevant for the processing of personal data. In such cases, the individual's ethical consent to participate in research remains necessary for the use of samples, but it has no independent legal force for the associated data.

Even when consent is selected as the legal basis, its force is limited. Personal data may still be further processed under a different lawful basis, provided one exists under the GDPR or national law. Crucially, adaptive consent models cannot override this regulatory structure. The limited power of consent therefore arises both from the plurality of legal bases available under the GDPR and from supplementary provisions enacted by member states, which together define the conditions for lawful data processing in research.

The GDPR also sets out both the principles that govern personal data processing and the rights afforded to data subjects (here: research participants). As Staunton et al. (2022) observe, fulfilling these principles and rights is particularly challenging in the context of scientific research. This difficulty was anticipated during the drafting of the Regulation, which includes specific provisions allowing derogations – exceptions or modifications – from certain processing requirements and rights when processing is carried out for scientific research purposes. These derogations may be invoked either directly under the GDPR or through

supplementary provisions in member state or EU law, further limiting the ability of participants to exercise meaningful control.

As Pormeister (2018) points out, several elements of the GDPR are deliberately designed to facilitate research, even at the expense of individual control. First, Recital 33 permits broad consent to *certain areas of scientific research* when it is not possible to fully specify the purpose at the time of data collection. Second, the purpose limitation principle in Article 5(1)(b) allows further processing for compatible purposes – such as scientific or historical research, public interest, or statistical purposes – without renewed consent. Third, the storage limitation principle in Article 5(1)(e) relaxes temporal restrictions, enabling long-term retention of personal data for research, provided safeguards are in place. Together, these provisions facilitate extensive data reuse and long-term storage irrespective of participants' ability to give or renew specific consent.

In addition, Pormeister (ibid.) highlights the discretion granted to member states to shape the scope of data subject rights in research. Article 9(4) permits states to impose further conditions on the use of genetic, health, or biometric data. Articles 9(2)(j) and 89(2) allow them to introduce derogations from rights such as access (Art. 15), rectification (Art. 16), restriction (Art. 18), and objection (Art. 21) where their exercise would undermine research. National implementations illustrate this discretion vividly: Estonia's draft law gave controllers and processors wide latitude to restrict these rights; Germany codified explicit statutory limits; Austria, by contrast, required Data Protection Authority approval and an *important public interest* before such processing could proceed. For Pormeister, these examples show that the GDPR not only recalibrates consent but also structurally reconfigures individual rights in a way that prioritises research feasibility over participants' control.

Shabani and Borry (2018) further stress that this wide discretion has the potential to fragment the European research landscape, undermining the GDPR's harmonising purpose. They argue that while the Regulation provides a common framework, divergent national approaches to derogations and special categories of data create uncertainty for both researchers and participants in cross-border studies. To address these gaps, they highlight the importance of governance mechanisms – such as ethics review, controlled-access systems, and data security protocols – as more effective safeguards for protecting participants than consent mechanisms alone.

Staunton et al. (2022) similarly underline that derogations are not intended as blanket permissions. Rather, they must be accompanied by appropriate safeguards designed to preserve the essence of data protection rights and maintain trust in research. These safeguards may take the form of technical measures (such as pseudonymisation and robust security protocols), governance mechanisms (such as independent oversight by ethics committees), and procedural arrangements (such as transparency and accountability frameworks). Yet the GDPR leaves the content of *appropriate safeguards* largely undefined, delegating their elaboration to member states and institutions. Staunton et al. caution that this vagueness risks uneven protection across jurisdictions and generates uncertainty for researchers

and participants alike. At the same time, they argue that safeguards serve not only a legal function but also a practical one: they are essential for ensuring the legitimacy of research practices in circumstances where participants' ability to exercise direct control is structurally limited.

Whereas Pormeister (2018) interprets the GDPR's derogations and flexibilities as deliberate policy choices – a recalibration of autonomy in favour of enabling research – Staunton et al. (2022) and Shabani & Borry (2018) emphasise the risks of leaving safeguards vague and discretion unchecked, warning that such an approach undermines both participants' rights and public trust. The resulting tension highlights a central debate: whether the GDPR should be read primarily as a framework that supports scientific research while managing risks, or as one that compromises individual control in ways that remain morally troubling.

1.3.3 National frameworks and broader implications

Turning to specific laws under the Union or member states, the GDPR grants EU member states flexibility to specify and adapt certain provisions of the Regulation, particularly in relation to the processing of genetic data, biometric data or data concerning health (Art. 9(4)). This means that the processing of these special categories of personal data for scientific research purposes without the data subject's consent may be authorised under national law. For example, Germany permits such processing *without consent* under both federal and state data protection laws (e.g., Bundesdatenschutzgesetz BDSG §27, Landesdatenschutzgesetz DSG M-V §9). As a result, even if dynamic consent mechanisms were implemented and consent determined as the legal basis, their ability to confer meaningful control is constrained by these parallel legal authorisations, which allow data processing to proceed independently of the participant's ongoing consent.

Estonia offers another illustrative example. The Estonian Human Genes Research Act (HGRA) provides the statutory framework for the Estonian Gene Bank (i.e., Estonian Biobank), regulating the collection, storage, and use of donated tissue samples and associated health data. Under the HGRA, the Gene Bank acquires ownership of donated samples and related data (§ 15), and the processing of personal data is expressly governed by the Estonian Personal Data Protection Act (§ 7 HGRA).

The Personal Data Protection Act (DPA) permits processing for scientific or historical research and for official statistics *without consent* (§ 6(1) DPA) and authorises restrictions on key data-subject rights – including access, rectification, restriction, and objection – where their exercise would impede research (§ 6(6) DPA). Accordingly, even if consent were used as the legal basis for the initial processing of personal data, these provisions would permit downstream processing on independent statutory grounds while limiting individuals' ability to exercise control over future uses.

In light of such examples, it becomes clear that even well-intentioned adaptive consent solutions must operate within these structural constraints. Taken together, these limitations reveal that adaptive consent solutions, despite their ethical

appeal, may not meaningfully enhance participant control over personal data. In practice, such control is determined by legal and institutional frameworks, rather than by individual choice – a systemic feature recognised across multiple jurisdictions (cf. Dove & Chen, 2020). As a result, dynamic consent may overstate the extent of participant agency, as individuals are not legally empowered to veto all future uses of their data. While these systems may improve communication and engagement, they do not modify the legal infrastructure that governs how data are processed, reused, or shared. In this light, dynamic consent may operate more as a mechanism of reassurance than as a vehicle for genuine empowerment, creating an appearance of control without expanding the actual scope of decision-making.

That said, the legal possibility of bypassing consent in dynamic consent models does not imply that this outcome is inevitable. Research institutions and individual researchers may voluntarily choose to respect participants' preferences and seek renewed consent for new research purposes, even when not legally required to do so. The aim here is not to suggest that bypassing will always occur, but rather to highlight that it is legally permissible – an important fact that weakens the claim that dynamic consent mechanisms significantly enhance participant control.

In summary, adaptive consent solutions such as dynamic consent do not overcome the fundamental problem of uncertainty regarding the future use of data at the time consent is given. This issue is particularly acute in research contexts where data sharing is mandated by law or incentivised by funders, while ethical frameworks continue to require that participants be adequately informed about how their data will be used. By presenting an illusion of ongoing control without addressing the underlying governance structures, adaptive consent may be more problematic than broad consent. Although broad consent is often criticised for its vagueness and inability to reflect evolving preferences, it does not promise more than it can deliver. In this sense, broad consent may offer a more honest representation of participation, potentially encouraging more reflective and deliberate decision-making at the outset.

However, recognising that adaptive consent is not a better alternative does not resolve the moral concern for which broad consent has been criticised: that it undermines participant autonomy. Although often regarded as an ethically acceptable compromise, broad consent still raises valid concerns about the moral legitimacy of authorisation when access to potentially pertinent information is severely limited. Importantly, this concern is not confined to biobank research. In the open science era, consent to research participation increasingly resembles broad consent, particularly in that data are no longer siloed but stored and shared for future, unspecified uses.

However, it bears to note that the current debate focuses on the problem of missing information at the time consent is given. But is the absence of information truly even the core issue? A look at the history of human research reveals something more troubling: even in clearly defined and invasive studies, where relevant information was fully available to researchers, participants were not always adequately informed. These historical cases suggest that the ethical failure

often lies not only in absent information, but in the failure to communicate honestly. The following section turns to this history of disclosure failures to better understand the deeper roots of the moral challenges surrounding informed consent.

1.4 Ethics of disclosure – a historical perspective

This section situates contemporary debates on informed consent within a broader historical perspective by examining how failures of information disclosure have shaped the normative account of consent. While recent discussions in open science and biobank research frequently emphasise the absence of specific information at the time consent is obtained, the moral challenges surrounding disclosure are not exclusive to research contexts characterised by informational gaps. Historically, profound failures in informed consent have occurred in invasive, higher-stakes forms of research where the relevant information was fully available to researchers or research institutions but deliberately withheld from participants. These precedents suggest that the central moral concern lies not solely in whether information is available, but in how researchers and research institutions choose to engage – or fail to engage – with participants as autonomous moral agents. In many cases, acknowledging uncertainty and communicating it transparently may itself constitute a form of morally adequate disclosure. This theme recurs in Articles I–III of the thesis, each of which examines the moral implications of failing to disclose information that was available to researchers or institutions but not communicated to participants.

1.4.1 The emergence of informed consent in human research

The origins of informed consent as a normative ideal are closely linked to the historical development of human experimentation. As medical science aligned more closely with the experimental methods of the natural sciences at the end of the 19th century, research involving human subjects became increasingly common. In response to publicised instances of harm and exploitation, ethical debates emerged concerning individual self-determination and, with it, the nascent concept of informed consent (Elkeles, 2004, pp. 19–27).

Although the concept of consent in research predates World War II, articulated by figures such as Albert Moll (1902, pp. 564–565) and Walter Cannon (1916), it gained international prominence following the Nuremberg Trials, which exposed the systematic atrocities committed under the Nazi regime in concentration camps. The resulting 1947 Nuremberg Code codified voluntary consent as an ethical cornerstone of human research, stipulating that participants must possess legal and mental competence, be free from coercion, and receive sufficient information to make an informed decision. The *Declaration of Helsinki*, adopted by the World Medical Association in 1964, expanded upon this foundation by identifying specific categories of information, such as research aims, risks, and methods, that must be disclosed to prospective participants.

Despite these formal codifications, the implementation of informed consent has repeatedly fallen short of its ethical promise. Even in relatively controlled research environments with clearly defined aims, researchers have at times withheld or downplayed material information. These omissions have not always resulted from malice or negligence. Rather, they have often reflected a belief that full disclosure might compromise study outcomes or unduly alarm participants (The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1977, pp. 1–20). Nonetheless, practices that obscure the nature or purpose of a study undermine the moral legitimacy of the consent process. Compounding the issue, institutional review boards – charged with overseeing these processes – have occasionally failed to remedy such deficiencies, often due to ambiguity in regulatory guidelines or inconsistent interpretations of ethical norms (Faden & Beauchamp, 1986, pp. 211–212).

1.4.2 Consent failures

Several historical cases of failed consent illustrate the moral consequences of these shortcomings. The Willowbrook Hepatitis Study, conducted between 1956 and 1971 at a state institution for children with developmental disabilities, involved deliberately infecting children with a strain of hepatitis in order to test the efficacy of gamma globulin in preventing infection (Krugman, 1986). Although participation required parental consent, serious doubts remain as to whether parents were adequately informed about the long-term risks of hepatitis, including liver failure and cirrhosis (Beecher, 1970, p. 125; Robinson & Unruh, 2008, p. 82). The possibility that consent was obtained without meaningful disclosure casts doubt on the moral legitimacy of the research.

A similarly troubling example is the 1963 Jewish Chronic Disease Hospital (JCDH) study, in which researchers in Brooklyn injected live cancer cells into 22 chronically ill patients to study immune responses to foreign tissue. Patients were told they would receive *some cells*, but the term *cancer* was deliberately omitted, and the experimental nature of the procedure was not disclosed. Researchers defended this omission by arguing that the intervention posed minimal risk (Langer, 1964). Nevertheless, by concealing essential facts, they deprived participants of the opportunity to make an informed decision.

More recently, in the late 1990s, the CDC and NIH conducted placebo-controlled AZT trials on HIV-positive pregnant women in Thailand, the Dominican Republic, and several African countries. Despite existing evidence that AZT significantly reduced mother-to-child transmission of HIV, participants in these trials were not informed that they might be placed in a placebo group and thereby denied effective treatment. Official records claimed that participants were made aware of the risks and benefits, but investigative reporting suggested that critical information had been obscured or omitted altogether. (Dyckman, 1999). As in the earlier examples, consent was formally documented but remained morally deficient.

These cases collectively underscore that failures in informed consent often stem not from a lack of information, but from a failure to disclose relevant information out of paternalism, institutional expediency, or indifference. As Kelman (1967) observed, such failures reflect a deeper moral discontinuity between how individuals are treated in everyday ethical life and how they are treated within research contexts. Acts of concealment, misdirection, or selective disclosure, however well-intentioned, undermine the foundational ethical premise that participants are entitled to make informed decisions about their involvement in research.

As already noted, the emergence of data-intensive research paradigms has introduced a new challenge: the absence of specific information at the time of consent. While such paradigms differ from traditional experimental models, they involve ethical concerns surrounding information disclosure. Yet the problem is not simply the absence of information about future research. Rather, it lies in whether researchers and research institutions acknowledge this uncertainty honestly. As data reuse, long-term storage, and institutional complexity become defining features of the contemporary research landscape, the moral legitimacy of consent will increasingly depend on the quality of the consent process rather than the completeness of information provided at a single point in time.

This historical and conceptual trajectory sets the stage for a deeper examination of what renders consent morally transformative. If the problem lies less in informational gaps and more in the quality of the consent process itself, then the question becomes how consent morally transforms the permissibility of actions that would otherwise be impermissible. The following section turns to this normative dimension, exploring competing philosophical accounts of morally transformative consent and their implications for informed consent in data-intensive research.

At the same time, these cases point to a deeper moral concern: when consent is secured through inadequate or misleading disclosure, one may legitimately ask whether the researchers and institutions who received it were ever morally entitled to act on it. The underlying intuition is that, by proceeding under such conditions, they wronged the participants – treating them as mere means rather than as autonomous agents. This concern leads directly into the next section, which examines the moral basis of consent's transformative power.

2 MORALLY TRANSFORMATIVE CONSENT

In bioethics, informed consent has traditionally been framed as a means of protecting and promoting participant autonomy. This view is most prominently articulated by Ruth Faden and Tom Beauchamp in their seminal work *A History and Theory of Informed Consent* (1986), where they stipulate that morally transformative consent requires intentional authorisation, substantial understanding of material information[4], and freedom from controlling influences[5]. On this model, hereafter referred to as the *autonomy-based model*, the moral legitimacy of research turns on whether participants have voluntarily and intentionally authorised it.

As Franklin Miller and Alan Wertheimer (2010, p. 83) observe, consent is widely understood to have the normative function of rendering an otherwise impermissible action permissible. The point of disagreement is not about whether consent can have this transformative effect, but about *why* and *under what conditions* it does so. Whereas autonomy-based accounts hold that moral transformation depends on the consent-giver's internal states – such as intentionality, understanding, and voluntariness – Miller and Wertheimer argue that it depends instead on whether the consent transaction is fair. On their view, the moral force of consent arises when the consent-receiver can rely on a fair process, regardless of whether autonomy-based conditions are fully met.

A clarification of terminology is needed here. Faden and Beauchamp (1986) use the term *informed consent* to refer to what Miller and Wertheimer (2010) would call *morally transformative consent*: consent that makes an otherwise impermissible act permissible by altering the normative relationship between researcher and participant. For Faden and Beauchamp, this transformative power arises only where autonomy conditions of intentional authorisation, understanding, and voluntariness are satisfied. Miller and Wertheimer, however, separate these ideas. They reserve the term *morally valid consent* for consent that meets autonomy conditions, while defining *morally transformative consent* as consent that actually provides the moral warrant to proceed, which depends on whether the transaction as a whole is fair. This thesis adopts Miller and

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[4] According to Faden and Beauchamp (1986, p. 302), substantial understanding requires grasping all facts the participant considers material to the decision to participate, even if not directly relevant to the proposed activity. This reflects the *subjective standard* of disclosure, whereby participants should receive information they themselves deem material. Yet, as Faden and Beauchamp note (pp. 305–308), in reality, this standard proves inadequate: participants may be unaware of facts they may want to know before consenting. They therefore expand the disclosure requirements to include not only what participants regard as material, but also what researchers judge to be material, as well as the information needed to establish the purpose of seeking consent.

[5] Rather than arguing for this account, Faden and Beauchamp offer it as a conceptual foundation for the analysis of informed consent.

Wertheimer's terminology, while recognising that Faden and Beauchamp effectively collapse validity and transformation into a single category.

This section proceeds as follows. Section 2.1 begins by examining the autonomy-based account of informed consent. On Faden and Beauchamp's standard view, moral transformation depends on the consent-giver's mental state – an internalist position, as defined in this thesis, because it locates the transformative force of consent in the individual's internal conditions of intention, understanding, and voluntariness. In data-intensive contexts, however, where project-specific information is unavailable at the time of agreement, such conditions are rarely met. Section 2.2 addresses this dilemma: either much research proceeds without moral warrant, or the criteria for morally transformative consent require revision.

Section 2.3 introduces Miller and Wertheimer's transactional account, which this thesis treats as an externalist model, because moral transformation here hinges on factors external to the consent-giver's mental states – namely, factors that can render the consent procedure fair. On this view, broad consent in biobanking and open science may still be morally transformative if the procedure is transparent and fair. Finally, Section 2.4 presents and responds to key objections to the transactional framework, thereby clarifying how the transactional and autonomy-based models can be understood as complementary – treating fairness as necessary and autonomy conditions as contextually required.

2.1 Autonomy-based (internalist) model

Drawing on various literatures on law, policy, and institutional guidelines, Faden and Beauchamp (1986, p. 235) argue that the purpose of asking people for informed consent in research is to respect their right to make their own decisions about research participation. In other words, informed consent is a way to put the idea of respecting a person's autonomy in making their own choices into practice. Accordingly, they contend that, in its most authentic sense, informed consent constitutes a kind of autonomous action – an interpretation that has become the standard view in bioethics.

What, then, makes an action autonomous? Faden and Beauchamp (ibid., pp. 238–239) adopt the view that autonomous action is characterised by three key features: intentionality, understanding of material facts, and freedom from external control – each necessary and jointly sufficient condition for autonomy. However, in their analysis, informed consent is not simply synonymous with autonomous action. What distinguishes it as a distinctive *kind* of autonomous action is its normative power: informed consent involves the act of authorising another to carry out a proposed intervention or course of action.

It is worth noting that Faden and Beauchamp (1986, pp. 238–240, 277–278) do not portray informed consent as something that can, in practice, be given with *complete* understanding and in *total absence* of external influence. Rather, they acknowledge that real-world instances of consent often fall short of ideal

autonomy yet still argue that informed consent should approximate this standard closely enough to retain moral significance. Accordingly, they contend that informed consent occurs only if it is given intentionally, with *substantial* understanding of material facts, and in *substantial* absence of controlling influences. If even just one of the conditions is not met, consent does not constitute an autonomous authorisation and therefore, informed consent does not obtain – even if the consent procedure complies with institutional standards. On their view, any subsequent action would proceed without informed consent and therefore would lack moral warrant.

This distinction is further underscored by Faden and Beauchamp's (ibid., p. 275) explicit refusal to equate informed consent with information disclosure or other procedural elements of consenting, such as uttering *I consent* or signing a document. In other words, although they characterise informed consent as a type of autonomous *action*, they do not reduce it to overt behaviour. It can thus be inferred that Faden and Beauchamp view informed consent essentially as a mental state: it occurs only when a participant understands a set of material facts about the research, and based on this understanding, freely and deliberately chooses to participate. In other words, on Faden and Beauchamp's account, informed consent is grounded in the internal cognitive and volitional states of the consent-giver.

Faden and Beauchamp's (ibid., p. 302) analysis further suggests that informed consent, as a mental state, is not simply a fleeting sense of agreement with a proposal, but a considered decision grounded in an understanding of what one is being asked to authorise. According to them, "*the condition of substantial understanding demands apprehension of all the material or important descriptions…*", which implies that informed consent is directed at a description of the proposed action, which in turn suggests that it is a mental state of a particular kind: a propositional attitude.

On this view, consent is akin to other propositional attitudes such as belief, desire, hope, or fear. Just as one does not simply believe something, but believes *that something is the case*, one does not simply consent to something, but consents to *something being the case*. In this sense, consent is always directed toward a description of the proposed action, rather than the action itself. For example, a person may agree to participate in a research study on the understanding that it involves only minimal risk and that confidentiality will be maintained. What she is consenting to, then, are not the physical procedures as such, but the described version of those procedures and their implications. This conception of consent as a propositional attitude is also supported by O'Neill (2001), Hurd (1996), and Alexander (1996), who each argue that consent is fundamentally an intentional mental state directed at the content of a proposal.

In sum, Faden and Beauchamp (1986) have stipulated that informed consent in the moral sense is an autonomous act in which the consent-giver intentionally authorises the proposed action with substantial understanding of material facts and with substantial absence of external influence. This section has argued that, based on this widely accepted characterisation of informed consent, consent is essentially a mental state of a specific kind – namely, a propositional attitude.

This raises the question: if informed consent is, ontologically speaking, a propositional attitude, what are the normative implications for broad consent, which entails consenting in the absence of potentially pertinent information? The next section addresses this question.

2.2 Normative implications for broad consent

According to Faden and Beauchamp (1986, p. 280), the moral significance of informed consent, understood as autonomous authorisation, is that it provides moral warrant for the consent-receiver to proceed with the proposed action. This presupposes that the individual's mental processes, such as intentional decision-making, substantial understanding, and voluntary choice, must be present for moral transformation to occur. Whether the consent-receiver is morally justified in proceeding on the basis of consent depends on the extent to which these internal conditions of autonomous choice are satisfied.

What does this mean for the practice of requesting *broad* consent for an open-ended range of research purposes? Broad consent, as explained in Section 1.2.1, involves agreeing to the future use of one's data or biological materials in research projects that have not yet been designed, described, or approved. As such, it constitutes consent to an undefined set of future studies on the basis of superficial and general information, often limited to broad categories of research or institutional safeguards. On Faden and Beauchamp's view, however, morally transformative informed consent requires substantial understanding of material facts that are crucial for the decision at hand. Since potentially material information is unavailable at the time of broad consent, participants cannot achieve this substantial understanding. Neither they nor the consent-receiver has access to such facts, and therefore the opportunity to make a genuinely informed and autonomous decision is absent. It follows directly from Faden and Beauchamp's account that broad consent cannot qualify as informed consent and is therefore not morally transformative.

This conclusion becomes even clearer when considered through the lens of Faden and Beauchamp's (1986, pp. 240, 277) conception of informed consent as a propositional attitude. As explained in the previous section, they view informed consent as not reducible to observable acts such as signing a form or uttering *I consent* but is instead a considered mental state directed at a description of the proposed action. The content of that description – the proposition to which consent is given – must include the material facts the individual considers relevant, as well as those the consent-receiver ought to regard as material to the decision. If these facts are missing, the propositional content is too underspecified to support the deliberative mental state of consent. In other words, the moral force of informed consent depends on the quality of the proposition itself: what is being consented to must be meaningfully described. Where the description is too vague, as in broad consent, the mental state of consent loses its normative force.

Nonetheless, Faden and Beauchamp (ibid., p. 280) themselves still allow for the possibility that consent-givers could authorise broadly, permitting consent-receivers to act within general guidelines even when specific future uses are not yet determined. This is a striking inconsistency: the very conditions Faden and Beauchamp set for morally transformative informed consent rule out broad consent, yet they nevertheless leave the door open for it.

In later work, however, Beauchamp's position appears to have shift. In publications such as Beauchamp (2011) and Beauchamp and Childress (2019, pp. 200–202), he expresses scepticism about the sufficiency of general information at the time of consent. This growing concern seems to have been shaped, at least in part, by high-profile cases such as that of the Havasupai Tribe in the 1990s. In that case, Tribe members believed they had consented to participate in research narrowly focused on the genetics of diabetes. They later discovered, however, that the samples had been used in studies on schizophrenia, inbreeding, and population migration. While these additional projects did not exceed the legal scope of the consent – as the tribe members had signed a broad consent document – participants experienced them as going far beyond what they understood themselves to have agreed to. These topics not only departed from their expectations but also came into direct conflict with their cultural values and self-understanding and were further perceived as stigmatising. The case illustrates how vague and broadly framed disclosures may be interpreted to authorise unanticipated – and, at times, objectionable – uses of data and samples, even where the formal consent requirements are met. A more detailed discussion of the Havasupai case is provided in Article I.

Although Beauchamp does not explicitly reject broad consent, his later reflections suggest a deepening recognition that, in the absence of specific information, broad consent is unlikely to meet the standard of informed consent as autonomous authorisation. This conclusion, however, raises an important question: if broad consent cannot meet the standards of morally transformative informed consent as defined by the autonomy-based model, does this imply that research involving data sharing and reuse inevitably lacks moral justification? Not necessarily. The fact that broad consent falls short of autonomy-based criteria does not, on its own, entail that researchers and institutions engaging in such practices are acting immorally. It is entirely coherent to acknowledge that broad consent fails to satisfy the internalist conditions of autonomous authorisation while still maintaining that research based on broad consent can be morally justified. To explore this possibility, the following section introduces a transactional theory of consent – an externalist account that shifts the focus from internal mental states to the outward, procedural features of the consent process itself.

2.3 Transactional (externalist) model

This section distinguishes two related but separable questions: (i) what informed consent is – an act of autonomous authorisation grounded in intention, understanding, and voluntariness; and (ii) when consent is morally transformative – that is, when it becomes permissible to act on consent. Miller and Wertheimer (2010, p. 94) accept (i) as a descriptive account of what consent is, but argue that (ii) turns on the fairness of the transaction rather than solely on whether the autonomy-based conditions are satisfied. Articles II and III extend this transactional perspective by examining whether fairness is realised in practice: Article II analyses how biobank consent documents communicate the lawful range of data uses under the GDPR, and Article III investigates how withdrawal rights are presented to participants.

The previous section argued that broad consent does not meet the standards of informed consent understood as autonomous authorisation. If the autonomy-based account is accepted as the sole basis for moral legitimacy, it follows that research relying on broad consent inevitably lacks moral warrant. However, this conclusion rests on the assumption that autonomy-based conditions are the only valid criteria for moral transformation. On the view defended here, autonomous authorisation is morally important but not strictly necessary or sufficient for moral transformation across contexts. By contrast, a fair consent context is always necessary and sometimes sufficient – because what fairness requires can include, and in high-risk settings effectively demands, robust approximations of the autonomy conditions. This section challenges the assumption that autonomy-based conditions alone determine moral legitimacy by demonstrating that the internalist standard becomes implausible when applied across different consent scenarios. To explore a more context-sensitive alternative, it turns to the transactional account of consent developed by Franklin Miller and Alan Wertheimer (2010).

This application of Miller and Wertheimer's transactional theory to the issue of broad consent represents a novel contribution to the existing literature. While their account has been influential in challenging autonomy-based models of consent more broadly, it has not, to current knowledge, been applied to evaluate the moral permissibility of broad consent in the context of open science and biobank research. The account is used here for two purposes: first, to challenge the sufficiency of the autonomy-based model of consent as articulated by Faden and Beauchamp, and second, to provide a more context-sensitive ethical framework for assessing the moral force of broad consent in contemporary research settings. By extending their framework to this domain, the aim is to demonstrate how consent can retain its moral force even when it departs from the internalist standards of intentionality, understanding and voluntariness, provided the consent transaction meets broader standards of fairness.

This analysis does not propose a revision or extension of Miller and Wertheimer's account. Rather, it draws on their framework to demonstrate the conceptual and normative limitations of Faden and Beauchamp's internalist model.

In particular, the autonomy-based conditions they propose are shown to be neither necessary nor sufficient for morally transformative consent. Miller and Wertheimer's approach helps to make sense of real-world scenarios where moral justification persists despite failures to meet these internalist criteria. This shift is instructive in assessing the moral force of consent when potentially material information is not available at the time of consent.

What is gained by adopting this perspective is the recognition that moral transformation in consent is not reducible to the presence or absence of psychological states in the consent-giver. Instead, it must be understood in terms of the fairness of the consent process and the specific relational obligations it entails. When applied to broad consent, this suggests that, even though such consent falls short under the autonomy-based framework, it can still be morally transformative if embedded within a context of transparency, mutual responsibility, and institutional fairness. In short, the Miller and Wertheimer model enables us to see that morally transformative consent is still possible in open science, even when autonomy conditions are only partially met, provided the transaction is fair. The implications of this model are explored in Article III, which investigates how withdrawal rights are communicated in biobank consent documents and whether they provide participants with a fair understanding of their options.

2.3.1 Miller & Wertheimer's challenge

Miller and Wertheimer (2010, pp. 80–81) draw attention to the fact that consent always takes place in specific contexts, shaped by social norms, roles, and expectations. They argue that moral transformation depends on these contextual elements, which ultimately determine whether consent carries moral legitimacy and permissibility, rather than on abstract autonomy-based conditions meant to apply uniformly across all cases.

While Miller and Wertheimer (ibid.) accept Faden and Beauchamp's (1986) description of informed consent as an act of autonomous authorisation, they challenge their assumption that autonomy-based conditions ground moral transformation. Their strategy is to show – by applying these conditions across a range of ordinary, everyday consent contexts – that such conditions are neither necessary nor sufficient for moral transformation. Their point is not to replace the autonomy model of what consent is, but to deny that its internal conditions settle when acting on consent is permissible. A consent transaction may still give the consent-receiver moral warrant to proceed even if the consent-giver lacks full intentionality, substantial understanding of material facts, or complete freedom from external influence. Conversely, the mere fulfilment of autonomy-based conditions does not automatically secure moral legitimacy.

The core claim of Miller and Wertheimer's theory of consent is that even when consent either fulfils or falls short of autonomy-based criteria, it still remains an open question whether the consent transaction is morally transformative. It is fundamentally a moral question – not an empirical one – whether the consent transaction renders it permissible for the consent-receiver to proceed.

To illustrate this point, consider the following four examples by Miller and Wertheimer (2010):

> *Department meeting.* A, a department chair, says, "*I'm going to appoint C to our new position unless anyone objects*". B is daydreaming and says nothing. A assumes that B has authorized him to appoint C. (Miller & Wertheimer, 2010, p. 85)

> *Trust.* A tells B, that B has breast cancer, and that she needs a surgery. As A begins to explain the options, B interrupts her and says: "*I trust you. Do whatever you think is best*". (Miller & Wertheimer, 2010, p. 87)

> *Pressure.* A tells B that due to B's health condition, he is facing a choice between death and consenting to surgery. B chooses surgery. (Miller & Wertheimer, 2010, p. 92)

> *Intentional non-disclosure.* A decides not to disclose B information about the risks involved in a clinical trial because A fears that B might refuse consent due to the overestimation of the importance of those risks. However, unbeknownst to A, B has managed to acquire information about the risks elsewhere, understands the information and gives consent to participate in the trial with substantial understanding. (Miller and Wertheimer, 2010, p. 100)

Through the three cases of *Department Meeting*, *Trust*, and *Pressure*, Miller and Wertheimer intend to demonstrate that the autonomy-based conditions proposed by Faden and Beauchamp are not *necessary* for moral transformation to occur. On Faden and Beauchamp's account, A would not be permitted to proceed in any of these cases, as the conditions for autonomous authorisation – intentionality, substantial understanding, or voluntariness – are not met. By contrast, Miller and Wertheimer's account allows that A may permissibly proceed in all three cases. In *Department Meeting*, B does not intend to authorise A to appoint C to the new position, yet A has every reason to believe that B does, making it permissible for A to proceed. In *Trust*, B consents to surgery while deliberately choosing not to receive full information about her options. Although this falls short of autonomous authorisation, it would be implausible to conclude that A is acting impermissibly by performing the operation. In *Pressure*, B technically faces a choice between two options, but only one is realistically viable. Still, A's decision to rely on B's consent can be morally justified, even if that consent lacks full voluntariness.

Nor are the autonomy-based criteria jointly sufficient. *Intentional Non-Disclosure* presents a case in which B's consent satisfies all the autonomy-based criteria, yet it remains highly questionable whether A is permitted to proceed, given that A has attempted to deceive B. Since A has intentionally withheld potentially relevant information and does not know whether B's consent is, in fact, substantially informed, A should not be permitted to act – despite the fact that B's consent constitutes an autonomous authorisation.

These four cases illustrate why autonomy conditions, while morally important, do not by themselves settle when it is permissible to act on consent. What does the normative work, on this account, is whether the transaction is fair.

Taken together, the cases also show how autonomy-based criteria, when applied across diverse consent contexts, tend to produce counterintuitive results. In *Department Meeting*, *Trust*, and *Pressure*, the criteria would render seemingly reasonable and morally acceptable actions impermissible, whereas in *Intentional Non-Disclosure*, they would suggest that clearly deceptive or problematic behaviour on the part of the consent-receiver has no bearing on the moral permissibility of proceeding.

Just as importantly, the cases highlight the bilateral nature of consent relations. Consent is not exhausted by the internal capacities or choices of the consent-giver but also imposes obligations on the consent-receiver, who must interpret silence, trust, or pressure responsibly and must not exploit gaps in information or understanding. At the same time, the consent-giver also bears responsibility: to take reasonable steps to understand what they are asked to authorise. These mutual responsibilities are integral to how consent functions in practice but are largely ignored by Faden and Beauchamp's autonomy-based account, which frames the legitimacy of consent solely in terms of whether certain internal conditions of the consent-giver are met. Miller and Wertheimer's approach, by contrast, foregrounds this relational dimension, showing that the moral force of consent depends on both parties fulfilling their respective roles within a social practice.

Notably, the disconnect between autonomy-based theory and consent as a social practice is not merely theoretical. Empirical studies of participant comprehension consistently show that participants often exhibit variable and frequently poor levels of understanding of key facts, including expected risks and the experimental nature of treatments, and yet it is not considered impermissible for the consent-receiver to proceed – or at least these findings have not sparked moral panic or led to systematic requirements for checking comprehension before enrolment.

A systematic review by Pietrzykowski and Smilowska (2021) found that participants in clinical trials generally understood well the research purpose (70–100%) and voluntary participation (54–96%), with comprehension varying by study and location. However, many had difficulty understanding key aspects like randomisation (10–96%), placebo (13–97%), risks (7–100%), benefits (36–97%), and alternative treatments (over 30% unaware). Only a small proportion (14.3%) demonstrated high knowledge of all components, while a significant number overestimated their understanding or did not fully read the consent form.

In the context of biobank research, Eisenhauer et al. (2019) conducted a systematic review of participants' comprehension of key aspects of research participation and found that participants generally had poor understanding of critical elements such as risks, alternatives, and confidentiality. While participants generally understood well that their participation was voluntary and that they would not be compensated for commercial products resulting from their biospecimens, understanding of other biobanking-specific aspects, such as the nature of genetic data, was particularly poor. The review also revealed significant variability in

understanding, influenced by factors such as education, recruitment setting, and the method of disclosure. Additionally, four of nine qualitative studies (44%) selected for the review reported inadequate understanding, while others described participants as "*confused*" or "*ambiguous*" about the information.

These deficits, whether due to participant inattention, limited background knowledge, or inadequate communication by researchers, have not provoked widespread condemnation of human subject research. As Joseph Millum and Danielle Bromwich (2021) observe, human subjects research continues to be regarded as ethically permissible, suggesting that real-world judgments about moral legitimacy are not closely tied to participants' internal cognitive states.

Further evidence for this view comes from an experiment by Laura Beskow and Kevin Weinfurt (2019), cited by Millum and Bromwich (2021), which examined research ethicists' willingness to exclude prospective biobank tissue donors who failed to adequately understand key information. While there was strong agreement (≥70%) among ethicists about which facts were essential for informed participation, when confronted with data showing that one-third of donors did not demonstrate adequate understanding, half of the ethicists were nonetheless willing to include them in the research. Beskow and Weinfurt conclude that the understanding requirement should be regarded as an ethical aspiration rather than a strict prerequisite. This finding reinforces the view that, even among experts, internalist criteria do not consistently determine moral permissibility in practice. Yet autonomy-based criteria continue to go largely unquestioned in the bioethics literature, where they are still widely treated as the normative gold standard for morally transformative consent.

2.3.2 Moralised consent

For clarity, the remainder of this discussion will treat the two models as complementary rather than mutually exclusive: the autonomy account specifies the concept of informed consent, while the transactional account specifies when consent morally transforms permissions. Fairness is always necessary; autonomy conditions are required to the extent that fairness in context demands them.

The underlying issue lies in how the Faden and Beauchamp framework predefines fixed criteria for moral transformation to be applied uniformly across diverse consent contexts. These criteria – intentionality, substantial understanding, and voluntariness – are understood as thresholds, and determining whether they are met is treated as an empirical task. Faden and Beauchamp (1986, p. 239) explicitly portray substantial understanding and voluntariness as scalar concepts: they can be represented along a continuum, with informed consent deemed present once it surpasses a minimum level of each.

While these thresholds may be morally significant, the process of determining whether consent is morally transformative is ultimately framed as a matter of verifying whether these conditions are satisfied. The contrast at stake here is not whether Faden and Beauchamp's conditions are moral – they clearly are – but rather a methodological difference in how moral permissibility is assessed. Their

approach treats this as an empirical question. By contrast, the Miller and Wertheimer framework treats moral transformation as context-sensitive and *irreducibly moral* – that is, it cannot be reduced to the presence or absence of specific internal psychological states. Instead, it requires a normative judgment about the fairness of the consent transaction as a whole, taking into account the social roles, responsibilities, and power dynamics involved. On this view, whether consent morally legitimises action is always a question of moral justification, not merely empirical verification.

One way to clarify this contrast is by examining how consent functions in justificatory reasoning. Consider the following argument schema provided by Wertheimer (2000):

Major premise:	If and only if B gives consent to A to do X, it is (ceteris paribus) permissible for A to do X.
Minor premise:	B gives A consent to do X.
Conclusion:	It is permissible for A to do X.

To assess whether the conclusion is warranted, one must determine whether the minor premise is true – that is, whether B has, in fact, given informed consent. Within the Faden and Beauchamp's framework, this question has been interpreted as a quest for conceptual analysis of consent, which can identify the necessary and sufficient conditions for informed consent. Once these conditions are established, the task then becomes one of checking whether they are met – essentially, a box-ticking exercise to determine whether A's action is permissible.

This type of framing the conditions for moral transformation explains why Faden and Beauchamp's autonomy-based conditions produce counterintuitive results when applied across different consent contexts. The issue here is not that this particular analysis of informed consent gets wrong the *meaning* of informed consent. Rather, the problem lies in the assumption that satisfying a set of pre-established conditions is necessary and sufficient, in and of itself, to render consent morally transformative. As Wertheimer (2000) puts it: "*It is a mistake to think that we can resolve the moral and legal issues in which we are interested by an analysis of the "meaning" of consent*".

These observations suggest that what is ultimately at stake in moral transformation is not merely whether certain psychological conditions are met, but whether the consent was obtained and given in a manner that is morally adequate to justify proceeding. Miller and Wertheimer (2010, pp. 81, 95) argue that consent transactions must be *fair* in order to be morally transformative. What fairness requires, however, depends on the context in which consent is given. In the context of scientific research, where information asymmetry is often significant between the research participant and the researcher, fairness may require that the more knowledgeable party make pertinent information available and accessible to the less knowledgeable one. Transparency is one important aspect of fairness in such settings, but it is not the only one. In high-risk research, for example, when comparing an experimental molecule with a standard treatment, fairness

might additionally require that researchers actively assess whether participants have understood the information provided. By contrast, in lower-risk research contexts, it may not be necessary for fairness that researchers verify participant comprehension to the same degree, provided they have taken reasonable steps to facilitate adequate comprehension.

Faden and Beauchamp would likely agree with many of these procedural responsibilities, as their framework emphasises the ethical duty to support autonomy through adequate disclosure. However, in their model, the moral legitimacy of consent ultimately turns on whether internal psychological criteria are satisfied. By contrast, the Miller and Wertheimer framework treats these conditions as insufficient by themselves. It holds that whether consent is morally transformative depends on a broader moral assessment of the fairness of the consent process, taking into account contextual features such as risk level, institutional norms, and the social roles of the parties involved. On this view, the permissibility of acting on consent is not determined by internal thresholds alone but requires a context-sensitive moral judgment about how the consent was obtained.

An important implication of this moralised theory consent is that *broad consent* can be considered morally transformative, even in the absence of specific information about future uses of samples and data at the time of consent. As long as the consent-receiver is transparent about the nature and implications of research participation and ensures that this information readily accessible to the potential consent-giver, the consent provided under these circumstances can be considered morally transformative. Rather than collapsing into *mere consent*, as some critics worry, broad consent in this framework functions as a decision to delegate future choices, provided that delegation is itself made transparent and fair (Sheehan 2011).

In sum, the core insight derived from Miller and Wertheimer's theory is that consent always occurs within a relational context, where both parties – the consent-giver and the consent-receiver – bear specific responsibilities. In research contexts, the consent-giver is typically expected to familiarise herself with the key facts about the proposed research and to signify consent in the agreed manner. The consent-receiver, in turn, is responsible for ensuring that the consent-giver is legally competent and for providing relevant information about research participation in an accessible and comprehensible way. Fairness, on this account, is supported not only by disclosure but also by institutional safeguards such as review boards, data protection frameworks, and regulatory oversight. Nevertheless, this moralised account of consent has not gone unchallenged. The next section considers key objections to Miller and Wertheimer's transactional model of consent.

2.4 Objections to the transactional theory

This section addresses key objections to Miller and Wertheimer's transactional theory of informed consent. It explores concerns regarding the model's conceptual foundations, its treatment of fairness, and its practical applicability in ethically

complex research settings. This does not sideline autonomy entirely: the autonomy model continues to provide the regulative ideal of what informed consent is, while the transactional model explains when that consent can permissibly ground action.

A useful starting point is the response of Beauchamp and Childress (2019, p. 121), who acknowledge that the transactional model offers a reasonable framework for evaluating whether institutional or procedural requirements for informed consent have been satisfied, for example, whether consent forms are properly completed or whether researchers have followed established protocols. However, they are critical of Miller and Wertheimer's attempt to replace the autonomous authorisation model with the transactional model as the basis for determining when consent is morally transformative. Without offering a detailed argument, they write: "*We see no justification for their claims that their model merits adoption in place of the autonomous authorization model and that consent is a bilateral transaction rather than the one-sided focus on the quality of the subject's consent to which the autonomous authorisation model is committed.*" While they acknowledge that bilateral informational exchanges often occur during consent processes, they maintain that such exchanges do not constitute the core of informed consent. In their view, informed consent cannot be reduced to transactional dynamics without losing sight of its defining moral structure.

This concern about the transactional model displacing, or at least overshadowing, the normative force of individual autonomy is developed further in the work of Taylor (2013) and Jansen (2020). Taylor questions whether the model rests on a sufficiently robust account of fairness, while Jansen worries that its emphasis on procedural dynamics may inadequately protect participant autonomy, particularly in high-risk research. Together, their critiques highlight the risks of shifting the moral foundation of consent from internal states of autonomy to external conditions of procedural and relational fairness.

Taken together, the critical responses from Beauchamp and Childress, Taylor, and Jansen help to clarify what is at issue. As discussed in Section 2.3, Miller and Wertheimer argue that the autonomy-based conditions proposed by Faden and Beauchamp are neither necessary nor sufficient for consent to be morally transformative: they show that action may permissibly proceed even when autonomy conditions are not fully met (e.g. *Department Meeting*, *Trust*, *Pressure*), and that these conditions may be satisfied even when acting on the basis of consent can be considered impermissible (*Intentional Non-Disclosure*). On their view, autonomous authorisation still captures the concept of informed consent, but moral transformation depends on whether the transaction is fair. Fairness is always required, whereas the autonomy conditions apply only when fairness in context demands them – for instance, in high-risk clinical trials, where greater participant comprehension may be required, but not necessarily in lower-risk settings such as biobanking or open-science data reuse, where institutional safeguards may suffice.

2.4.1 Conceptual and practical concerns: Taylor's critique of fairness and consent

Taylor (2013) observes that while Miller and Wertheimer's transactional model of consent offers a valuable corrective to certain limitations of Faden and Beauchamp's autonomy-based account, it remains underdeveloped at the conceptual level, particularly with respect to the concept of fairness. He contends that the model lacks a substantive account of what constitutes fair terms of cooperation, which raises concerns about its normative clarity and practical applicability.

Miller and Wertheimer (2011) acknowledge the absence of a comprehensive theory of fairness, though they do not explicitly present this as a deficiency requiring resolution. Instead, their model draws on a common-sense understanding of fairness, grounded in widely shared moral intuitions concerning coercion, deception, and exploitation in research contexts. This approach bears some resemblance to Thomas Scanlon's (1998, p. 153) contractualist reasoning, insofar as it appeals to socially embedded moral understandings and rests on the assumption that moral principles, such as those governing morally transformative consent, derive their normative force from judgments that no reasonable person could reject. In both frameworks, the moral content of fairness is shaped less by theoretical deduction than by reflection on socially recognised norms.

Taylor's concern about the model's conceptual grounding is particularly focused on its practical implications. Yet it is not self-evident that a fully developed theory of fairness is necessary for the transactional model to function effectively in real-world research settings. Practical reasoning often proceeds in the absence of comprehensive theoretical frameworks. Judgments about fairness, like those about justice, are routinely made in legal, political, and everyday contexts by reference to tacit norms and shared understandings. Justice, for example, is frequently operationalised through procedural rules and mechanisms, such as due process, without presupposing a complete theory of justice. In much the same way, fairness in practice often involves adherence to established procedures and norms. This procedural orientation is already embedded within research ethics, where review bodies assess consent on the basis of criteria such as transparency, voluntariness, and proportionality – none of which require fully articulated theoretical accounts for these bodies to function.

Of course, the absence of a unified theory does not eliminate the possibility of disagreement. Equally, even the presence of a unified theoretical account would not resolve all disagreement, since disputes about what is fair or just frequently persist despite shared frameworks. Questions about fairness are bound to arise when common understandings are lacking or when competing conceptions persist despite extensive deliberation. Such challenges are familiar across moral, legal, and political domains and are typically addressed through institutional procedures – majority decisions, legal precedent, or reasoned compromise. In this respect, the transactional model aligns well with a broader tradition of practical reasoning. Its strength lies not in conceptual completeness but in its responsiveness to the normative complexity of real-world consent practices.

Taylor further argues that the transactional model does not constitute a theory of consent in a strict sense but rather offers a framework for determining when apparent consent may be relied upon. He suggests that this orientation risks conflating procedural verification with the act of consenting itself, potentially diluting the normative significance of informed consent, especially in high-risk research where understanding and voluntariness carry heightened moral weight. While this concern raises important questions, it may reflect a reading that does not fully capture the model's internal distinctions. Miller and Wertheimer explicitly differentiate between the ontology of consent as autonomous authorisation and the normative conditions under which it is permissible to act on such consent. Their model does not seek to redefine the meaning of consent but instead to foreground the fairness of the consent transaction, understood relationally and in context.

2.4.2 Proceduralism and participant agency: Jansen's critique of the transactional model

Jansen (2020) raises concern that the transactional model of informed consent undermines the very point of consent by equating procedural fairness with moral transformation. More precisely, her concern is that consent is treated as morally transformative whenever the investigator has acted fairly, even if the participant has not genuinely understood or appreciated what the information means for her. Jansen's position, by contrast, can be interpreted as holding that the decisive question is not whether the researcher acted fairly, but whether the participant truly understood what she agreed to. For her, the essence of informed consent lies in the participant's internal states of voluntariness, understanding, and appreciation of disclosed information. No amount of procedural correctness can compensate for a failure to meet these conditions. Accordingly, Jansen presses to retain the autonomy conditions as the decisive standard, whereas Miller and Wertheimer treat them as fairness-sensitive requirements – sometimes mandated, sometimes not.

Jansen's critique echoes Faden and Beauchamp's concern (1986, p. 281) that informed consent must not be reduced to a bureaucratic formality of disclosure while neglecting the participant's actual understanding and voluntariness. Their model of informed consent was designed precisely to resist such reductions by grounding moral transformation in the internal states of the consent-giver rather than in procedural aspects.

At the same time, Jansen (2020) acknowledges the practical appeal of the transactional model, which emphasises researchers' reasonable, good-faith efforts. Yet she cautions that this focus risks conflating duties with the actual conditions of valid informed consent. Her concern is illustrated by cases where fairness and validity diverge: in one, an investigator acts blamelessly, but a transcription error in the consent documents prevents valid consent; in another, the investigator culpably withholds information, but the participant acquires it elsewhere and

nevertheless gives free and informed consent. Jansen intends these examples to show that fairness governs the responsibilities of researchers, but it cannot by itself determine whether informed consent has truly been secured.

Jansen's critique is particularly forceful in high-risk research settings, where the moral weight of comprehension and voluntariness is greatest. She cautions that procedural fairness may be insufficient if participants do not genuinely understand what they are consenting to. Miller and Wertheimer respond that fairness is not a fixed standard but one that must be calibrated to the level of risk involved: the greater the potential harm, the stronger the requirements for understanding and voluntariness. In high-stakes contexts, investigators may therefore be morally obliged to take additional steps to ensure that participants grasp the relevant information for their decision. Far from lowering moral standards, the transactional model can thus support robust protections by scaling the demands of fairness to the moral stakes at hand.

Like Faden and Beauchamp, Jansen insists that voluntariness, understanding, and appreciation of information are the core of genuine informed consent. Yet her proposed remedy diverges from theirs: while Faden and Beauchamp frame it as the researcher's responsibility to ensure, through dialogue with participants, that these internal conditions are met, Jansen shifts the focus to institutional responsibility, calling for systemic safeguards to support the autonomy-based standard. As a practical way of addressing the fact that even the best efforts at genuinely informed consent can fail, Jansen argues that the problem should not be framed as one of individual researchers' shortcomings but as a structural responsibility. Rather than lowering the standard of informed consent, she contends that responsibility for tackling hard-to-detect flaws should rest at an institutional level. The research community, she maintains, carries a collective obligation to develop tools and safeguards to mitigate these vulnerabilities. Such measures are necessary because even diligent, fair-minded researchers cannot always ensure that participants attain the requisite level of understanding. Institutional responsibility, rather than diluting autonomy-based conditions, is intended to secure them more effectively in practice.

In full agreement with Jansen, Miller and Wertheimer (2011) likewise stress that institutional protections, such as ethics committees, review boards, and regulatory frameworks, are not external add-ons to informed consent but integral to the fair treatment of participants. Somewhat surprisingly, then, Jansen's proposal here converges with Miller and Wertheimer's emphasis on institutional safeguards, despite her otherwise autonomy-based orientation. For Miller and Wertheimer, these mechanisms constitute part of what it means to treat participants fairly: they secure the values of autonomy and well-being even when individual comprehension is partial or imperfect. They clarify this with consumer-protection analogies: diners do not need to inspect kitchens to be safe from health risks because regulations fulfil that role; mortgage customers should be shielded from exploitative terms through financial oversight, even if they cannot grasp every contractual detail. The 2008 subprime mortgage crisis illustrates the danger when such safeguards collapse: the failure lay not in individual borrowers'

understanding but in systemic oversight. The same analogies show how procedural fairness can sometimes conceal exploitation if not coupled with robust protections, as in formally compliant but predatory contracts. The fair transaction model therefore builds moral legitimacy into consent by treating institutional support as an essential component of fairness itself. These tensions between legal structure and moral ideal are explored empirically in the later articles (see Chapter 3, particularly Articles II and III), which analyse how biobank consent documents actually communicate lawful data uses and withdrawal rights under the GDPR.

The divergence between Jansen (2020) and Miller and Wertheimer (2010; 2011) lies less in whether autonomy-based conditions matter – they all agree they do – than in the relative weight given to them. Jansen insists they remain the decisive standard for moral transformation, whereas Miller and Wertheimer argue that fairness and systemic protections are equally indispensable. Yet despite this theoretical difference, both approaches converge on a shared practical prescription: strengthening and maintaining institutional safeguards. Taken together, the accounts are complementary. The autonomy model orients us to what genuine informed consent ideally consists in; the transactional model tells us when consent can permissibly be relied upon – namely, when the surrounding context is fair. This resolves the practical question animating open science: how to preserve autonomy as the moral core without imposing impracticable burdens on researchers – by embedding consent within fair, well-designed institutional safeguards that scale the autonomy demands to the risk and context.

2.4.3 Synthesis and implications

To conclude this section, the critiques advanced by Taylor and Jansen raise important questions about the transactional model of consent, particularly its conceptual clarity and reliance on procedural fairness. These concerns warrant scrutiny of the model's normative foundations, but a closer reading of Miller and Wertheimer's framework suggests that such objections often underestimate its contextual nuance and responsiveness to ethical risk. The model does not replace autonomy-based conditions as the core of informed consent; rather, it clarifies when consent can permissibly be relied upon and thus when it effects a moral transformation. Its strength lies in offering a flexible, practice-oriented account that reflects the realities of research, resisting bureaucratic reduction while safeguarding dignity and enabling research to proceed responsibly. Faden and Beauchamp's contribution remains equally important: their autonomy-based model is best understood as a model of informed consent itself, providing the compass that specifies what genuine informed consent is in the strict sense. As argued in this thesis, its account of moral transformation is not persuasive, but it nevertheless captures the ideal with clarity and precision. The transactional model, by contrast, is a model of moral transformation, specifying the conditions under which consent acquires moral force in practice. The task, then, is to let the autonomy-based model orient institutions while relying on the transactional model as the

operational framework that makes consent workable in practice without losing sight of autonomy as the ultimate aim.

In open science and biobank contexts, this means that consent can still be morally transformative even if project-specific understanding is unattainable, provided that the institutional setting is fair: transparent about legal bases and the limited effect of withdrawal and objection, and governed by credible oversight.

3 INDIVIDUAL ARTICLES IN THIS THESIS

The preceding sections have set out the theoretical and legal frameworks underpinning this dissertation's approach to informed consent. This section turns from theory to application by presenting the three constituent articles. Article I addresses the challenge of broad consent in open science, arguing that it can be morally transformative if embedded in fair and transparent procedures. Articles II and III both examine information disclosures in biobank consent documents, assessing whether they facilitate a fair consent procedure under the GDPR: Article II focuses on disclosures about lawful data uses, while Article III analyses how the right to withdraw consent is communicated. Together, the three articles translate the theoretical distinctions and legal analyses of earlier chapters into concrete evaluations and normative recommendations for practice.

3.1 Summary of Article I:
"Facilitating a Fair Consent Procedure in Open Science – Recommendations for Information Disclosure"

Article I, "*Facilitating a Fair Consent Procedure in Open Science – Recommendations for Information Disclosure*", sets out the core conclusion of this thesis: data sharing can be morally justified on the basis of consent, provided the consent procedure is fair. It develops a practical programme for fairness in open science by specifying what must be disclosed, by whom, and why, so that participants have a fair chance to understand what their participation entails. In doing so, it operationalises the transactional account introduced in Section 2.3: moral transformation depends on the fairness of the consent transaction, with autonomy conditions required only insofar as fairness in context demands them.

The argument is motivated by the well-known Havasupai Tribe case against Arizona State University. Tribe members had consented to a diabetes genetics study, but their biological samples were later used in unrelated research, including studies on schizophrenia and population migration, without their knowledge or approval. While the consent was legally valid, it failed morally because material implications of participation – storage, sharing, and divergent future research uses – were not transparently communicated. Drawing on Heidi Hurd's (1996) notion of *stained permission*, the article frames this as a paradigmatic instance in which formal validity diverges from moral legitimacy: consent, obtained without forthright disclosure of scope and implications, can license actions in law while wronging participants on a moral level.

The article then situates this issue within the regulatory landscape of the EU. Because research data that qualify as personal data fall under the GDPR, researchers and institutions must comply with data protection rules in addition to research-ethical guidelines. Although the GDPR is not designed as a research regulation, its provisions significantly shape research ethics by determining what

counts as lawful data use and conditioning the responsibilities of those seeking consent.

Within this framework, the article focuses on three legal bases most relevant to research under the GDPR – consent (Art. 6(1)(a)), public interest (Art. 6(1)(e)), and legitimate interest (Art. 6(1)(f)) – and explains how each bears on what participants reasonably need to know for a fair decision. These include: the range of lawful future uses of the data (including compatible further processing under Art. 5(1)(b)); who determines purposes and access (the controller, not the participant); and the categories of actors who may process data (such as universities, public bodies, or commercial companies), since the GDPR regulates the purpose of processing more than the identity of the processor.

A key analytic move is to distinguish data-collection procedures from data-processing procedures and to map this distinction onto scope. When consent is the legal basis, it potentially covers both collection and processing for specified purposes, though compatible further processing may proceed without re-consent. Withdrawal can terminate both research participation and the legal basis for processing, unless another lawful basis exists. By contrast, when public or legitimate interest is the legal basis, consent covers collection only; processing relies on a non-consent basis, so withdrawal of research consent does not by itself halt processing. Participants retain GDPR rights, but these may be derogated in research (Art. 89(2)) or limited by balancing tests (in the case of legitimate interests) (see Section 1.3.2).

Because data controllers determine purposes and access, the article assigns the primary duty to inform to institutions, while recognising that researchers retain frontline communicative responsibilities. Fairness, on this view, requires that controllers ensure clear, accessible disclosure of implications that are legally and practically salient to the participant's decision.

To translate fairness into practice, the article offers concrete disclosure recommendations tailored to open science. Consent procedures should ensure that participants are informed in ways that are:

- Clear about scope: be explicit about the activities that require consent and for which consent is being sought.
- Transparent about the legal basis: state which basis has been chosen and explain its consequences.
- Transparent about future uses: indicate that data may also be used for compatible or public-interest purposes beyond the original study.
- Precise about governance: identify who will determine secondary access and describe the oversight procedures in place.
- Specific about actors: state the kinds of organisations that may gain access, including commercial entities.
- Honest about withdrawal: explain plainly the actual effects of withdrawing consent.
- Accessible in language: communicate in terms participants can readily understand.

The central message of Article I is that the absence of project-specific information at enrolment need not render consent morally inert. If institutions and investigators meet their duty to inform in the ways set out above – transparent about legal bases and compatible uses, transparent about control and limits of withdrawal, and precise about scope – then broad consent can still be morally transformative. In the architecture of the thesis, the article thus provides the procedural toolkit for the fairness-based account defended in Section 2.3 and prepares the ground for Article II's communicative analysis of how potential participants are informed about lawful data uses and for Article III's scrutiny of how the right to withdraw and its consequences are presented.

3.2 Summary of Article II:

"Biobank Consent Under the GDPR: Are Potential Sample Donors Informed About All Lawful Uses of Biobank Data?"

Article II, "*Biobank consent under the GDPR: are potential sample donors informed about all lawful uses of biobank data?*", investigates whether potential biobank donors are adequately informed about the full range of lawful uses of their data under the GDPR. The central concern is not only whether consent documents are legally accurate, but whether they communicate fairly: that is, whether participants without specialised knowledge of data regulation are likely to form a correct understanding of what their data may be used for. Assessing the fairness of biobank consent procedures cannot be achieved by a purely legal or semantic reading of consent forms. Such readings determine whether the text is factually correct, but they fail to capture the morally significant difference between literal content and communicated content. Ordinary readers may draw narrower conclusions about the scope of lawful uses than the law permits, leaving them with a mistaken impression of the consequences of participation. This gap between what is written and what is understood is precisely where the risk of undue influence over decision-making arises.

To address this challenge, the article introduces, for the first time, a Gricean content analysis of informed consent documents. The method was developed to assess not only what is explicitly stated, but also what an ordinary reader is likely to infer from the way information is presented. It builds on Paul Grice's (1975) theory of conversational implicature, according to which communication is governed by conversational maxims – Quantity, Quality, Relation, and Manner – that guide how meaning is conveyed in practice. This analytic approach maps the explicit propositions disclosed in consent documents and assesses them against Grice's four maxims. Particular attention is paid to where omissions, ambiguities, or wording choices generate conversational implicatures that could mislead potential donors about the lawful scope of data use. In this way, the method reveals how consent forms may convey incomplete or distorted meanings even when the text itself appears legally compliant.

The method is operationalised in three steps: (1) identifying relevant statements in the consent documents, (2) assessing their truth value in light of applicable legal and policy frameworks, and (3) evaluating their likely interpretation by non-expert readers against Grice's maxims. To the best of current knowledge, this represents the first development and application of such a Gricean method to the analysis of consent materials.

Applying this framework to two biobank consent documents – from Finland and Germany – the article finds that both truthfully describe the intended biomedical research uses of donated data, thereby satisfying the Maxim of Quality. However, they omit to disclose the wider range of lawful uses permitted under the GDPR, including processing on public interest grounds for purposes such as statistics, evidence-based policy, or forensic use. This omission violates the Maxims of Quantity and Relation, because participants are not given sufficient and relevant information about how their data might legally be processed. As a result, participants are likely to form the false belief that their data can only be used for biomedical research.

From the standpoint of Miller and Wertheimer's transactional theory of consent, such omissions undermine fairness. While legally valid, the consent thus obtained cannot be considered morally transformative because participants have not been given a fair opportunity to understand the implications of research participation. The article therefore concludes by recommending two improvements to consent practices. First, consent documents should clearly explain the legal scope of the donor's authorisation, distinguishing between consent to research use of samples and other lawful grounds for processing personal data. Second, they should explicitly disclose the full range of lawful uses of biobank data, including the general categories of purposes and the actors who may access it. Only by openly communicating these points can biobanks ensure that broad consent satisfies the fairness conditions required for moral legitimacy.

3.3 Summary of Article III:

"Right to Withdraw Consent from Biobank Research – A Weak Right Wrapped in Empty Promises?"

Article III, "*Right to Withdraw Consent from Biobank Research – A Weak Right Wrapped in Empty Promises?*", investigates whether biobank consent documents communicate withdrawal rights in a way that is fair – that is, whether participants are likely to gain a realistic understanding of what withdrawal actually entails under the GDPR. Like Article II, it analyses the same Finnish and German consent documents and, by doing so, interrogates the fairness of ongoing information disclosure practices. The central concern is not only that the right to withdraw is formally acknowledged, but whether institutions provide information that enables participants to appreciate its real scope, limits, and consequences. Ethical guidelines often present withdrawal as absolute, yet the legal and practical reality is far

more constrained, both when data processing is based on the public interest and when consent itself is the legal ground.

Building on the Gricean content analysis introduced in Article II, the article refines the method to better capture how institutional communication shapes participant understanding. In addition to identifying conversational implicatures, the analysis distinguishes between semantic implications, explicit institutional promises, and pragmatic interpretations available to ordinary readers. While Article II employed a similar three-step analytical framework, Article III introduces a key methodological refinement. Rather than merely asking whether statements in consent documents are true or false, the present article assesses whether they are normatively consistent with applicable regulations, laws, guidelines, and policies. This shift reflects the fairness-based concern that participants should not merely receive accurate fragments of information but should be enabled to form an accurate understanding of their rights and obligations. It also recognises that truth value is an overly rigid evaluative standard: institutional documents may offer additional guarantees, fill normative gaps, or even deviate from legal norms under certain conditions. Accordingly, the analysis focuses on the extent to which institutional statements align – or fail to align – with relevant legal and ethical standards.

Applied to the consent documents, the analysis shows that while withdrawal is formally acknowledged, its limits are obscured. German materials imply comprehensive deletion or anonymisation of personal data, while Finnish materials conflate withdrawal with the right to object under the GDPR and even promise the removal of all health-related data – assurances not borne out by law or practice. These selective disclosures may be legally valid, yet they generate misleading expectations and an inflated sense of participant control. From the perspective of fairness, such communication is deceptive: it does not equip participants to understand the actual consequences of their decisions and thus fails to establish the reciprocity that makes consent morally transformative.

Beyond these specific findings, the article underscores that consent forms function not merely as legal artefacts but as institutional communications that actively shape participants' expectations and trust. Overstating the degree of control that withdrawal provides risks misleading donors and undermining the legitimacy of biobank governance. Transparency is therefore both a legal duty and a moral practice: participants must be told not just what rights exist in theory, but how those rights operate in practice, including their limits.

The article concludes that biobanks must move beyond merely citing withdrawal rights. To sustain both legal compliance and moral legitimacy, institutions should clarify in accessible terms the true scope and limitations of withdrawal – distinguishing between samples and data, between withdrawal and objection, and between legal requirements and additional institutional practices. Only by providing this level of candour can consent procedures uphold autonomy without overstating control and thereby maintain trust in the governance of biobank research.

Taken together, the three articles develop and substantiate the fairness paradigm that anchors this dissertation. Article I contributes by showing how broad consent in open science, though inevitably limited in specificity, can still be morally transformative when embedded in procedures that meet fairness-based disclosure requirements. It operationalises fairness as the criterion that determines what participants reasonably need to know, thereby offering a practical framework for structuring informed consent even under conditions of deep uncertainty. Article II extends this paradigm by demonstrating how biobank consent documents, though legally accurate, may nonetheless mislead participants if they obscure the full range of lawful data uses under the GDPR. Article III deepens the analysis by applying an enhanced Gricean method to withdrawal rights, showing that inflated promises may satisfy formal validity but fail to establish reciprocity and erode trust.

Taken together, the three articles converge on the idea that the moral transformation of consent hinges on whether the procedure is fair. Article I puts fairness into practice, offering recommendations for how fairness can guide information disclosures under the EU/EEA framework for research data. Articles II and III apply this fairness lens to biobank consent documents, showing that while these materials formally comply with ethical guidance, they often fall short of enabling participants to form a realistic understanding of what their consent entails. In practice, disclosures resemble efforts to align with research-ethical guidelines, but the promises they make about the scope of lawful data use and the effects of withdrawal are not consistently backed by Union or member state law. This gap does not necessarily render consent legally invalid, but it does mean that institutional communication can mislead participants, inflate expectations of control, and erode the reciprocity and trust on which morally transformative consent depends. Put bluntly, the terms and conditions of research participation in open science need to be brought into line with the actual regulatory framework of personal data governance if consent is to remain both ethically credible and legally robust.

CONCLUSION

This thesis has explored the normative foundations of informed consent in order to investigate the possibility of morally transformative consent in the context of open science, where research data may be stored indefinitely and reused for yet-undefined future research. Rather than approaching consent as a purely institutional formality, the thesis has treated it as a communicative and moral practice – one that is shaped by the institutional and regulatory contexts in which it is sought and given. It has argued that morally transformative consent in open science is possible, provided that prospective participants are treated fairly by those seeking their consent. One key feature of such fairness is that participants are provided information about the nature and implications of participation in open science in a clear and accessible manner.

Importantly, this thesis has not set out to redefine what informed consent means – Faden and Beauchamp's classic 1986 analysis already provides an authoritative account of it as an autonomous action. Rather, the focus has been on informed consent as a moral practice embedded in social relations and governed by social norms. The central question has been: under what conditions can consent bring about moral transformation? This question presupposes that such transformation is possible; the task is to identify how. The account developed here seeks to capture the intuitive sense in which informed consent in open science can be morally adequate: by treating it as a practice structured by social norms and obligations, in other words, by asking what researchers and institutions owe to participants in concrete situations.

In contrast, if one insists that moral transformation depends solely on the internal states of the consent-giver, obtaining consent becomes both opaque to the consent-receiver and counterintuitive in practice. In real-world research settings, what matters is that the consent-receiver has taken reasonable steps to secure informed consent. One can affirm, without contradiction, that informed consent is a type of autonomous action, as Faden and Beauchamp describe, while denying that moral transformation in practice hinges on the mental states of the consent-giver alone. This reframing not only offers a plausible solution to the problem of informed consent in open science but also opens avenues for examining consent in other domains where social roles and obligations matter – for example, in clinical care, contractual agreements, or political decision-making. Moral transformation, thus understood, pushes us to conceive of consent in a broader way: as a practice shaped by social roles, obligations, and power relations. It also highlights that the consent-giver, no less than the consent-receiver, may bear obligations in consent situations.

The empirical work conducted in this thesis – the close analysis of two biobank consent documents – has provided insights into how information about research participation can be communicated in practice. The purpose was not to establish generalisations about all consent practices, but to use these documents as illustrative cases for assessing fairness in disclosure. What emerged was

troubling: both documents contained misleading communication on crucial aspects, such as the scope of data use, withdrawal rights, and the potential for future research. Notably, these shortcomings did not stem from the absence of material information but from the way available information was presented – or, more often, not communicated clearly. These examples highlight how even within legally compliant frameworks, significant gaps can arise in the fairness of the consent process, thereby undermining its moral legitimacy.

These findings also illuminate why Miller and Wertheimer's transactional theory of consent offers a particularly compelling framework for understanding the moral legitimacy of consent. On this account, what justifies action is not the internal psychological state of the consent-giver but the procedure by which consent is obtained. The fact that consent-receivers withheld or misrepresented certain information is, in itself, sufficient reason to conclude that the action purportedly justified by that consent lacks moral legitimacy. One need not ask whether any individual participant was actually misled or whether she understood the situation correctly. The procedural defect – the unfairness in communication – is enough to render the consent morally intransformative. In this way, the transactional account does not relax the standards for moral legitimacy; rather, it underscores their strictness, since the transformative power of consent collapses the moment the fairness of the process is compromised.

This does not mean, however, that the mental states of participants are irrelevant. On the contrary, the transactional account presupposes that the consent-giver has a fair opportunity to understand what she is agreeing to, even if she chooses not to read or reflect carefully. It is her right not to engage with the information provided; it is the consent-receiver's obligation to take reasonable steps to ensure that such an opportunity exists. When the stakes are higher – for example, in invasive clinical research – the consent-receiver may even be obligated to go further and actively ensure comprehension. Thus, the fairness of the process requires attention not only to the disclosure of information but also to the practical conditions under which participants can exercise their right to informed self-determination. Seen in this light, the transactional account links naturally to a broader concern: the legitimacy of the institutions that design and administer consent procedures. If fairness at the level of individual consent transactions is compromised, institutional legitimacy itself is called into question.

This thesis has highlighted two dimensions of institutional legitimacy: the legal and the moral. It showed, in practice, how these can come apart. Compliance with the law does not guarantee moral acceptability, just as morally commendable conduct is not always mandated by law. The focus here has been on institutional communication as a source of moral legitimacy. While institutions may shield themselves against legal claims through formal compliance, they are not thereby absolved of moral culpability. Indeed, the cost of moral failure can be higher than the cost of illegality: the erosion of trust and the disengagement that follows. In a liberal society, the fact that individuals are willing to entrust their personal information to scientists is not something to be taken for granted. What is troubling,

therefore, is that institutions expected to command trust still fail to act in a trustworthy manner.

That said, institutional communication is itself a demanding task. The readership for consent documents is highly diverse: participants vary in their levels of literacy, prior knowledge, and familiarity with scientific concepts. Very complex structures therefore need to be explained in language that is as simple as possible, yet still accurate and succinct. Consent documents must not become so lengthy or cumbersome that they deter careful reading. Striking this balance is undoubtedly difficult. Yet the documents analysed in this thesis could easily have done better. With only minor adjustments in wording, they could have conveyed a more accurate picture of what research participation actually entails, without sacrificing clarity or accessibility. In this sense, their failure was not inevitable but avoidable.

The biobank consent documents analysed in this thesis are not intended to serve as generalisations about institutional practices. Rather, they are presented as examples that illustrate a structural issue: the gap between research ethical ideals, legal frameworks, and communicative practices. These cases show how even legally valid disclosures can give rise to misunderstandings if participants are left with misleading impressions about the scope of data use or the effect of withdrawal rights. Such gaps undermine the fairness of the consent transaction and, with it, its moral legitimacy.

This thesis began with the observation that informed consent becomes problematic in open science because of the lack of information about possible future uses of data collected for a defined research project. It ends with the conclusion that this lack of information need not halt moral transformation, provided that consent-receivers are transparent and honest about the full scope of consent and its implications. While some potentially pertinent information will inevitably be missing, this gap can be acknowledged. At the very least, researchers and institutions can provide participants with the terms and conditions of future data use and dissemination among different kinds of actors, as well as a realistic account of what consent withdrawal actually entails.

In conclusion, consent – when given in the absence of information about particular future uses of the data – is not inherently incompatible with morally transformative consent. Its moral adequacy depends above all on the communicative fairness of the process by which it is obtained. While it may fall short of the ideal of fully autonomous authorisation, it can still justify action when institutions provide clear, accessible, and honest information about what participation entails. Together, the three articles demonstrate how these theoretical and legal insights can be translated into concrete recommendations for fair consent procedures in data-intensive research. In this light, the moral force of consent does not lie exclusively in its alignment with ideal autonomy, but also in how it mediates responsibility and trust in relationships governed by asymmetries of knowledge and power.

A useful way to frame this thesis's contribution is to acknowledge that the transactional framework departs from traditional understandings of informed consent in research ethics. What it sets aside is not informed consent itself, but

the assumption that its moral force depends on participants possessing comprehensive knowledge of future data uses. Instead, it makes explicit the uncertainties inherent in open science and demands that whatever is known is communicated fairly to participants. Consent in these contexts may fall short of autonomy-based ideals, yet it can still be morally transformative when the process is procedurally fair. Thus, rather than rejecting informed consent, the transactional approach reframes it: its justificatory force lies not in informational completeness, but in the fairness and honesty with which consent is obtained.What emerges is a view of moral transformation in consent contexts that is both realistic and compelling: one that recognises its grounding in social norms and reciprocal obligations, rather than treating it as an inscrutable mental state. This account is not only more consistent with real-world practice but also far more intuitive than the unilateral, almost solipsistic model associated with Faden and Beauchamp.

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PUBLICATIONS

SUMMARY IN ESTONIAN

Teadliku nõusoleku eetika avatud teaduses: autonoomiast õigluseni

Sissejuhatus

Avatud teadus on oluliselt muutnud teadusandmete ringlust. Kui varem koguti andmeid ühe konkreetse projekti jaoks ja need võis hiljem kustuda, siis nüüd jagatakse teadusandmeid üle institutsioonide, riigipiiride ja teadusvaldkondade eesmärkidel, mida andmete kogumise hetkel ei ole võimalik ette näha. Inimuuringute puhul tekitab see muutus olulise eetilise probleemi: osalejaid ei saa täielikult teavitada kõigist võimalikest tulevastest andmekasutustest. Siit kerkib väitekirja keskne küsimus: kuidas ja millistel tingimustel saab teadlik nõusolek avatud teaduse kontekstis säilitada oma moraalset kehtivust?

Sellele küsimusele vastamine eeldab arutelu selle üle, millal võib nõusolek olla moraalselt transformatiivne – st anda nõusoleku saajale eetilise õigustuse tegutsemiseks. Eesmärk ei ole teadliku nõusoleku mõistet ümber defineerida, vaid hinnata, millistel tingimustel säilitab see moraalse tähenduse olukorras, kus kogu asjakohast teavet ei saa ette anda.

Bioeetikas on levinud seisukoht, et nõusoleku moraalne jõud tuleneb selle andja sisemisest seisundist. Ruth Fadeni ja Tom Beauchampi (1986) järgi on teadlik nõusolek autonoomne autoriseerimisakt, mis eeldab tahtlikkust, olulist arusaamist ja kontrolli puudumist. Sellest vaatenurgast saab nõusolek moraalselt transformatiivseks ainult siis, kui need tingimused on täidetud. Kuid avatud teaduses, kus andmete tulevased kasutusviisid on olemuslikult ettenägematud, ei ole nende tingimuste täitmine võimalik. Kas see tähendab, et teadlik nõusolek kaotab oma moraalse tähenduse?

Väitekirja keskne väide on, et ei kaota. Tuginedes Franklin Milleri ja Alan Wertheimeri (2010) tehingupõhisele nõusolekumudelile, väidetakse, et nõusoleku moraalne jõud ei sõltu osaleja sisemistest seisunditest, vaid nõusolekuprotsessi õiglusest. Nõusolek võib olla moraalselt transformatiivne ka siis, kui autonoomia on puudulik – tingimusel, et protsess on õiglane: teave on tõene, arusaadav ja mitte eksitav ning osapooled on suhtes võrdses positsioonis. Õiglus ei ole eraldiseisev väärtus, vaid realiseerub läbipaistvuse, aususe ja vastutustundliku institutsionaalse käitumise kaudu.

Euroopa Liidu kontekstis reguleerib isikuandmete kogumist ja kasutamist andmekaitse üldmäärus (General Data Protection Regulation, ehk GDPR), mis määratleb, millistel alustel võib andmeid töödelda. Üldmäärus sätestab, et nõusolek ei ole enam peamine õiguslik alus andmete kasutamiseks – selleks on andmekaitseõigus. Seega sõltub nõusoleku moraalne kehtivus sellest, kas osalejaid teavitatakse mitte ainult uuringust, vaid ka sellest, kuidas GDPR nende andmeid reguleerib ja millistel tingimustel neid võib uuesti kasutada.

Väitekirja empiiriline osa analüüsib, kuidas see teoreetiline raamistik praktikas toimib, keskendudes biopangauuringutes kasutatavale laiale nõusolekule.

Analüüs näitab, et isegi kui nõusolek vastab formaalselt õiguslikele ja eetilistele standarditele, võib eksitav või puudulik kommunikatsioon õigluse nõude rikkuda ja seeläbi nõusoleku moraalse kehtivuse kahtluse alla seada.

Lõputöös järeldatakse, et nõusolek avatud teaduses võib olla moraalselt transformatiivne, kui osalejatele antakse täpne ja arusaadav teave nõusoleku ulatuse, andmete õiguspäraste kasutusviiside ning nõusoleku tagasivõtmise tagajärgede kohta – sealhulgas nende kohta, mis on määratletud GDPR-is. Nii mõtestatakse teadlik nõusolek ümber mitte üksnes autonoomia kaitsemehhanismina, vaid ka kommunikatiivse moraalipraktikana, mis legitimeerib tegevuse ning määratleb, millised on uurijate ja osalejate vastastikused kohustused.

I osa: Teadlik nõusolek

Peatükk süüvib kesksesse küsimusse: millal ja kuidas kannab teadlik nõusolek moraalset tähendust, analüüsides, kuidas avatud teaduse andmejagamine seab proovile traditsioonilised autonoomiapõhised mudelid. Nõusolekut käsitletakse nii moraalse kui kommunikatiivse praktikana, mida kujundavad õiguslikud ja institutsionaalsed kontekstid. Selgub, et puudulik teave ei ole juhuslik viga, vaid andmemahuka teaduse struktuurne tunnusjoon.

Biopangauuringute näitel käsitletakse kolme peamist lähenemist nõusolekule, mida iseloomustab teatav määramatus selle kohta, mis andmetest edasi saab:

1. Lai nõusolek (“asendajad”) – nõusoleku ümberdefineerimine, et hõlmta määratlemata tulevasi kasutusviise. Töötav mudel, kuid piirab autonoomiat; moraalselt kaitstav ainult siis, kui osalejatele antakse aus ja arusaadav teave.
2. Kohanduv nõusolek (“muutjad”) – protseduuride täpsustamine (nt astmeline, dünaamiline või GDPR-iga kooskõlas olev nõusolek), mis sarnaneb projektipõhise nõusolekuga. Eetiliselt atraktiivne, kuid ei muuda õiguslikke struktuure, mis võimaldavad andmete taaskasutust ilma uuesti nõusolekut küsimata.
3. Nõusolekust loobumine (“loobujad”) – seisukoht, et kui olulist teavet ei ole võimalik osalejatele anda, tuleks nõusolek asendada parema halduse, läbipaistvuse ja vastutuse mehanismidega.

Peatükk rõhutab, et GDPR kujundab neid arutelusid põhimõtteliselt. Kuigi nõusolek on üks võimalik õiguslik alus, võivad paljud andmetöötluse vormid – näiteks ühilduv või avalikes huvides tehtav teadustöö – toimuda ka ilma selleta. See tekitab pingeid teadliku nõusoleku moraalse ideaali ja juriidilise reaalsuse vahel, kus andmekaitseõigus reguleerib eeskätt teadusandmete kasutamist. Selleks et nõusolek säilitaks oma eetilise tähenduse, peavad teadlased neid piire tunnistama ja neid ka ausalt kommunikeerima. Õiglus eeldab seega läbipaistvust selles osas, kuidas GDPR kujundab andmete kasutamist, tagasivõtmist ja teisest ligipääsu, ning ausust selles, mida nõusolek saab ja mida ta ei saa autoriseerida.

II osa: Moraalselt transformatiivne nõusolek

Lähtudes 1. peatüki järeldusest, et teabe puudulikkus on avatud teaduse struktuurne omadus, arendab 2. peatükk välja normatiivse raamistiku selle hindamiseks, millal võib nõusolekul sellest hoolimata olla moraalne kaal. Esmalt rekonstrueerin autonoomiapõhise (internalistliku) mudeli, mille järgi nõusolek on moraalselt kehtiv ainult siis, kui osaleja sisemised seisundid (tahtlikkus, arusaamine, vabatahtlikkus) on olemas. Rakendatuna laiale nõusolekule tähendaks see, et suur osa andmemahukast teadusest oleks moraalselt õigustamatu.

Seejärel tutvustatan tehingupõhist (eksternalistlikku) mudelit, mille järgi muutub nõusolek moraalselt transformatiivseks siis, kui tehing on õiglane: teave on täpne, arusaadav ja mitte eksitav; võimuerinevusi tunnistatakse; institutsionaalsed kaitsemehhanismid on usaldusväärsed. Analüüs näitab, et autonoomia tingimused ei ole ei vajalikud ega piisavad, samas kui õiglus on alati vajalik ja sageli piisav.

Biopanganduse ja avatud teaduse kontekstis võib seega lai nõusolek omada moraalset kaalu juhul, kui osalejatele antakse selge ja tõene teave andmete taaskasutuse, nende nõusolekust sõltumatu töötlemise, nõusoleku tagasivõtmise piiride ning andmehaldusstruktuuride kohta. Tehingupõhine mudel täiendab, mitte ei asenda autonoomial põhinevaid kaitsemehhanisme: autonoomia määratleb, mis on nõusolek, samas kui õiglus määrab, millal nõusolekule tuginemine on moraalselt õigustatud.

III osa: Artiklid väitekirjas

See peatükk liigub teooriast rakenduste juurde. Tuginedes 1. ja 2. peatüki analüüsidele, uurin siin, kuidas õiglusel põhinev moraalselt transformatiivne nõusolek toimib kolme konkreetse juhtumi puhul. Üheskoos rakendavad need uuringud teoreetilist eristust autonoomial ja õiglusel põhineva nõusoleku vahel, et hinnata tegelikke nõusolekumenetlusi nii normatiivses kui ka empiirilises plaanis.

Artikkel I: "Õiglase nõusolekumenetluse võimaldamine avatud teaduses – soovitused teabe avaldamiseks"

Artikkel arendab õiglusmudeli protseduurilist alust. Selles väidan, et lai nõusolek – kuigi spetsiifikas piiratud – võib siiski omada moraalset transformatiivset mõju, kui see on integreeritud õiglaselt kujundatud protsessi. Artikkel täpsustab, mida õiglus avatud teaduses eeldab: selgust andmete kogumise ja töötlemise osas, läbipaistvust GDPR-i alusel rakendatava õigusliku aluse osas, ausust andmete ühilduvaiks või avalikes huvides taaskasutust lubavate võimaluste suhtes ning täpsust selles, kes otsustab teisese ligipääsu üle. Artikkel illustreerib, kuidas formaalselt kehtiv nõusolek võib olla juriidiliselt korrektne, ent moraalselt puudulik, kui andmete jagamise, taaskasutuse või tagasivõtmise tagajärgi ei avalikustata ausalt, pakkudes institutsioonidele menetluslikku mudelit moraalselt kaitstava laiaulatusliku nõusoleku jaoks.

Artikkel II: "Biopanga nõusolek GDPR-i alusel: kas prooviannetajaid teavitatakse kõigist seaduslikest kasutusviisidest?"

Artikkel II testib õiglusmudelit empiiriliselt, analüüsides, kas biopanganduse nõusolekuvormid annavad doonoritele teavet kõigi GDPR-i alusel lubatud andmetöötlusviiside kohta. Kasutades Grice'i sisuanalüüsi Soome ja Saksamaa materjalide põhjal, leian, et kuigi vormid on juriidiliselt korrektsed, jätavad need olulised õiguslikud andmetöötlusvõimalused – eriti avalikes huvides töötlemise – avaldamata, mistõttu osalejad eeldavad, et nende andmeid kasutatakse ainult biomeditsiinilises teadustöös. Artikkel järeldab, et sõnaselge täpsus ei ole moraalseks legitiimsuseks piisav: õiglus eeldab läbipaistvust kõigi andmetöötluse lubatud aluste osas ning osaleja piiratud kontrolli osas.

Artikkel III: "Õigus biopangauuringus nõusolek tagasi võtta – nõrk õigus, maskeeritud tühjade lubadustega?"

Artikkel III uurib, kuidas nõusolekudokumendid teavitavad teadusuuringutes osalejaid ühest tunnustatud õigusest – õigusest oma nõusolek tagasi võtta ning selle õiguse kasutamise tagajärgedest. Näitan, et kuigi nii Soome kui Saksamaa materjalid tunnistavad tagasivõtmise õigust, varjutavad need sageli selle piiranguid: Saksamaa vormid viitavad täielikule andmete kustutamisele, samas kui Soome vormid sulandavad tagasivõtmise GDPR-is sisalduva vastuväite õigusega, andes mulje suuremast kontrollist kui seadus tegelikult ette näeb. Sellised liialdatud lubadused tekitavad ebarealistlikke ootusi ja kahjustavad õiglusel põhinevat vastastikust suhet.

Kokkuvõttes toetavad kolm artiklit lõputöö keskset väidet, et nõusoleku moraalne transformatsioon tugineb eelkõige protseduurilisel õiglusel, mitte üksnes täielikul arusaamisel või vabatahtlikkusel. Artiklites näitan, kuidas institutsioonid saavad kooskõlastada eetilisi ideaale GDPR-i alusel toimiva andmehaldustegevuse juriidiliste ja kommunikatiivsete praktikatega.

Kokkuvõte

Moraalselt transformatiivne nõusolek avatud teaduses on võimalik isegi siis, kui tulevasi andmete kasutusviise ei saa täielikult määratleda – tingimusel, et nõusoleku andmise protsess on õiglane. Õiglus, mitte ainult autonoomia, on aluseks nõusoleku moraalsele kehtivusele. Õiglus nõuab, et institutsioonid edastaksid tõese teabe osalemise ulatuse ja piiride kohta, võimaldades otsuseid usaldusel põhinevas, mitte illusioonidel tuginevas kontekstis.

Lõputöö ei taotle teadliku nõusoleku ümberdefineerimist, vaid mõtestab selle ümber moraalse ja kommunikatiivse praktikana, mis on lahutamatult seotud institutsionaalsete ja sotsiaalsete suhetega. Tehingupõhine nõusoleku mudel näitab, et kuigi autonoomia määratleb nõusoleku vormi, otsustab õiglus, millal tegutsemine on õigustatud.

Biopankade nõusolekumaterjalide empiirilised analüüsid näitavad, et isegi juriidiliselt korrektsed dokumendid võivad kahjustada õiglust, edastades teavet valikuliselt või kaudselt. Sellised puudujäägid ei tulene teabe puudumisest, vaid sellest, et teabe esitamine jätab osalejatele eksitava mulje kontrolli ulatusest.

Lõputöö paigutub GDPR-i raamistikku ja rõhutab, et andmekaitseõigus – mitte üksnes nõusolek – reguleerib teadusandmeid. Õigusakt kitsendab seda, mida nõusolek võib õigustada, võimaldades samal ajal andmete taaskasutust muudel õiguslikel alustel, näiteks avalikes huvides. See juriidiline reaalsus suurendab institutsioonide moraalset vastutust: nad peavad tagama, et osalejad mõistaksid mitte ainult seda, milleks nad annavad nõusoleku, vaid ka seda, kuidas seadus reguleerib andmete edasist kasutamist.

Lõputöö esitab kolm normatiivset tähelepanekut:

1. Nõusoleku moraalne transformatsioon sõltub protseduurilisest õiglusest, mitte üksnes sisemisest autonoomiast.
2. Avatud teaduse kontekstis ühendab õiglus kommunikatiivse aususe institutsionaalse terviklikkusega, nõudes läbipaistvat teabe avaldamist ja vastutustundlikku valitsemist.
3. Juriidiline nõuetele vastavus on vajalik, kuid mitte piisav moraalseks legitiimsuseks; institutsioonid, mis varjavad lubatud andmetöötlusviise või liialdavad uuringutes osalejate poolse kontrolli ulatusega, ei saa väita, et nende tegevus on moraalselt õigustatud.

Kokkuvõttes säilib teadlikul nõusolekul avatud teaduses moraalne kaal, kui see tugineb õiglaselt kujundatud protsessile. Selle transformatiivne jõud ei peitu ideaalsetes autonoomsetes tingimustes, vaid protsessi terviklikkuses – pakkudes realistlikku ja moraalselt kestlikku alust andmerikkas teadustöös nõusoleku andmiseks.

Väitekiri ei määra teadlikku nõusolekut ümber, vaid käsitleb seda moraalse ja kommunikatiivse praktikana, mis on juurdunud institutsionaalsetes ja sotsiaalsetes suhetes. Tehingupõhine mudel näitab, et autonoomia määratleb nõusoleku vormi, kuid õiglus määrab, millal selle alusel tegutsemine on moraalselt õigustatud.

Empiirilised analüüsid näitavad, et isegi juriidiliselt korrektsed dokumendid võivad õigluse rikkuda, kui teave on esitatud eksitavalt. Seetõttu ei piisa formaalsest vastavusest – moraalne õigustus eeldab ausat ja arusaadavat kommunikatsiooni.

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Publications (non-peer-reviewed)

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Conference, Colloquium, and Workshop Talks

05/2022 "Data sharing and reuse – a challenge for informed consent to research" *Responsible Open Science in Europe (rosie) General Assembly*, Oslo, Norway.

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08/2022 "In the Name of Science? The GDPR, Biobank Consent, and the Problem of Scope" *European Society for Philosophy of Medicine and Healthcare. 34th European Conference: Diversity and Bioethics*, Warsaw, Poland.

06/2023 "How Norms of Conversation Can Help in Assessing the Moral Validity of Informed Consent?" *Semmelweis Medical Linguistics Conference*, Budapest, Hungary.

07/2023 "How Grice's Maxims can help assess the fairness of informed consent?" *Tartu-Uppsala Graduate Workshop*, an online event.

07/2023 "GDPR and consent: Biobanking legislation" *ENLIGHT Summer School: Blurred Meanings in Law, Regulations and Guidelines etc.*, Tartu, Estonia.

08/2023 "Should individuals have the right to decide about research participation even if the research involves no risk of bodily harm?" *Nordic-Baltic Network of Philosophy of Medicine Annual Workshop*, Riga, Latvia.

08/2023 "What does it mean to withdraw consent in biobank research?" *European Society for Philosophy of Medicine and Healthcare. 35th European Conference: Methodological Pluralism in Bioethics and Philosophy of Medicine*, Riga, Latvia.

06/2024 "European Health Data Space and Secondary Use of Health Data – A Breach of Medical Confidentiality?" *Nordic-Baltic Network of Philosophy of Medicine Annual Workshop*, Reykjavik, Iceland.

08/2024 "Large Language Models in Healthcare – A Call for a Rights-Based Ethical Assessment" *European Society for Philosophy of Medicine and Healthcare (ESPMH) 36th European Conference on Philosophy of Medicine & Health Care*, Frankfurt Offenbach, Germany.

06/2025 "Secondary Use of Patient Data: Legal Frameworks vs. Public Expectations" *Nordic-Baltic Network of Philosophy of Medicine Annual Workshop*, Vilnius, Lithuania.

06/2025 "Crossing the Social Border of Data Sharing – Addressing Confidentiality in the European Health Data Space" *7th Nordic STS Conference*, Stockholm, Sweden.

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05/2022 "Data sharing and reuse – a challenge for informed consent to research" *Responsible Open Science in Europe (ROSiE) General Assembly*, Oslo, Norra.

06/2022 "Is it possible to give informed consent to biobank research?" *Nordic-Baltic Network of Philosophy of Medicine Annual Workshop*, Greifswald, Saksamaa.

08/2022 "In the Name of Science? The GDPR, Biobank Consent, and the Problem of Scope" *European Society for Philosophy of Medicine and Healthcare. 34th European Conference: Diversity and Bioethics*, Varssavi, Poola.

06/2023 "How norms of conversation can help in assessing the moral validity of informed consent?" *Semmelweis Medical Linguistics Conference*, Budapest, Ungari.

07/2023 "How Grice's Maxims can help assess the fairness of informed consent?" *Tartu-Uppsala Graduate Workshop*, veebiüritus.

07/2023 "GDPR and consent: Biobanking legislation" *ENLIGHT Summer School: Blurred Meanings in Law, Regulations and Guidelines etc.*, Tartu, Eesti.

08/2023 "Should individuals have the right to decide about research participation even if the research involves no risk of bodily harm?" *Nordic-Baltic Network of Philosophy of Medicine Annual Workshop*, Riia, Läti.

08/2023 "What does it mean to withdraw consent in biobank research?" *European Society for Philosophy of Medicine and Healthcare. 35th European Conference: Methodological Pluralism in Bioethics and Philosophy of Medicine*, Riia, Läti.

06/2024 "European Health Data Space and Secondary Use of Health Data – A Breach of Medical Confidentiality?" *Nordic-Baltic Network of Philosophy of Medicine Annual Workshop*, Reykjavik, Island.

08/2024 "Large Language Models in Healthcare – A Call for a Rights-Based Ethical Assessment" *European Society for Philosophy of Medicine and Healthcare (ESPMH) 36th European Conference on Philosophy of Medicine & Health Care*, Frankfurt Offenbach, Saksamaa.

06/2025 "Secondary Use of Patient Data: Legal Frameworks vs. Public Expectations" *Nordic-Baltic Network of Philosophy of Medicine Annual Workshop*, Vilnius, Leedu.

06/2025 "Crossing the Social Border of Data Sharing – Addressing Confidentiality in the European Health Data Space" *7th Nordic STS Conference*, Stockholm, Rootsi.

08/2025 "Policing the Covid-19 Epidemic in England – A Breach of Confidentiality?" *European Society for Philosophy of Medicine and Healthcare (ESPMH) 37th European Conference on Philosophy of Medicine & Health Care*, Manchester, Ühendkuningriik.

11/2025 "Reading between the lines: a Gricean method for analysing consent documents" International conference: *Laws Many Users: Legal Interpretation Within and Beyond Legal Institutions,* Tartu, Eesti.

Õpetamine, juhendamine ja muud sellega seotud tegevused

Bakalaureuseõppe kursused

2024 *Social and Ethical Aspects of Engineering*
Filosoofia osakond, Tartu Ülikool

2025 *Social and Ethical Aspects of Engineering*
Filosoofia osakond, Tartu Ülikool

Akadeemiline teenistus

Artiklite retsenseerimine

Retsensent järgmistes ajakirjades: *Etikk i Praksis – Nordic Journal of Applied Ethics*; *Medicine, Health Care and Philosophy*

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