BIG DATA, PRIVACY, AND PUBLIC UTILITY: TOWARDS HARMONISATION

Master Thesis MA Applied Ethics

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Abstract

Big data biomedical research practices are put under pressure, due to the practical problems with consent as information practices. Current consents cannot meet the requirements of big data research. Therefore, I propose to assess the issue with the underlying norms of privacy and the utility of science in a broader perspective. Furthermore, the current issues with consent practices are revealed. Consent practices lack the dynamicity for modern data, and fail to educate and inform participants. I propose an adaption to the broad consent model, that accommodates the changing duties in the big data medical research environment. By assessing the values of autonomy and privacy, the risks of big data practices are revealed, and points to new directions of governance to relieve these tensions in a meaningful and enlightened way.

1. Introduction

Around the world, companies, research institutions, and governments use large amounts of data to find long-term solutions to complex, multi-causal issues. The increased availability, storage and means to analyse data is referred to as the 'big data phenomenon.'[1] The increased reliance on big data has led to the 'digitisation' of society,[2] a transformative development that impacts lives, social relations, and ultimately, transforms our view of ourselves.[3] Researchers welcome the big data development, because big data provides valuable insights in the physiology and biology of diseases.

The increased volume of data makes it possible to discover patterns and predict outcomes on a scale that was previously not feasible.[4] For example, it is possible to design predictive models which identify groups of patients with a higher risk to develop a certain disease or condition.[5] From a political perspective, the proactive identification of possible is also attractive because early intervention prevents the emerge of long-term, difficult-to-treat health problems.[6]

The availability of large volumes of data have incentivised researchers to band together in large-scale international research platforms that strive to deliver durable insights in the causes, treatment, and prevention of diseases. One of these initiatives is the BigData@Heart initiative, which is a five-year project that consists of multiple private and public stakeholders across Europe, such as the Utrecht University academic hospital (UMCU), pharmaceutical companies, patient networks, and IT platforms.[7] The area of research covers the reduction of the societal burden and improvement of treatment of various heart conditions, such as atrial fibrillation, acute coronary syndrome, and heart

[1] Vayena, E. and Tasioulas, J. (2016). The dynamics of big data and human rights: the case of scientific research. *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences*, 374(2083), p. 2.

[2] Ibid., p. 2.

[3] ibid., p. 2.

[4] HealthITAnalytics (2019), *10 High-Value Use Cases for Predictive Analytics in Healthcare*. [online] Available at: https://healthitanalytics.com/news/10-high-value-use-cases-for-predictive-analytics-in-healthcare Accessed 20 Jun. 2019.

[5] Ibid.

[6] Ibid.

[7] Bigdata-heart.eu. (2019), *BigData@Heart > Home*. Available at: https://www.bigdata-heart.eu/ Accessed 20 Jun. 2019.

failure.[8] The ultimate goal of the multi-party data initiative is ''to develop a Big Data-driven translational research platform of unparalleled scale and phenotypic resolution in order to deliver clinically relevant disease phenotypes, scalable insights from real-world evidence and insights driving drug development and personalised medicine through advanced analytics.''[9]

The opportunities that big data offers for private and public life, and healthcare in particular, are accompanied with ethical issues of fairness, respect for individual-self-determination, privacy, transparency, and accountability. Electronic health record data are a valuable source of information for data initiatives, because they contain a large amount of standardised and relevant clinical information that can be used for multiple research purposes.[10] The standard practice is to anonymise these clinical data, which discharges researchers from the legal and moral obligation to obtain consent for the use of these data.[11] Practical and moral reasons make the obtainment of consent for large amounts of data problematic.[12] The moral justification for this is that the disclosure of these anonymised data ''to third parties is necessary for many scientific advances, and it can further people's interests to share in, and benefit from, such advances.''[13] Despite the anonymisation of these data, it remains an ethical issue for two interrelated reasons. Firstly, the absence of informed consent undermines individual autonomy and deteriorates trust in research bodies.[14] Secondly, it is not always clear if the research purposes serve a societal interest, especially if commercial parties are involved.[15]

This thesis is concerned with the question on how to bridge the gap between current

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[8] Ibid., 'Objectives.' Available at: https://www.bigdata-heart.eu/About/Objectives. Last accessed June 20, 2019.

[9] Ibid.

[10] Vayena, E. and Tasioulas, J. (2016), p. 9.

[11] Kalkman, S. (2019). *Big Data versus de individuele patiënt: hoe verdedigbaar is het algemeen belang? | deFusie*. Available at: http://defusie.net/big-data-versus-de-individuele-patient-hoe-verdedigbaar-het-algemeen-belang/ Accessed 20 Jun. 2019.

[12] Vayena, E. and Tasioulas, J. (2016), p. 9.

[13] Ibid, p. 9.

[14] Kalkman, S. (2019), *Big Data versus de individuele patiënt: hoe verdedigbaar is het algemeen belang? | deFusie*. Available at: http://defusie.net/big-data-versus-de-individuele-patient-hoe-verdedigbaar-het-algemeen-belang/. Last accessed 20 June, 2019.

[15] Kalkman, S. (2019). *Big Data versus de individuele patiënt: hoe verdedigbaar is het algemeen belang? | deFusie*. Available at: http://defusie.net/big-data-versus-de-individuele-patient-hoe-verdedigbaar-het-algemeen-belang/. Last accessed 20 June, 2019.

informed consent procedures, individual autonomy, and the social benefits of sharing data for research purposes. A modified version of broad consent is presented, which represents the incentive by researchers and participants to harmonise the public utility of scientific research and privacy norms as the foundation of individual self-determination and our democratic values.

Chapter two presents the relevant concepts and theories that play a key role in the big data debate in biomedical research. It explains what big data is and what kinds of promises it holds for biomedical research. The power that big data has over people's lives also has risks associated with it. Its deterministic properties jeopardize the intrinsic value a democratic society places on individual self-determination. The implementation of the General Data Protection Regulation in 2018 aims to regulate the way institutions and large corporations handle personal data. The regulation assigns a number of rights to the individual, which gives the individual a means of control to determine who has access to his personal data. The legal obligation to obtain consent from participants compromises the scientific innovation and validity of biomedical big data research, and the next chapters explore how to move forward from this dilemma.

Chapter three presents why current consent practices do not have the capacity to deal with big data practices. The chapter assesses why traditional consent practices lack the means to handle big data biomedical research. Narrow consent lacks the dynamicity to handle big data, and other consent practices that are better equipped for big data practices, limit individual autonomy. The chapter provides insight in what current consent practices lack, and what might be needed to move forward.

Chapter four makes up the balance of the previous chapters and presents a move forward from the issue whether consent is too much of a barrier that should be removed in favour of scientific progress, or whether it should remain. An alternative approach is an exemption to consent as a means to address the tensions between individual autonomy, consent, and big data medical research. A research exemption has a number of legal, ethical, and organisational difficulties. Most importantly, researchers have a moral obligation to respect the intrinsic value of individual self-determination. While this is by no means a final and perfect solution, a broad consent approach with an exclusion clause offers the flexibility needed for scientific research, respects individual autonomy, and assures a

commitment to a fair and accountable manner of data processing.

2. Conceptual framework

Medical research becomes increasingly reliant on big data that are personable and identifiable. Big data medical research carries the promise to unravel the causes of many kinds of diseases, because researchers are able to collect, link, and analyse data on a larger scale than ever before. One of the prospects that is heralded as the breakthrough of big data in medical research is 'personalised medicine', a medical data-based scientific approach that tailors treatments, interventions, and decisions to the individual, based on their predicted response to said treatment and/or risk of disease.[16]

Despite these prospects, there are also various ethical risks associated with big data. The combination of sensitive data with algorithms and automated learning triggers actions that targets individuals and groups at large, which could affect their legal and social rights. As a response to these concerns, the EU invoked the General Data Protection Regulation that became enforceable on 25 May 2018. The GDPR attempts to give individuals control over their personal data and holds data-processing institutions accountable for the fair processing of personal data.

The chapter assesses the historical and conceptual roots of autonomy, which underscore the normative appeal to individual control as a form of self-determination. Individual control over one's personal data is defended as a prerequisite for a free and just liberal society, in which individuals live their lives free from societal oppression and without interference, which extends to big data influences. The issue with the normative standard of individual control over personal data, as purported by the GDPR, is that it results in a clash with the standard of big data biomedical research.

The GDPR conceptualises personal data as a form of property, which gives the individual the responsibility, by means of rights, to exercise control over their data. The GDPR fully commits to the normative standard of individual control as a means of data protection, but the emphasis on individual control as the legitimate basis for data processing infringes upon the standards of biomedical big data research. This chapter

[16] Nuffield Council on Bioethics (2015). *The collection, linking and use of data in biomedical research and health care: ethical issues*. London: Nuffield Council on Bioethics, p. 12.

assesses the underlying normative assumptions of individual control and explains why a legal standard of individual control as data protection impedes upon the standards of biomedical scientific research. The GDPR frames consent as the lawful basis that permits data processing, but the scientific standards of big data biomedical research are incompatible with the legal requirements of consent. Since the balance between the two normative standards cannot be fully regulated by a legal appeal on control as data protection, a solution to address the issue must be found elsewhere.

The historical origins of autonomy

The right to exercise control over personal data is grounded on the principle of individual autonomy. The modern-day normative appeal to individual control over personal data in contemporary society has never been more relevant than today and has its historical roots in the Era of the Enlightenment. The Enlightenment era was a series of events in the sciences and philosophy that began in Europe during the early Modern period until the greater part of the 18th century.[17] The events placed a new value on rational thought and scientific reason, as opposed to the dogmatic practices of traditional institutions such as the monarchy and the Catholic Church.[18] The advancements in science took flight in the 18th century and marked a process of a fundamental intellectual change towards the understanding of natural phenomena, which is called the scientific revolution.[19]

The scientific revolution triggered the major political and philosophical developments that place the individual center stage, which inspired the conception of ideals such as liberty, toleration and the separation of church and state.[20] Most notably, the philosophy of Immanuel Kant, which states that moral duty follows from practical reason gained influence and is still a widely accepted and discussed formula.[21]

The philosophical and political movements of the Enlightenment era provided the groundwork for the development of modern-day scientific and intellectual institutions.[22]

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[17] Grant, E. (1996). *The Foundations of Modern Science in the Middle Ages: Their Religious, Institutional, and Intellectual Contexts. Cambridge: Cambridge University Press.* p. 29–30.

[18] Zafirovski, M. (2010), *The Enlightenment and Its Effects on Modern Society*, p. 144.

[19] Zafirovski, M. (2010), p. 2.

[20] Zafirovski, M. (2010), p. 2.

[21] Hill, T. (1980). Humanity as an End in Itself. *Ethics*, 91, pp. 84-99.

[22] Brewer, D. (2008), *The Enlightenment Past: reconstructing eighteenth-century French thought*. p. 1.

The medical profession was no exception to the case. The publication of the Pamphlet *Medical Ethics; or, a Code of Institutes and Precepts*[23]by physician Thomas Percival in 1803 exemplified the beginning of a growing consciousness and professionalisation of the study of ethics as a medical institutional discourse.[24] In this era, the study of ethics primarily focused on the importance of good conduct by the physician towards patients, expressed by the statement that physicians "must unite tenderness with steadiness, and condescension with authority, as to inspire the minds of their patients with gratitude, respect and confidence.''[25]

The idea that individual autonomy is a *basic* moral and political value is a modern development.[26] One of the events that accelerated the introduction of autonomy as a basic value in the research and medical discourse, were the unethical medical procedures on humans during WWII, which triggered the establishment of universal and international guidelines to protect the individual and to preserve his welfare.[27]

The western philosophical tradition in the 20th century emphasises the protection of humans as a universal moral duty, grounded on the ideal of universal human rights, which has become the core approach in the medical and scientific institutional practices.[28] The Declaration of Helsinki is the fundamental addition to the institutionalisation of the protection of humans in the research practice by the authorisation of a systematic approach to evaluate experiments on human subjects and the establishment of hospital ethics committees.[29] In other words, individual autonomy in the present-day western tradition is a foundational principle for many institutions.

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[23] Percival, T., (1803), Medical Ethics; or, a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons, London, S. Russell. The modern edition is Percival's Medical Ethics, ed. Chauncey Leake (Baltimore: Williams & Wilkins,1927). **Cited from**: Jonsen, A. (2008), p. 58.

[24] Jonsen, A. (2008), p. 58.

[25] Percival, T., Chapter I. 1, in Leake (ed.), Percival's Medical Ethics, p. 71. **Cited from***:* Jonsen, A, (2008), p. 58.

[26] Christman, J. (2018), Autonomy in Moral and Political Philosophy. *The Stanford Encyclopedia of Philosophy,* Edward N. Zalta (ed.), Accessible at: https://plato.stanford.edu/archives/spr2018/entries/autonomy-moral/. Last accessed May 22nd, 2019.

[27] Dankar, F., Gergely, M. and Dankar, S. (2019), Informed Consent in Biomedical Research. *Computational and Structural Biotechnology Journal*, 17, p. 464.

[28] Dankar, F., Gergely, M. and Dankar, S. (2019), p. 464 - 465.

[29] Kim, W. (2012), Institutional review board (IRB) and ethical issues in clinical research. *Korean Journal of Anesthesiology*, 62(1), p. 5.

Autonomy: from a substantive to a procedural approach

Autonomy is a multi-dimensional concept, and its prominence stretches from debates in moral philosophy, politics, and social theory to the medical and research discourse.[30] Autonomy plays various roles within these fields, and covers topics such as the theoretical account of personhood, the formulation of moral obligations and responsibilities, and the justification of social policies.[31] Gerald Dworkin sketches that the social, moral, and political area endorse a notion of the self ''which is to be respected, left unmanipulated, and which is, in certain ways, independent and self-determining.''[32]

Moral autonomy, generally, refers to the Kantian conception of autonomy, which encompasses the idea that the self-imposition to the universal moral law is the ultimate ground for moral obligation.[33] The self-imposition to the moral law is grounded on practical reason, which refers to the rational capacities of humans to set ends for ourselves.[34] Our practical reason enables us to make value judgments on what ends are morally valuable to follow.[35] Since those ends that are morally worthy to follow are those that align with our practical reason, a moral duty is one whose content is free from any substance outside of our rationality, such as desires.[36] The moral law is universal, because we act on those maxims that pass the rationality requirements of practical reason.[37] The self-imposition to the moral law implies that we recognise ourselves as moral beings and that we owe the same respect to others.[38] Reason as the foundation for moral obligation establishes a conceptual link between autonomy as independence in the sense that rational beings are committed to courses of action that follow the exercise of practical reason.[39]

The Kantian concept of autonomy as substantive independence features

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[30] Christman, J. (2018) "Autonomy in Moral and Political Philosophy", *The Stanford Encyclopedia of Philosophy,* Edward N. Zalta (ed.), URL: https://plato.stanford.edu/archives/spr2018/entries/autonomy-moral/. Last Accessed May 22nd, 2019.

[31] Ibid.

[32] Dworkin, G. (1988), *The Theory and Practice of Autonomy*. Cambridge: Cambridge University Press. p. 12.

[33] Hill, T. (1980), Humanity as an End in Itself. *Ethics*, 91(1), p. 85.

[34] Ibid., p. 86.

[35] Hill, T. (1980), Humanity as an End in Itself. *Ethics*, 91(1), p. 86.

[36] Ibid., p. 88.

[37] Ibid., p. 86.

[38] Ibid., p. 89.

[39] Ibid., p. 89.

prominently in ethics, and its importance cannot be overstated. An issue with autonomy as substantive independence, however, is that the concept fails to place a moral substance on the elements of affections and attachments, which are features that give meaning to the ideal of the liberal society, where all people are recognized as equals.[40] A substantive conception of autonomy places the moral value on our rational abilities, and views our emotions and social and affective attachments as external if they do not align with our practical reason.[41] The constraints that reason places on individual autonomy, makes a substantive account of autonomy incompatible with values that fall outside the scope of reason, but are clearly important for individuals and society.[42]

Autonomy as substantive independence undervalues the positive aspect of our emotions, which drive us to respond morally in many situations in daily life.[43] There are numerous examples of actions that do not rely on reason (exclusively), but are clearly autonomous. For instance, a physician considers various treatment options based on his professional judgment, and also based on compassion for the patient's situation. Clearly, compassion is not less valuable than reason in the process of deciding which treatment is best for the patient's well-being. Another example is the commitment of parents to the needs of their children. Parental commitments are informed and determined by what their children need, but does it follow that parenthood is incompatible with autonomy? This is clearly not the case. In other words, our judgments about the world are not necessarily non-autonomous if they do not stem from reason.

The understanding of autonomy as a purely cognitive concept led Gerald Dworkin to claim that autonomy as independence is not a supreme value, if it is inconsistent with commitments that have an emotional and/or affective ground.[44] Unlike a substantive account of autonomy, procedural autonomy is not committed to a supreme value,[45] and adopts a value-neutral stance towards individual action.[46] A procedural account of

[40] Dworkin, G. (1988), p. 20.

[41] Dworkin, G. (1988), p. 22 - 23.

[42] Ibid., p. 23.

[43] Ibid., p. 23.

[44] Dworkin, G. (1988), p. 26.

[45] Dworkin, G. (1988), p. 10.

[46] Christman, J. (2018), Autonomy in Moral and Political Philosophy. *The Stanford Encyclopedia of Philosophy,* Edward N. Zalta (ed.), Available at: https://plato.stanford.edu/archives/spr2018/entries/autonomy-moral/. Last Accessed May 22nd, 2019.

autonomy defines autonomy as the development and self-fulfillment of one's identity. People give meaning to their own lives because they develop themselves, which makes them autonomous and entitled to moral respect. What matters is the individual entitlement to be free from forces that interfere with personal development, the constitution of friendships, and the expression of one's individuality. Thus, Dworkin's theory of procedural autonomy is a value-neutral account which emphasises the moral value of *individual* self-determination.

The capacity to give meaning to one's life rests on the components of authenticity and competency. Authenticity is the capacity to reflect upon one's first-order desires to understand whether these are compatible with one's second-order desires.[47] Frankfurt introduces the distinction between first- and second-order desires as a view of free action,[48] and Dworkin adopts the distinction to outline that autonomy includes ''some ability both to alter one's preferences and to make them effective in one's actions, and, indeed, make them effective because one has reflected upon them and adopted as one's own.''[49]

First-order desires are feelings about something that one wants to happen or own, such as the desire to become a parent or get a car.[50] A second-order desire is an attitude about one's first-order desires.[51] The distinction between first- and second-order desires implies that individuals are not motivated by their impulses only, but they may also form certain attitudes about their desires by resenting them, or being motivated by them.[52] It is a necessary condition of autonomy to have the capacity ''to raise the question whether I will identify with or reject the reasons which which I now act.''[53] Thus, authenticity is a necessary component of autonomy and consists of the ability of persons to engage in critical reflection on their desires that ''define their nature, give meaning and coherence to their lives, and take responsibility for the kind of person they are.''[54]

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[47] Dworkin, G. (1988), p. 15.

[48] Frankfurt, H. (1971), Freedom of the Will and the Concept of a Person. *The Journal of Philosophy*, 68 (1), p. 10- 11.

[49] Dworkin, G. (1988), p. 17.

[50] Frankfurt, H. (1971), p. 7.

[51] Dworkin, G. (1988), p.15.

[52] Ibid., p. 15.

[53] Ibid., p. 15.

[54] Ibid., p. 20.

Competency is specified as a set of mental capacities, which Buchanan defines as ''the mental capacities to reason and deliberate, hold appropriate values and goals, appreciate one's circumstances, understand information one is given, and communicate a choice.''[55] Buchanan and Brock underscore two important normative assumptions of competency, which refer to the manner competency is judged by the law. The first one is that competency, understood as the capacity to make a decision on the whole is decision-relative.[56] In other words, the ability to act competently stands in direct relation to the context, time, and specific sort of decision that needs to be made.[57] The second assumption is that competency is understood as a minimum standard.[58]

But what does it mean to be an authentic person if it is inevitable that one's identity is formed by external influences from infancy? People naturally have heteronomous desires, values, and attitudes about life, because these are formed by the institutions that we grow up in and the members that sustain these institutions.[59] This raises the question on how to understand autonomy as self-determination, or to live one's own life despite the influence of inescapable societal external factors.[60] At the same time, it is unrealistic that there is much choice involved in the development of such attitudes because it is a process over time that starts from infancy.[61] Autonomy as procedural independence stresses the importance that one's *evaluative* abilities are truly their own, because it is a prerequisite for a genuine and independent mode of identification with one's first-order desires.[62] Unlike the Kantian conception that defines autonomy as substantive independence, Dworkin outlines a notion of autonomy that includes authenticity as a necessary requirement that is linked to a notion of procedural independence.[63]

Autonomy as procedural independence ''ensures that those higher-order aspects of an individual's psychology which evaluate and authenticate the individual's lower-order

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[55] Buchanan, A. and Brock, D. (1989). *Deciding for others*. Cambridge: Cambridge University Press. p. 24 -25.

[56] Ibid, p. 18–20.

[57] ibid, p. 18 - 20.

[58] Ibid, p. 26–29.

[59] Dworkin, G. (1988), p. 11.

[60] Ibid., p. 11.

[61] Ibid., p. 11.

[62] Oshana, M. (2016), *Personal Autonomy in Society,* Ashgate Publishing Limited, Farnham., p. 33.

[63] Ibid., p. 32.

reasons for acting have developed in ways that are consonant with action that is under the agent's control.''[64]Procedural autonomy, then, is a value-neutral theoretical account that stresses the importance of individual self-determination in terms of the self-fulfillment of authentic desires.[65] People that are able to pursue their own ends are considered autonomous.[66] Procedural autonomy, then, can be understood as a form of basic autonomy, which prescribes that the ability to make an autonomous decision marks the status of being an independent agent and be recognised as such.[67]

Procedural autonomy and authority

Most social interactions are shaped by the presumption and recognition that people have full autonomy in the sense that they have the capacity to set their own ends. Thus, autonomy as the capacity for self-fulfillment notion functions as a model for the assessment of social, moral, and political developments, because it helps to make distinctions between legitimate and illegitimate ways of influencing the attitudes of people in a society, despite it being a weaker notion than autonomy as substantive independence.[68] The inherent vague character of the procedural account is one of the criticisms against it.[69] However, the subjective nature of procedural autonomy is the essence of a fundamental basis of respect for other people.[70]

The ambiguities on the conditions of self-reflection, raises the question why self-reflection grounds moral obligation in the first place.[71] If autonomy frames an action as independent that follows from the alignment of one's first-order desires with one's second-order desires by means of self-reflection under suitable circumstances, what are the

[64] Ibid., p. 33.

[65] Dworkin, G. (1988), p. 8, 18, 19.

[66] Christman, J. (2018), Autonomy in Moral and Political Philosophy. *The Stanford Encyclopedia of Philosophy,* Edward N. Zalta (ed.), URL: https://plato.stanford.edu/archives/spr2018/entries/autonomy-moral/, last accessed May 22nd, 2019.

[67] Ibid.

[68] Dworkin, G. (1988), p. 11.

[69] Christman, J. (2018), Autonomy in Moral and Political Philosophy. *The Stanford Encyclopedia of Philosophy,* Edward N. Zalta (ed.), URL: https://plato.stanford.edu/archives/spr2018/entries/autonomy-moral/, last accessed May 22nd, 2019.

[70] Dworkin, G. (1988), p. 30.

[71] Christman, J. (2018) Autonomy in Moral and Political Philosophy. *The Stanford Encyclopedia of Philosophy,* Edward N. Zalta (ed.), Accessible at: https://plato.stanford.edu/archives/spr2018/entries/autonomy-moral/. Last Accessed May 22nd, 2019.

conditions of self-reflection that ground autonomy as the source of moral respect?[72] If autonomy is conceived as a procedural concept only, then it obscures under what conditions of self-reflection autonomy is established, and obscures how procedural autonomy should be understood as the seat of moral obligation.[73] Moreover, if the competencies for self-reflection, such as rational reflection, vary across people, how does it support the notion that the decisions of all people are worthy of equal moral respect?[74] A defense would be ''that our normative commitments do not arise from our actual capacities to reflect and to choose (though we must have such capacities to some minimal degree), but rather from the way in which we must *view ourselves* as having these capacities.''[75] The normative value placed on our self-identity, despite its variety of expression in real-life, is a fundamental premise for a society in which all individuals are recognized as equals:

''Our notion of who we are, of self-identity, of being this *person is linked to our capacity to find and re-fine oneself. The exercise of the capacity is what makes a life* mine. *And, if I am to recognise others as persons, as independent centers of consciousness, as* them*, then there is a requirement that I give weight to the way they define and value the world in deciding how I should act.*''[76]

Stressing the interdependent normative value of one's affections in relation to one's rational deliberations raises the concern that the authenticity component of autonomy severs the link with responsibility for one's actions.[77] Dworkin puts forward the following example to reject this view by considering a person who takes life as it comes, and who drifts along in reaction to circumstances that occur in the present moment: the underlying assumption is that only the person who actively and consciously pursues a course of action is an agent, and therefore, can be held responsible.[78] Instead, Dworkin argues that a lack of

[72] Ibid.

[73] Ibid.

[74] Ibid.

[75] Ibid.

[76] Dworkin, G. (1988), p. 32.

[77] Ibid., p. 28.

[78] Ibid., p. 28

reflection on one's motives should not be equated to a dismissal of moral responsibility, because it is precisely the escape of responsibility that is also an action, which implies that a lack of action is something that a person can be held accountable for.[79]

Thus, as a moral ideal, procedural autonomy functions as a beacon that signals paternalistic and perfectionist ideals in social institutions.[80] Paternalistic treatments or perfectionist ideals oppose the value-neutral account of procedural autonomy, because such treatments oppose the *neutrality* value of the treatment of people.[81] The threat of paternalistic treatment to procedural autonomy resides in the fact that it severs the link between self-reflection and self-determination.[82] Paternalistic treatments prevent people from giving meaning to their own life, because people are treated in such a manner that they cannot share the purpose of those that impose the paternalistic treatment.[83]

Information, observation, and privacy

The respect for the value of autonomy entitles people to a private sphere that is essential for the reflection needed for autonomous decision-making.[84] This draws the attention to the value of the individual right to privacy. The value of privacy is fundamentally connected to respect for the intrinsic value of personhood, but privacy can also be understood as a utility practice and its protection creates various goods for society.[85] People share and exchange information about themselves to form relationships and bonds. In such cases, people give up the exclusive entitlement over their private sphere as a part of a mutually beneficial agreement.[86] Privacy, then, can be understood as a social contract which consists of rules about privacy that govern how, what, for whom, and for what purpose personal information is used.[87] The context, relationships between people, and the kind of information shape the norms and expectations about what is considered private information, and which acts violate

[79] Ibid., p. 28.

[80] Ibid., p. 10.

[81] Dworkin, G., (1988), p. 10 - 11.

[82] Dworkin, G., (1988), p. 31.

[83] Ibid., p. 31.

[84] Nuffield Council on Bioethics, (February 2015), p. 47.

[85] Hunt, C. (2011), Conceptualising Privacy and Elucidating its Importance, 37 (1), Queen's Law Journal, p. 167, 202. **Cited from:** Tzanou, M. (2017), *The Fundamental Right to Data Protection*: Normative Value in the Context of Counter-Terrorism Surveillance. Oxford: Hart Publishing, p. 6.

[86] Martin, K. (2015). Understanding Privacy Online: Development of a Social Contract Approach to Privacy. *Journal of Business Ethics*, 137(3), p. 553.

[87] Ibid., p. 557.

the privacy norms within the contract.[88]

Privacy as property

The social contract recognises and negotiates people's rights as a means to control the access to their personal information.[89] One of these rights is the right to property. The right to property protects our interest in restricting the access of others to our personal information. Today, the bundle theory is the most prevalent model of property rights in legal and philosophical thought.[90] The bundle theory of property rights was put forward by twentieth-century jurist Anthony Honore, who proposed a liberal conception of ownership. Ownership, on his account, is defined as ''the greatest possible interest in a thing which a mature system of law recognises.''[91]Individual ownership is a 'cardinal feature' of the institution, which includes the right to exclude others, and an immunity from expropriation[92] There are a total of eleven standard incidents of ownership, which ''are not individually necessary, though they may be together sufficient, conditions for the persons of inherence to be designated owner of a particular thing in a given system.''[93] But why is the right to privacy not derivative to the right to property? If ownership would be only understood as a concentration of entitlements in one single person, the other social and legal privacy norms and rights that determine the owner's position within a social contract would be disregarded.[94]

So, privacy also has an intrinsic value that goes beyond the rights and entitlements associated with the control over personal information. If the importance of privacy for individual autonomy is overlooked within the social contract,''there may come a time when we think we are merely limiting some personal or property right in favor of some greater good, when in fact we are really sacrificing something of much greater value.''[95]

Privacy as intimacy

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[88] Martin, K. (2015), Understanding Privacy Online: Development of a Social Contract Approach to Privacy. *Journal of Business Ethics*, 137(3), p. 557.
[89] Ibid.
[90] Bell, A., and Parchomovsky, G., (2005), *A Theory of Property,* 90 (3) *Cornell Law Review*, p. 546.
[91] Honore, A.M. (1961), 'Ownership' in A.G. Guest (ed.) *Oxford Essays in Jurisprudence*, Oxford: Oxford University Press. p. 370.
[92] Honore, A.M. (1961), p. 370 -371.
[93] Ibid., p. 370.
[94] Ibid., p. 370.
[95] Reiman J.H., (1976), Privacy, Intimacy, and Personhood, In: *Philosophy and Public Affairs* 6(1), p. 28.

If the value of privacy cannot be explained in reference to the right to property alone, what exactly does it aim to protect? A strong argument, put forward by Charles Fried and James Rachels, is that the value of privacy rests on the creation of intimacy through the sharing of personal information.[96] Rachels argues that the ability to control who has access to our personal information enables us to form and maintain relationships with other people.[97]

Different kinds of relationships are signaled and constituted by different degrees of the sharing of information: one shares more and different kinds of information with a close friend than with an acquaintance.[98] Intimacy as the sharing of personal information allows observation that was previously not allowed or shared with others.[99] Thus, the ability to control the degree how much personal information about ourselves is revealed makes it possible to share information whenever we allow intimate observations of ourselves, which constitute intimate relationships.[100]

Fried puts forward the view that the constitution of intimacy depends on the sharing of the kinds of information that one does not share publicly and to which one has a right not to share them.[101] From this perspective, the protection against the unwanted observation of one's behaviour follows from the idea that without it, one cannot reveal one's personal information in that exclusive manner which is necessary for intimacy.[102]

There are two problems with Fried's view. First, Jeffrey Reiman argues that Fried overlooks that intimacy is more than the sharing of information that would otherwise be restricted to the public.[103] What is also important is the desire to share a meaningful experience together. But the meaningfulness of an experience as the formation of intimacy does not rest on some notion of exclusivity.[104]

For instance, the intimacy between a pair of lovers does not stem from an exclusive reveal of the nakedness of their bodies to each other, but from the care they feel for each other.[105] This example shows that intimacy can exist without the need to commit to the idea that some exclusivity is required for the creation of it.[106] Intimacy may be a function of caring, but it is

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[96] Rachels, J. (1975), Why Privacy is Important. *Philosophy & Public Affairs*, 4(4), p. 328. **Cited from:** Reiman J.H.,(1976), pp. 26 – 44.

[97] Rachels, J. (1975), p. 329. **Cited from:** Reiman, J.H., (1976), p. 30.

[98] Rachels, J. (1975),p.327. **Cited from**: Reiman, J.H., (1976), p. 30.

[99] Reiman J.H., (1976), p. 31.

[100] Rachels, J. (1975), p. 329. Cited rom: Reiman, J.H., (1976), p. 30.

[101] Fried, C. (1970), An Anatomy of Values: Problems of Personal and Social Choice. Cambridge: Harvard University Press, p. 142. Cited from: Reiman, J.H., (1976), p. 31.

[102] Reiman J.H., (1976), p. 36.

[103] Ibid. p. 34.

[104] Ibid, p. 34.

[105] Ibid., p. 34 - 35.

[106] Ibid., p. 35.

not necessarily required for it.[107] If intimacy as the sharing of exclusive information would be a necessity for human relationships, Reiman points out that a second problem would be that the right to individual privacy becomes derivative from the right to form relationships.[108] This is a very limited conception of the right to privacy, and Reiman points out that the privacy-as-intimacy view implies that one who has no options or wish to enter into social relationships has no ground to claim a right to privacy.[109] Even if this were true, as Reiman points out, this view would not provide a *fundamental* ground for the right to privacy that applies to *all* individuals.[110]

Privacy as a social ritual

So far, what is missing from the analysis is a fundamental argument why privacy is important for *all* individuals. Dworkin asserts that the value of individual autonomy depends on the exercise of authentic desires that are integral to one's identity. To be one's own person and to develop one's personal identity, one needs privacy. But why is privacy a *necessary* precondition for personhood? According to Reiman, privacy has a unique value because it confers to the person the moral entitlement that his existence is his own:

To be a person, an individual must recognise not just his actual capacity to shape his destiny by his choices. He must also recognise that he has an exclusive moral right to shape his destiny. And this in turn presupposes that he believes that the concrete reality which he is, and through which his destiny is realized, belongs to him in a moral sense.''[111]

The presupposition that the reality of the individual is his own in a moral sense is based upon a complex social ritual in which a social group acknowledges and re-affirms the entitlement of an individual to their own moral existence. [112] Reiman frames privacy as a twofold symbiotic relationship. Firstly, the social ritual of privacy is a requirement for the process that shapes persons from infancy. Privacy as a social ritual ''conveys to the developing [person] the recognition that his body to which he is uniquely connected is a

[107] Ibid., p. 35.
[108] Reiman, J.H. (1976), p. 36.
[109] Ibid., p. 36.
[110] Ibid., p. 36.
[111] Ibid., p. 39.
[112] Ibid., p. 39.

body over which he has some exclusive moral rights.''[113] Secondly, privacy as a social ritual continuously confirms the respect for persons who are developed as individuals.[114] Without the social ritual of privacy, the individual would not be entitled to an existence that he would be able to claim as his own.

The social practice of privacy suggests, then, that people have *ownership* over their bodies in the *moral* sense.[115] The social ritual of privacy entitles people (1) to have a right to do with their bodies as they see fit, and (2) control when and by whom their bodies are experienced.[116] The active component of moral ownership consists of the power to use and control a body as one desires.[117] Reiman defines the cognitive component of ownership as the knowledge that my body is ''mine'' to the extent that I know that it is ''mine'', from which follows the recognition that it is only ''I'' that is entitled to do with my body as I see fit.[118]Thus, control over the cognitive appropriation of one's body requires that the individual is entitled to be in control in determining by whom and when his ''concrete reality'' is experienced.[119] It follows that the right to privacy as a social practice recognises the right to ''conditions necessary for me to think of myself as the kind of entity for whom it would be meaningful and important to claim personal and property rights.''[120]

The claim to a space free from unwanted observation is required to achieve one's own personal authentic desires.[121] These conditions express a claim to be protected against unwanted observation, because ''the respect of others for your attempts to enforce your right to privacy so as to ensure that you are not observed and scrutinised, is an expression of respect for your personhood.''[122]

The essence of one's personal identity is threatened if a loss of privacy is experienced through the unwanted observation by others. If people experience that they are being unwantedly observed, the social fabric of privacy as the moral entitlement to

[113] Reiman, p. 39.
[114] Ibid., p. 39.
[115] Reiman, J.H. (1976), p. 40.
[116] Ibid., p. 42.
[117] Ibid., p. 40.
[118] Ibid., p. 42.
[119] Ibid., p. 42.
[120] Ibid., p. 43.
[121] Sloot, B. and de Groot, A. (2019). *The handbook of privacy studies*. Amsterdam: Amsterdam University Press, p. 151.
[122] Ibid., p. 151.

one's own concrete reality is eroded.[123] Without the moral entitlement to a sphere of one's own, one cannot develop a sense of self.[124]

The practice of consent

The sharing of personal information has an important social function, as Fried and Rachels point out on the privacy-as-intimacy-view.[125] The practice of restriction and disclosure of information between people and communities establishes social relationships, and demarcates social borders of inclusion and exclusion of people and groups.[126] Within these social interactions, individuals are entitled to *control* their personal information as a means to determine whether or not their existence as a moral entity becomes part of the experience of others.[127] Privacy as a social practice entitles the individual to the conditions (control) to do so, and the view that the individual has of himself in a moral sense is a reflection of how others treat him.[128]

There are many kinds of contexts and practices with different rules and norms regarding the sharing of information, and the sharing of information is subject to various norms in each context.[129] Specifically, the norms regarding the use and disclosure of information in the medical and biomedical research practice are guided by a high degree of confidentiality.[130] Confidentiality ensures that the information disclosed by people will not be further disclosed without their permission, unless it is in accordance with pre-existing laws and rules.[131] It ensures that the information disclosed serves the purposes of the relationship between the person and the other party.[132]

In the medical and research context, informed consent is a communicative and social model that regulates the transaction of information between individuals and researchers.[133] Consent, essentially, is an instrument ''to waive important ethical, legal and other

[123] Ibid., p. 152.
[124] Ibid, p. 152.
[125] Fried, C. (1975), p. 241.; Rachels, J. (1975), pp. 328-329. **Cited from**: Reiman, J.H., (19676), pp. 30-31.
[126] Nuffield Council on Bioethics, (February 2015), p. 49.
[127] Reiman, J.H. (1975), p. 43.
[128] Reiman, J. H. (1976), p. 43.
[129] Nuffield Council on Bioethics, (February 2015), p. 49.
[130] Ibid., p. 49 -50.
[131] Ibid., p. 50.
[132] Ibid., pp. 49-50.
[133] Ibid., p. 50.

requirements in limited ways in particular contexts.''[134] Consent can legitimise certain actions in three ways: (1) it modifies the expectations that follow from certain norms, (2) it waives the rights of the individual, and (3) obtains official authorisation for the permission of actions which are otherwise not permitted.[135] Specifically, if it is likely that the disclosure of personal information poses concerns for the entitlement to individual privacy, consent is a tool that renegotiates the entitlements of the control over his private information that would otherwise be seen as undermining to individual autonomy.[136]

Health information in particular is a sensitive kind of personal information, and a lack of control over its disclosure could undermine individual autonomy. For instance, the Havasupai tribe case illustrates that an experienced lack of control over the disclosure of their personal information is a violation of individual privacy. In this case, the members of an indigenous tribe sued researchers from Arizona State University for misinforming them about the uses of their personal information.[137] The tribe was informed that the collection of their body materials would be used for research on the causes of diabetes, but the tribe was not informed about the uses of their bodily tissues for research on mental health and migration of communities.[138] The tribe argued that the research on migration patterns contradicted with their beliefs about the origins of the tribe.[139] Furthermore, the tribe claimed that the use of the tribe's samples for research on mental health put make them vulnerable to group stigmatisation, and discrimination.[140]

Through the provision of the adequate kind of information, it is assumed, the individual is able to form an informed decision.[141] The Havasupai case makes it evident that consent as the transaction of information between parties rests on the expectations and assumptions on what *types* of information should be exchanged to the consenting party to reach an autonomous decision.[142] On the other hand, consent is more than the provision of adequate information to secure an autonomous decision from the individual: consent also

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[134] Manson, N. and O'Neill, O. (2008), *Rethinking Informed Consent in Bioethics*. Cambridge: Cambridge University Press, p. 72.
[135] Ibid., p. 73.
[136] Nuffield Council on Bioethics, (February 2015), pp. 51 - 52.
[137] Mello, M. and Wolf, L. (2010). The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples. *New England Journal of Medicine*, 363(3), p. 204.
[138] Ibid., p. 204.
[139] Ibid, p. 204.
[140] ibid., p. 204 – 205.
[141] Manson, N. and O'Neill, O. (2008), pp. 28-29.
[142] Ibid., pp. 28 - 29.

communicates the reasons researchers and clinicians have for the collection of information or the performance of a procedure.[143] O'Neill points out that the communication of reasons can inspire trust and confidence in patients or research subjects: ''even if the patient does not understand what is disclosed, or understands it poorly, he may (reasonably) infer that the clinician is trustworthy simply because 'she is not trying to hide anything'.''[144]

While consent is an instrument that sets aside the interests of the individual in varying degrees (dependent on the context), it does not eliminate the right to individual privacy.[145] In other words, ''consent should not be thought of as shifting the liability for any privacy infringements from the user of data to the 'consenting' person, and simply obtaining consent does not exhaust the moral 'duty of care' owed by the user of the data.''[146]

Therefore, consent is ''relevant only where there are already legal, ethical or other requirements and the question of setting them aside arises.''[147] The recognition of the pre-existing underlying norms, ethical and legal claims serves as the justificatory basis for the pre-identified and selective set of purposes or individual reasons that are waived or set aside by consent procedures.[148]

Big data and the biomedical research practice

Historically, science and related institutions have been involved in the production, analysis, and utility of data in order to understand and make sense the causes of various issues in society.[149] Data enable the monitoring, regulation, and generation of profit from the phenomena that are studied to make sense of the world.[150] Therefore, data have a value for the businesses, scientific institutions, and governments that utilise them. Traditionally, data have been time-consuming and costly to generate, and have been offering a static view of phenomena.[151] Nowadays, the production of data is accelerated due to the rise of information and communication technologies that enable a wide, varied, relational, and

[143] Ibid., p. 32.
[144] Manson, N. and O'Neill, O. (2008), p. 32.
[145] Nuffield Council on Bioethics, (February 2015), p. 53.
[146] Ibid., p. 53.
[147] Ibid., p. 73.
[148] Manson, N. and O'Neill, O. (2008), p. 73.
[149] Kitchin, R. (2017). *The data revolution: Big Data, Open Data, Data Infrastructures, and their Consequences*. Los Angeles [etc.]: Sage. Preface.

[150] Ibid., Preface.

[151] Ibid., Preface.

deep production of data that is free from the limits of scarcity and staticity.[152] The explosive accumulation of data is referred to as 'big data.'[153] Big data are defined by the 3Vs: 1. volume, 2. velocity, 3. diverse in variety.[154] Big data is a new set of technologies that challenges the way we think about the world,[155] which incentivises the need to think about its social, ethical, and political implications.[156]

The enablers for the success of big data are the ICTs (Information and Communication technologies); fixed and mobile Internet and widespread access to it through a range of devices; analytics software, and developments in the design of database storage and information management, amongst other innovations.[157] The phenomena of the world that are generated produce data that is fine-grained, meaning that the density on the collection of data on certain phenomena is larger than ever before, due to the relational nature of the networks.[158] The enhanced density of data is accompanied with the identification of people, products, and transactions in various contexts, which means that data has become indexical in nature.[159] The context determines the value of the data, and if the context is changed, so does the value of the data.[160] For instance, ''data about our individual biology collected to diagnose disease or predict disease risk may also serve to identify us or establish our relationship to others.''[161]

The digitisation of information has also occurred in the medical practice, where the

[152] Ibid., Preface.

[153] Šercar, T., Mayer-Schönberger, V., and Kenneth Cukier, K., (2013), Big Data: A Revolution That Will Transform How We Live, Work, and Think. *Organizacija znanja*, 18(1-4), p.47.

[154] Doug Laney,(2001) "3D Data Management: Controlling Data Volume, Velocity, and Variety", Gartner, file No. 949. Accessible at: http://blogs.gartner.com/douglaney/files/2012/01/ad949-3D-Data-Management-ControllingData-Volume-Velocity-and-Variety.pdf. Last accessed June 2, 2019. **Cited from:** Patgiri, R.et al. (206), Big Data: The V's of the Game Changer Paradigm. 2016 IEEE 18th International Conference on High Performance Computing and Communications; IEEE 14th International Conference on Smart City; IEEE 2nd International Conference on Data Science and Systems, p. 17.

[155] Šercar, T., Mayer-Schönberger, V., and Kenneth Cukier, K., (2013), p. 47.

[156] Kitchin, R. (2017), *The data revolution: Big Data, Open Data, Data Infrastructures, and their Consequences*, Chapter 10, Ethical, Political, Social, and Legal Concerns.

[157] Kitchin, (2017), Chapter 5, Enablers and Sources of Big data, p. 19.

[158] Ibid., p. 19.

[159] Ibid., p. 12.

[160] Nuffield Council on Bioethics (2015), p. 5.

[161] Ibid., p. 5.

collection of clinical data is a standardised practice in the continuous process of patient care, [162]''allowing multidisciplinary teams to work together across health care sites, specialties and agencies.''[163] The collection of laboratory, genomic, and administrative data in electronic health records is an integral part of the medical practice, and records contain a wide range of information about an individual such as diseases, treatments, prescribed drugs, laboratory tests, and administrative information such as insurance records.

Moreover, the analysis of clinical data enables tailor-made treatment options. In particular, laboratory and genomic data have proven to be an important part of 'personalised medicine'. Laboratory data are generated by diagnostic techniques that evaluate the chemical and cellular composition of tissues and blood.[164] Genomic data are particularly valuable for research purposes, because they are stable and uniquely distinguishable forms of data.[165] The data is a stable tool for research, because the makeup of the data changes little over decades.[166]

Clinical data are an increasingly valuable source of information for research studies.[167]One of the objectives of The Big Data at Heart data initiative is setting up a knowledge infrastructure that relies on the analysis of of clinical data to stimulate breakthroughs in the development of new drugs.[168] In response to the need to make sense of the complexity of knowledge infrastructures, new techniques, such as data-mining, have emerged that rely on automated procedures, such as algorithms, to ''discover non-obvious patterns and phenomena through finding correlations within the dataset.''[169] Furthermore, ''this may be done with or without a prior hypothesis about the causal relationships involved.''[170]

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[162] Ibid., p. 8.

[163] Nuffield Council on Bioethics, (February 2015), p. 8.

[164] Ibid., p. 11.

[165] Dankar, F., Gergely, M. and Dankar, S. (2019), p. 467.

[166] Ibid., p. 467.

[167] Nuffield Council on Bioethics, (February 2015), p. 8.

[168] Research Objectives of the BigData@Heart Data Initiative, Available at: https://www.bigdata-heart.eu/About/Objectives, Last accessed May 11, 2019.

[169] Nuffield Council on Bioethics, (February 2015), p. 16.

[170] Nuffield Council on Bioethics, (February 2015), p. 16.

Through the convergence of separate data sets, automated analytics procedures reveal patterns of information about individuals, individuals in relation to others, about whole groups, or in the case of medical research, patterns between diseases and individual behaviors.[171] Thus, a flow of information is created that is more than the sum of its parts and has predictive properties.[172] Cohen points out that the predictive properties of data hold the promise to uncover ''a preexisting reality that is determined and discoverable.''[173]

Medical data are considered sensitive because the information it contains can (1) identify individuals and their relatives, (2) it is valuable for research and commercial purposes.[174] The use of big data in clinical practice and biomedical research suggest that data is seen ''as a resource amenable to a wide variety of uses and in pursuit of an unbounded range of purposes.''[175] This creates a situation where ''a) there is virtually no limit to the amount of information that can be recorded, b) there is virtually no limit to the scope of analysis that can be done - bounded only by human ingenuity and c) the information may be stored virtually for ever.''[176]

Big data practices: autonomy at risk

Big data practices offer promising perspectives for research practices. But there are also risks associated with big data. First of all, the data can be applied to manipulate behaviours, raising concerns about individual autonomy. Theses influences range from deliberately manipulating the range of options people are presented with to enforce certain kinds of patterns of behaviour that are considered favoured, to enforce coercive measures to ban certain unfavourable behaviours.

For example, I am looking for white sneakers on a webshop. Algorithms process my online behaviour and transform the data about my shopping behaviour into patterns of

[171] Vayena, E. and Tasioulas, J. (2016). p. 6.

[172] Cohen, J. (2000). Examined Lives: Informational Privacy and the Subject as Object. *Stanford Law Review*, 52(5), p. 1402.

[173] Ibid., p. 1402.

[174] Nuffield Council on Bioethics (February 2015), p. 34-40.

[175] Ibid., p. 16.

[176] Nissenbaum, H. (1998) Protecting Privacy in an Information Age: The Problem of Privacy in Public' :aw and Philosophy, 17, p. 576.

information.[177] While I click through the options on the website, the algorithm saves and processes what kind of sneakers have caught my attention. These patterns are analysed and utilised to select and predict the kind of online content that is likely to appeal to me, based on my current online behaviour.[178] When I return to the webshop I am offered personalised content based on my earlier preference for white sneakers, which is likely to grab my attention. Algorithms, then, create a self-fulfilling prophecy by aiming to influence future behaviours based on earlier shown preferences.[179] My range of options to choose from is manipulated by the algorithm to enforce a behaviour that the algorithm is programmed to promote, which is to continue buying from the store.[180]

This is an example that seems relatively harmless, but the same manipulation technique can be applied to platforms where political views are exchanged.[181]Due to the potential harm such an approach has on society, it is important to consider that the relation between data research and human behaviour is not as straightforward as it appears to be.[182] Firstly, the big data paradigm conflates information with knowledge as the truth about reality.[183] But information has no value without an pre-existing framework that gives information its particular worth.[184] A heuristic technique is necessary to make sense of the meaning to the information that is discovered in relation to the world out there.[185] The big data paradigm purports a specific framework of thinking, [186] takes up the form of rationalisation.[187]

While human behavior is predictable to a certain extent, not all behaviors can be predicted for the reason that ‘’human motivation is internal, partly emotional, and often

[177] van Damme, A. (2016) *Zo bepalen algoritmes jouw wereldbeeld.* NOS Nieuws. Published on December 23rd, 2016. URL: https://nos.nl/op3/artikel/2149923-zo-bepalen-algoritmes-jouw-wereldbeeld.html, last accessed July 7, 2019.
[178] Ibid.
[179] Ibid.
[180] Ibid.
[181] Ibid.
[182] Cohen, J. (2000), p. 1402 - 1403.
[183] Cohen, J. (2000), p. 1404.
[184] Ibid., p. 1404.
[185] ibid., p. 1404.
[186] Ibid., p. 1404.
[187] ibid., p. 1404.

adventitious.''[188] This dimension in the big data paradigm is ignored because it is inherently unmeasurable.[189] Another concern is the inherent bias purported by the algorithms that are used for data-mining, which can lead to a discriminatory classification of groups.[190] The design process that precedes the act of data-mining means that certain factors have been given more weight than others, which can produce or perpetuate discriminatory outcomes.[191] The conflation of information with knowledge purports the view that big data holds the truth,[192]which has profound and fundamental consequences for the exercise of self-determination:

''The view of human nature reinforced by dataprocessing algorithms is both unforgiving and ungenerous. There is little room, or tolerance, for randomness, idiosyncrasy, or mistake, and little allowance for learning effects and second chances. The dataprocessing paradigm holds individuals rigidly accountable for their past experiences—even as it seeks to coopt agency prospectively.''[193]

The digitisation of our self, raises concerns about discrimination and stigmatisation, with broader adverse social consequences.[194]For instance, the disclosure of sensitive sexual and fertility data through digital health-services, such as tracking apps, transforms and quantifies the subjective nature of the data by subjecting them to rigid normalised categories.[195] Consequently, ''the ever-increasing forms of data that are collected by self-tracking apps work to configure new norms of behaviour, based on the patterns that these large masses of aggregated data reveal.''[196]

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[188] Ibid., p. 1405.

[189] Ibid., p. 1405.

[190] Barocas, S. and Selbst, A. (2016), Big Data's Disparate Impact. *California Law Review,* 104, p. 674.

[191] Ibid., p. 708.

[192] Cohen, J. (2000), p. 1407.

[193] Cohen, J. (2000), p. 1407 - 1408.

[194] Andrejevic, M. (2014), The Big Data Divide. *International Journal of Communication*, 8, p. 1681.

[195] Lupton, D. (2014) Quantified sex: A critical analysis of sexual and reproductive self-tracking using apps. *Culture, Health & Sexuality*, 17 (4), p. 449.

[196] Ibid., p.449.

In the worst case, states could apply big data technologies to force politically approved behaviours on citizens. From 2020 onwards, it is feared that China will implement a nation-wide social credit score system.[197] The system processes various social and financial data from citizens to ascribe a score to each individual.[198] Good behaviours increase the score, while behaviours that are disapproved of decrease it. The higher one's score, the more benefits people enjoy. Low scores are penalised by forbidding people from certain activities, such a getting a mortgage or buying ticket for public transport.[199] The system is intrusive in the sense that it turns every kind of behaviour into a micro-transaction that is calculated against the state-approved norm.[200] This leaves no room for individuals to make up their own minds about matters and decide for themselves what actions and thoughts resonate with their identity.

The asymmetric balance of power and information between the individual and institutions is described as the 'big data divide.'[201] The loss of privacy that results from these practices, may directly influence, and interfere, with the choices of individuals.[202]The loss of control, privacy, and equal footing are compelling reasons to invoke a means of protection over one's data.

Data protection rights

Personal data in the big data paradigm have sensitive properties because they make the individual vulnerable to stigmatisation, discrimination, and paternalism. The rationalisation of human behaviours creates an imbalance of power between the individual and the controlling institution.[203] The individual ''cannot predict with sufficient certainty what

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[197] Campell, C. (2019), *How China Is Using Big Data to Create a Social Credit Score*.Time.com. URL: https://time.com/collection/davos-2019/5502592/china-social-credit-score/?utm_source=twitter.com&utm_medium=social&utm_campaign=social-share-article, Last accessed August 1, 2019.

[198] Ibid.

[199] Ibid.

[200] Campell, C. (2019), *How China Is Using Big Data to Create a Social Credit Score*.Time.com. URL: https://time.com/collection/davos-2019/5502592/china-social-credit-score/?utm_source=twitter.com&utm_medium=social&utm_campaign=social-share-article, Last accessed August 1, 2019.

[201] Andrejevic, M. (2014), p. 1674.

[202] van den Hoven, J. et al. (2018), ''Privacy and Information Technology", *The Stanford Encyclopedia of Philosophy,* Edward N. Zalta (ed.), URL: https://plato.stanford.edu/archives/sum2018/entries/it-privacy/. Last accessed June 19, 2018.

[203] Cohen, J. (2000), p. 1415.

information about himself in certain is known in his social milieu, and cannot accurately estimate the parties to whom communication may possibly be made (...).''[204]

Given the importance of privacy for the social structure of society, it is important to recognise the value to have an interest, as individuals, to be involved in decisions about data that describes who we are and how we live.[205] In order to develop ourselves as persons and in accordance with our own ends, a degree of control over the flow of information is required.[206]

The GDPR is a legal response to the moral obligation for individual control over personal data, and underscores the importance of an universal normative standard of personal data regulation in the EU. It elevates established principles of data protection in terms of rights and obligations in a normative and practical sense.

The regulation frames personal data as a form of property, and the 'data subject'[207] is the individual that is recognized as the legal owner of his personal data. The GDPR reaffirms that the individual, or 'a natural person', has a normative appeal to exercise agency over his own personal data. This is further clarified in Recital 7, which notes that:

''natural persons should have control over their own personal data.''[208]

'Controllers' are the natural or legal stakeholders that ''determine the purposes and means of the processing of personal data,''[209]and hold the legal obligation to collect and process the personal data in accordance with the GDPR jurisdiction. Controllers are legally obliged to establish a lawful basis that permits data processing. In the case of the processing of data for research purpose, the accepted lawful basis is the obtainment of consent from the individual whose data are processed.

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[204] Tzanou, M. (2017), *The Fundamental Right to Data Protection*: Normative Value in the Context of Counter-Terrorism Surveillance. Oxford: Hart Publishing, p. 30.

[205] Vayena, E. and Blasimme, A. (2017), p. 503.

[206] Ibid., p. 503.

[207] *GDPR,* 25 May 2018; Definitions, Article 4(1). Accessible at:https://gdpr-info.eu/art-4-gdpr/. Last accessed 5 June, 2019.

[208] *GDPR*, 25 May 2018; Recital 7. Accessible at: https://gdpr-info.eu/recitals/no-7/. Last accessed June 5, 2019.

[209] *GDPR,* 25 May 2018; Definitions, Article 4(7) . Accessible at:https://gdpr-info.eu/art-4-gdpr/. Last accessed 5 June, 2019.

The data protection framework issues two goals in terms of data governance. First, the regulation strives to improve the protection of the individual data subject and second, it strives to clarify the obligations institutions and third parties have to safeguard the use and processing of personal data. These goals are underpinned by the guiding principles for data processing, which are lawfulness, fairness, and transparency as stated in article 5(1).[210]
The property-based data protection regulation creates a tension between the fundamental right to fair data processing, and the context-dependent right to exercise control over one's property as the exercise of the moral entitlement to personhood. In the practice of scientific research, it is difficult to establish who the owner of the health data is as both the individual and the research institution have rights assigned to them that are associated with property[211]
Data concerning health in general, and genetic and biometric data are categorised in their own right because are labeled as sensitive data by the GDPR.[212] They are forbidden to process for the ''purpose of uniquely identifying a natural person.''[213] This implies that controllers are not authorized to process and collect personal data, unless they do so (1) for only those purposes that are in accordance with these values, and (2) there is a lawful base that authorizes the collection and use of personal data by a controller.

Depending on what kind of data is collected and processed and for what purpose, the controller is obliged to align the processing of personal data in accordance with at least one lawful base. There are six lawful bases, which are (a) consent, (b) the performance of a contract, (c) compliance with a legal obligation, (d) the protection of the vital interests of the data subject, (e) a task carried out in the public interest, and (f) a legitimate interest of the data controller and the individual.[214] The controller needs to prove that there is a legitimate ground for the processing of personal data, and it must be made known to the

[210] *GDPR,* 25 May 2018; Principles Relating to Processing of Personal Data, Article 5(1)a, Accessible at: https://gdpr-info.eu/art-5-gdpr/. Last accessed June 5, 2019.

[211] Vayena, E. and Blasimme, A. (2017), Biomedical Big Data: New Models of Control Over Access, Use and Governance. *Journal of Bioethical Inquiry*, 14(4), pp.504-505.

[212] *GDPR,* 25 May 2018; Processing of special categories of personal data, Article 9(1). Accessible at: https://gdpr-info.eu/art-9-gdpr/. Last accessed 5 June, 2019.

[213] Ibid.

[214] *GDPR,* 25 May 2018; Lawfulness of Processing, Article 6(a)-(f). Accessible at:https://gdpr-info.eu/art-6-gdpr/. Last accessed 5 June, 2019.

individual that his data are being processed and for what purposes.[215]

Data controllers must be transparent about the identity of the controller and the objectives, the risks, the extent to which the personal data are being processed, and the specific purposes for which the data are processed at the moment of collection.[216] In the case of medical scientific research, the lawful base that applies to the collection and processing of sensitive data is consent.[217] Each lawful basis is accompanied with a system of checks and balances, and consent is no exception to this. The legal requirements for consent are that consent must be voluntarily given, specific, and informed.[218]

Given the increasing data-intensiveness of medical research, researchers and medical institutions discuss the legal and ethical acceptability of consent as a lawful basis, because the data-intensive medical research environment challenges the requirements of consent. Consent poses practical difficulties for data processing for research purposes.[219] At present, scholars discuss the possibility to authorise the collection of sensitive research data for reasons of substantial public interest.[220] This implies a departure from the legal understanding of personal data as a form of privately owned property, and requires a redefinition of the legal and governance structures that assign the rights and obligations of control and access to these data. Whether this is a path to consider, will be discussed in later chapters.

Derogation of individual rights for research purposes

As mentioned before, medical research is a special category of data processing, which places restrictions on the individual exercise of rights as a measure of control. The protection of health data is further subjected to the legislation in national law, as member States have the

[215] *GDPR,* 25 May 2018; Principles of Data Processing, Recital 39. Accessible at:https://gdpr-info.eu/recitals/no-39/. Last accessed 5 June, 2019.

[216] Ibid.

[217]*GDPR,* 25 May 2018; Processing of special categories of personal data, Article 9(2)(j). Accessible at: https://gdpr-info.eu/art-9-gdpr/. Last accessed June 10, 2019.

[218] *GDPR*, 25 May 2018, Conditions for Consent, Recital 32, Accessible at: https://gdpr-info.eu/art-7-gdpr/, Last accessed June 10, 2019.

[219] Mosterd, M. (2019) BigData@Heart Webinar on Privacy, published 29 October 2018, URL: https://www.bigdata-heart.eu/Webinars/WP7-webinar-data-privacy; 4:00. Last accessed June 6, 2019.

[220] Mosterd, M., Bredenoord, A., Biesaart, M. and van Delden, J. (2016), Big Data in medical research and EU data protection law: challenges to the consent or anonymise approach. *European Journal of Human Genetics*, 24, p. 957.

authority ''to maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.''[221] These must be in accordance with the GDPR legislation, as ''Union or Member State law should provide for specific and suitable measures so as to protect the fundamental rights and the personal data of natural persons.''[222]

These factors pose a fundamental challenge to the practical exercise of the rights and obligations between data subjects and controllers in the field of medical research. Being owner of one's personal data, the data subject has a normative appeal to exercise individual control over the flow over personal information. The control over one's data is translated in a number of rights, which gives data subjects a legal mandate to manage the flow of information generated by the data controller. In the case of medical research, the purposes of the scientific practice restricts or exempts the exercise of the rights of the data subject as a means of control over their data.

The right of access in Article 15 specifies that ''the data subject shall have the right to obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed, and, where that is the case, access to the personal data.''[223] The following information must be provided as well, which are the purposes, categories, all party recipients, and the storage period of the processed data.[224]

On the one hand, the data controller has an obligation to be transparent about the flow of information, and on the other hand, the individual has a right to access to the flow of information that is directly identifiable to him. However, research data initiatives are characterized by the convergence of multiple stakeholders that combine, use, and re-use data sets that are collected across multiple databases, creating an elaborate data environment. An essential feature of such a 'data ecosystem' is that ''they blur conventional distinctions between data types produced in different settings, thus turning virtually any

[221] *GDPR*, 25 May 2018, Processing of Sensitive Data in Health and Social Sector, Recital 53, Accessible at: https://gdpr-info.eu/recitals/no-53/, Last accessed June 10, 2019.

[222] Ibid.

[223] *GDPR*, 25 May 2018, Right to Access, Article 15(1),Accessible at: https://gdpr-info.eu/art-15-gdpr/. Last accessed June 8, 2019.

[224] Ibid., Article 15(1)(a)-(h). Last accessed June 8, 2019.

form of data into health-relevant data.''[225]

The flow of information that is generated becomes so large and interlinked with other sets of data, that it becomes difficult to communicate what purposes, categories, recipients, and period of storage the data is at stake in the case of a study participant. Therefore, it is unclear to what extent the right of access should be applied within the convergence of data sets and stakeholders.

Revision rights also present an epistemological and ethical issue with regards to the ownership issue. Article 16, the right to rectification, states that ''The data subject shall have the right to obtain from the controller without undue delay the rectification of inaccurate personal data concerning him or her.''[226] There is an epistemological problem with the exercise of the right, as the increased complexity of the data sets and the algorithms of the data analytics are likely to exceed human comprehension.[227] The epistemological issue creates an ethical issue, because it cannot be reasonably expected that data sets can be fully understood and interpreted by data subjects. The issue that flows from the right to rectification is that may ''open datasets to mistakes and inaccurate modification by data subjects, while not addressing questions of accuracy of interpretations or the completeness of the data representations.''[228] Article 89(2) exempts the right to rectification for the purposes of scientific research.[229]

Finally, article 17, the right to be forgotten, states that ''The data subject shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay and the controller shall have the obligation to erase personal data without undue delay.''[230] Similar with the right to revision, the right to be forgotten raises

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[225] Jain, S.H., Powers, B.W., Hawkins, J.B., , and Brownstein, J.S. (2015) The digital phenotype. *Nature Biotechnology* 33 (5), p. 462–463. **Cited from**: Vayena, E. and Blasimme, A. (2017), Biomedical Big Data: New Models of Control Over Access, Use and Governance. *Journal of Bioethical Inquiry*, 14(4), p. 502.

[226] *GDPR*, 25 May 2018, The Right to Rectification, Article 16, Accessible at: https://gdpr-info.eu/art-16-gdpr/, Last accessed June 8, 2019.

[227] Callebaut, W. (2012), Scientific perspectivism: A philosopher of science's response to the challenge of big data biology. *Studies in History and Philosophy of Science Part C: Studies in History and Philosophy of Biological and Biomedical Sciences, 43*(1), p. 70.

[228] Mittelstadt, B. and Floridi, L. (2015), The Ethics of Big Data: Current and Foreseeable Issues in Biomedical Contexts. *Science and Engineering Ethics*, 22(2), p.319.

[229] *GDPR,* 25 May 2018, ''Safeguard and Derogations (...) for statistical purposes.'' (title abbreviated), Article, 89(2), Accessible at: https://gdpr-info.eu/art-89-gdpr/. Last accessed June 3, 2019.

[230] *GDPR*, 25 May 2018, Right to be Forgotten, Article 17(1), Accessible at: https://gdpr-info.eu/art-17-gdpr/, Last accessed June 7, 2019.

concerns about the completeness of scientific data sets. The GDPR exempts the right to be forgotten for scientific research purposes, as stated in Article 17(3)(d).[231]

Privacy norms and public utility at conflict

Big data practices offer numerous benefits for the good of society. At the same time, big data practices can be used to manipulate people's behaviours or actively coerce them. Therefore, now is more important than ever to re-affirm and the rules and expectations that people are entitled to the moral respect that protects them from intrusion.

Privacy as a social practice entitles the individual to the conditions (control) to claim and re-affirm the moral respect for privacy as a precondition of personhood. Within these social interactions, individuals are entitled to *control* their personal information as a means to determine whether or not their existence as a moral entity becomes part of the experience of others.[232] In the biomedical research practice, the norms of confidentiality only reinforce the particular importance of individual mechanisms of control as the protection of individual privacy.

Control is the transactional model that communicates the entitlement to the individual that his decision is worthy of moral respect, and is therefore vital to establish relations between data subjects and researchers that pursue privacy and trust.[233] It is important to recognise that persons have a moral interest in controlling others' access to and disclosure of information relating to them held in circumstances they regard as confidential[234] because it is a premise for a society that values the privacy of individuals as the foundation for a morally valuable existence.[235]

Despite these considerations, the legal obligation to implement mechanisms of control to respect individual privacy put big data medical research practices under pressure. The complexities of the data infrastructures make it difficult to adequately govern the rules and expectations of the contractual agreement between the research institution and the consenting individual. Therefore, I conclude this chapter with the claim that consent as a

[231] Ibid.

[232] Reiman, J.H. (1975), p. 43.

[233] Vayena, E. and Blasimme, A. (2017), Biomedical Big Data: New Models of Control Over Access, Use and Governance. *Journal of Bioethical Inquiry*, 14(4), p. 503.

[234] Ibid., p. 87.

[235] Reiman J.H., (1976), p. 48.

legal obligation hinders the flow of information for scientific research purposes. This claim will be further assessed in the following chapter.

3. Consent practices: an obstruction to big data medical research

Big data practices put current norms of individual privacy under pressure. The GDPR has been invoked as a response to the ethical and social concerns over the developments in the field of big data. The GDPR is an addition to the fundamental right to privacy, and sets out rules and standards that attempt to ensure a fair, transparent, and lawful processing of data. It prohibits the processing of personal data in the broadest sense, unless the controller demonstrates compliance to one of the six lawful bases that are specified by the GDPR. Currently, consent is the lawful basis that permits the processing of data for biomedical research purposes. This means that consent practices are faced with a formidable task. For consent to be meaningful, they need to set aside current privacy norms in a meaningful manner. Simultaneously, consent needs to facilitate a flexible access to personal information to facilitate big data medical research.

Current informed consent practices rely on the disclosure of *information* about aspects of the research to patients.[236] The informational obligation to disclose certain kinds of information about the research, such as objectives, re-usage, risks, costs, benefits is justified on the basis that this would accommodate autonomous decision-making.[237] The standard consent practices frame the informational obligation on the basis of the kind of purposes consent needs to achieve. By assessing the five standard consent practices (narrow, broad, tiered, broad, and dynamic consent), I will show that the more stringent the informational obligation to disclose information is taken, the less flexibility consent offers for big data medical research. The less stringent the informational obligation is, the more flexibility it offers for a broad range of scientific research purposes.

However, the lack of informational disclosure raises concerns about autonomous decision-making. Ultimately, it is shown that current consent practices impede big data research, which begs the question: should only those research practices be allowed that fulfill a narrow informational obligation, and prevent certain big data research practices

[236]Manson, N. and O'Neill, O. (2008), *Rethinking Informed Consent in Bioethics*. Cambridge: Cambridge University Press. p. 27.
[237] Ibid., p. 27.

from coming off the ground? Or are there grounds that justify a more lenient approach to the informational obligation?

The legal requirements for consent

The GDPR defines consent as ''any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.''[238] The data controller is legally obliged to facilitate the individual with the means to authorize the statement or action. Article 7 of the GDPR specifies the conditions for consent, which are the following: the individual is able to consent, the consent is distinguishable as consent, individuals have the right to withdraw consent, and consent is proportionate to the situation.[239]

Firstly, for consent to be judged voluntary, it ''should cover all processing activities carried out for the same purpose or purposes.''[240] Data-processing activities that cover multiple and separate purposes require that consent is given for all of them.[241] This means that consent should be re-obtained for every act of data-processing that falls outside the scope of original purposes. Therefore, ''consent is presumed not to be freely given if it does not allow separate consent to be given to different personal data processing operations despite it being appropriate in the individual case (...).'' [242]

The second requirement of consent is specificness. Article 7(2) specifies the procedural conditions: consent is specific if: 1. it is clearly distinguishable as a request for consent, if presented alongside other matters 2. the request is intelligible and accessible, 3. the language is clear and plain.[243] Moreover, the condition of specificness implies that each

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[238] *General Data Protection Regulation*, entered into full force 25 May 2018 (Hereafter referred to as GDPR, 25 May 2018); Definitions, Article 4(11). Accessible at: https://gdpr-info.eu/art-4-gdpr/. Last accessed June 5, 2019.

[239] *GDPR,* 25 May 2018; Conditions for Consent, Article 7(1) -(4). Accessible at: https://gdpr-info.eu/art-7-gdpr/. Last accessed 5 June, 2019.

[240] *GDPR,* 25 May 2018, Conditions for Consent, Recital 32, Accessible at: https://gdpr-info.eu/recitals/no-32/. Last accessed June 5, 2019.

[241] Ibid.

[242] GDPR, 25 May 2018, Recital 43, Accessible at: http://www.privacy-regulation.eu/en/recital-43-GDPR.htm, last accessed June 5, 2019.

[243] *GDPR,* 25 May 2018; Conditions for Consent, Article 7(1) -(4). Accessible at: https://gdpr-info.eu/art-7-gdpr/. Last accessed 5 June, 2019.

act of data processing must be explained in relation to the purposes of the processing of data, as outlined in recital 39.[244]

Thirdly, the requirement of 'informedness' obliges the controller to demonstrate that the participant has given consent to the data-processing activities that have been communicated, and the minimum requirements are that ''data subject should be aware at least of the identity of the controller and the purposes of the processing for which the personal data are intended.''[245]

The legal requirements are underpinned by the justification that it respects individual autonomy. In the clinical and research discourse, informed consent is a mode of transaction that permits the performance of an action by a third party, that was previously not allowed.[246] There are many different conceptions of autonomy that justify the normative value of informed consent.[247] What is important to stress here is the *function* of informed consent in relation to individual autonomy, which is that consent should provide assurance that patients and others are neither deceived nor coerced.[248] Moreover, genuine consent enables the individual to make up his own mind whether he is deceived or coerced.[249] This implies that consent is not valid if the individual is forced, manipulated, or coerced to consent.[250]

Autonomous authorisation and effective consent

The possibilities of big data medical research and the pressure it puts on consent practices are an incentive to review the uses of current consent strategies. The theory of autonomous authorisation and effective consent is a descriptive tool that helps to understand why most big data medical research fail to meet the minimum standards of informed consent. It offers

[244] *GDPR*, 25 May 2018, Principles of Data Processing, Retical 39. Accessible at: http://www.privacy-regulation.eu/en/recital-39-GDPR.htm. Last Accessed June 7, 2019.

[245] *GDPR,* 25 May 2018, Burden of Proof and Requirements for Consent, Accessible at: http://www.privacy-regulation.eu/en/recital-42-GDPR.htm. Last accessed June 5, 2019.

[246] Manson, N. and O'Neill, O. (2008). *Rethinking informed consent in bioethics*. Cambridge etc.: Cambridge University Press, p. 5

[247] O'Neill, O. (2003), p. 4.

[248] Manson, N. and O'Neill, O. (2008), p.6.

[249] Manson, N. and O'Neill, O. (2008), p. 6.

[250] O'Neill, O. (2003), p. 5.

some practical insight in the applications of consent practices to big data research, and how these practices fail to establish informed consent.

There are two institutional standards of informed consent, which are consent as autonomous authorisation and effective consent.[251] Autonomous authorisation is the form of consent that is mainstream in clinical practice.[252] It is the individual's personal choice to authorise a medical professional to perform an action which is considered invasive to one's bodily integrity, such as a surgery or procedure.[253] The permission given to perform an action is valid only if the individual has the competency capacities required for such authorisation.[254] The individual must understand the action he gives permission for, fully anticipates it, and is not coerced into giving permission.[255]

Effective consent takes a different approach to the matter of choice as a reflection of individual autonomy. Rather than conceptualising consent as the expression of individual independent choice, effective consent places the requirements for consent in a broader institutional context, and refers to the institutional and legal validity of consent.[256]Beauchamp and Faden argue that effective consent does not necessarily entail autonomous authorisation,[257] because the former does not presuppose the latter.[258] Their conclusion is that informed consent as a legal doctrine does not presuppose autonomous authorisation, but does not exclude it either.[259]

Epstein critiques this standpoint and argues that, while autonomous authorisation and effective consent are not mutually exclusive, ''neither necessarily entails the other, the former does not presuppose the latter, and what is more important—*the latter does not presuppose the former either.''*[260] This creates a tension between the aspirational aspects of

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[251] Faden, R., King, N. and Beauchamp, T. (2010), A history and theory of informed consent. New York: Oxford University Press. p. 277 - 282.

[252] Ibid, p. 277.

[253] Ibid., p. 277.

[254] Ibid., p. 277 - 278.

[255] Ibid., p.277 - 278.

[256] Epstein, M. (2006), Why effective consent presupposes autonomous authorisation: a counterorthodox argument. *Journal of Medical Ethics*, 32(6) p. 342.

[257] Faden, R., King, N. and Beauchamp, T. (2010), p. 281.

[258] Faden, R., King, N. and Beauchamp, T. (2010), p. 283.

[259] Faden, R., King, N. and Beauchamp, T. (2010), 293 - 294.

[260] Epstein, M. (2006), p. 343.

consent and its practical effectiveness, ''as meeting the requirements of effective consent neither reflects nor guarantees autonomous authorisation.''[261] The observation that effective consent presupposes autonomous authorization *once it has been obtained*,[262] implies that the contextual circumstances that gives data their value do not play a role of significance for consent in the legal sense.[263] This becomes clear if we take a closer look at narrow consent.

Narrow consent is a form of opt-in consent and provides information about a single study that has a specific purpose, and a pre-defined timespan.[264] Narrow consent, traditionally, is a non-digital process and consent is obtained at the start of the study, ''resulting in a static process that locks consent information to that single time point, and requires all future data usages to be specified at the time of the initial consent.''[265]
Big data research, on the other hand, is a dynamic and multi-purpose form of research. The characteristics of big data research makes it impossible to foresee all future uses and applications of the data at the initial time of collection. Narrow consent requires to pre-define and disclose all the uses of the data beforehand, but this limits the possibilities of re-using the data for new research purposes. Dankar et al. point out that ''pre-defining an array of future uses on the dataset limits creativity, and can act against the incremental nature of research.''[266] Therefore, narrow consent fails to establish a sensible authorization for big data research. Neither does it inform the individual of all uses and purposes of the research data that goes past a point in time after the initial consent, and neither does it establish the permission to use these data past the point of initial authorization.

Broad and tiered consent

The traditional narrow consent mechanism has evolved towards a more modern practice in

[261] Ibid., p. 342.

[262] Epstein, M. (2006), p. 342.

[263] Manson, N. and O'Neill, O. (2008), p. 114.

[264] McGuire, A. and Beskow, L. (2010). Informed Consent in Genomic and Genetic Research. *Annu. Rev. Genomics Hum. Genet*, 11, p. 363.

[265] Dankar, F., Gergely, M. and Dankar, S. (2019), Informed Consent in Biomedical Research. *Computational and Structural Biotechnology Journal*, 17, p. 468.

[266] Dankar, F., Gergely, M. and Dankar, S. (2019), p. 468.

response to the development of data technologies.[267] Data can be stored, re-used, and rec-combined, which incentivises the need to frame consent as a long-term dynamic contract instead of a predefined agreement that permits the use of personal information for only a single study.[268] Broad, or general, consent refers to a process by which individuals permit the collection and processing of their data for a broad range of future studies, which are subject to specified restrictions.[269] Broad consent differs from blanket consent, in the sense that blanket consent does not include any framework of pre-set research restrictions on the future usages of data.[270] Rather than giving consent for every independent study, like narrow consent, broad consent consists of a framework of future research of certain types.[271] This includes the ''ethical review of each specific research project by an independent ethics committee as well as strategies to update regularly the biobank donor and ongoing withdrawal opportunities.''[272] If the standards of the framework are changed or revised, the participant is asked to re-consent.[273]

The ethical considerations on the permissibility of broad consent are discussed extensively in the academic literature, mainly in the context of biobanks and genomic research.[274] Reason for this is the scientific progress made in genomic and genetic research, due to the increasing emergence of large-scale population studies and genomic databases.[275] Due to the abundance of information, it becomes harder to strictly define the exact study purpose by researchers in advance. Broad consent omits the informational obligation to fully inform the individual about the precise purposes of scientific research in advance, as the individual consents to the research framework for future studies of a specific type, rather than a single-purpose study. The other side of the coin is that the broad

[267] Ibid, p. 469.
[268] Ibid, p. 469.
[269] Steinsbekk, K., Kåre Myskja, B. and Solberg, B. (2013), Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem?. *European Journal of Human Genetics*, 21(9), p.897.

[270] Ibid., p. 897.

[271] Ibid, p.897.

[272] Ibid, p. 897.

[273] Steinsbekk, K. and Solberg, B. (2011), Biobanks--When is Re-consent Necessary?. *Public Health Ethics*, 4(3), p. 238.

[274] Karlsen, J., Solbakk, J. and Holm, S. (2011), Ethical Endgames: Broad Consent for Narrow Interests; Open Consent for Closed Minds. *Cambridge Quarterly of Healthcare Ethics*, 20(4), p. 572.

[275] McGuire, A. and Beskow, L. (2010), p. 362.

consent model is criticised for not establishing informed consent, as certain ''aspects of future research projects are today often unspecified and to some extent unforeseen.''[276]

Tiered consent aims to address the concerns of broad consent, based on the premise, put forward by Bunnik et al, that ''consumers should at least know what test results they will receive and be given the opportunity to opt out of receiving test results which they anticipate may harm them or which they do not wish to receive.''[277] The statement underscores the ethical importance to manage the social and emotional impact of research studies that make use of sensitive medical data, and the implications it may have for people's personal lives and their relatives.[278] Tiered consent classifies the information in anticipation to the differences in the social and emotional needs that people have. Rather than giving consent to a whole range of studies of a specific type, tiered consent divides consent in tiers or packages for the research on genomic traits and diseases.

A differentiation approach, thus, ''can help consumers make deliberate choices with regard to the information they do or do not want to receive.''[279] The model consists of a default package and optional packages. The 'default package' contains information that should always be reported back to participants such as directly life-saving information.[280] The optional packages are context-dependent, and ''include data of moderate clinical validity, data of reproductive significance and data of 'personal or recreational' interest.''[281]

Tiered consent practices tailor the information in such a sense that it up to the individual to attribute what value the packages have.[282] By classifying the disclosed information, it is up to the individual to determine what value is attributed to the kind of

[276] Steinsbekk, K., Kåre Myskja, B. and Solberg, B. (2013), p. 897.

[277] Bunnik, E., Janssens, A. and Schermer, M. (2012). Informed Consent in Direct-to-Consumer Personal Genome Testing: The Outline of A Model between Specific and Generic Consent. *Bioethics*, 28(7), pp.343-351. p. 349.

[278] Bunnik, E., Janssens, A. and Schermer, M. (2012), A tiered-layered-staged model for informed consent in personal genome testing. *European Journal of Human Genetics*, 21(6), p. 597.

[279] Ibid, p. 597.

[280] Bredenoord, A., Onland-Moret, N. and Van Delden, J. (2011). Feedback of individual genetic results to research participants: in favor of a qualified disclosure policy. *Human Mutation*, 32(8), p. 861.

[281] Bunnik, E., Janssens, A. and Schermer, M. (2012), p. 597.

[282] Bredenoord, A., Onland-Moret, N. and Van Delden, J. (2011), p. 862.

information disclosed, and to determine what he wishes to know and for what reasons.[283] The underlying assumption is that individual autonomy presupposes that participants have a right to benefit from the results of research.[284]

The disclosure of information as an individual benefit creates epistemic and normative difficulties for data initiatives. The first significant question is: who should decide the selection of information to be disclosed? One option would be that participants decide what information should be provided. However, the available raw data would need to be transformed into intelligible and interpretable information, which requires a resource-intensive and extensive research infrastructure.[285] Furthermore, the information would be highly complex and, in the case of genetic research, analyses can have a probabilistic character.[286] Researchers might be in a more qualified position to interpret the raw data, but it should not be assumed that researchers know the social and emotional value of feedback results for participants or that they share the interests of the study participants.[287] After all, a data initiative combines many disciplines and research groups to focus on the creation of a public good (such as the reduction of the burden of heart diseases on society). A request to receive individual feedback from studies that employ a broader method may not be possible, because ''the methods used for research purposes are usually less accurate than would be the case when used for clinical purposes, resulting in a lower analytic validity.''[288]

Tiered consent frames individual autonomy as the ability to define one's life in accordance with one's values, hence the presupposition that the individual benefit stems from the ability make one's own decisions to know what kind of information. While tiered consent offers more informational autonomy than broad consent, it is still limited by the pre-set and general uses of the data.[289] This includes the processing of data that could generate predictive outcomes, which could carry the possibility to impair individual autonomy. Tiered consent as the classification of information in anticipation to people's social needs brings an important aspect of the decision-making process of autonomy into

[283] Ibid, p. 862.
[284] Ibid., p. 862.
[285] Ibid, p. 864.
[286] Ibid, p. 861 - 862.
[287] Ibid, p. 864 - 865.
[288] Ibid, p. 863.
[289] Dankar et al. (2019), p. 469.

perspective. However, it is up for debate whether the information offered is specific enough to establish informed consent.

Dynamic consent

Dynamic consent is a relatively new form of consent as it leans on digital innovation as a means to continuously inform and update the individual about his data use. Dynamic consent defines consent as ''personalised, online consent and communication platforms.''[290] The main objective of dynamic consent is to facilitate consent by means of a ''two-way, ongoing communication between researchers and research participants.''[291]

Unlike the tiered consent approach, dynamic consent aims to structure consent around the privacy preferences of the individual.[292] Dynamic consent tailors its process around the subjective view of privacy and interference of the individual, rather than the purpose of the research study. The benefit is that researchers gain insight in the ''levels of privacy risks research participants are willing to take and which data may or may not be used in the research.''[293]

For instance, ''researchers may give participants the choice to consent to some or all aspects of the research depending on their personal preferences and beliefs.''[294]

However, the increased customisation of consent according to one's preferences goes at the expense of comprehensibility on the short and long term, ''as data sharing spans several years and a variety of projects, research participants may struggle to decide which data sharing scenarios are or are not acceptable to them.''[295] Furthermore, the range of information that dynamic consent covers is too broad, which implies an impossible range of obligations on behalf of the researcher to inform the data subject.[296]

[290] Budin-Ljøsne, I., et al. (2017), p. 3.

[291] Ibid., p. 3.

[292] Ibid., p. 3

[293] Ibid., p. 5.

[294] Ibid., p. 5.

[295] Ibid., p. 7.

[296] Manson, N. and O'Neill, O. (2008), p. 114.

The anonymisation of data: a solution?

The anonymisation of personal health data is one of the standard forms of data protection in medical research.[297] The data is anonymised by removing the individual identifiers of a data set that contains sensitive personal health properties.[298] Further implications are that the ownership issue is bypassed, for which consent is the legal basis for data processing.[299] Thus, the anonymisation of personal data bypasses any legal requirements for consent, as there is no legal obligation towards an individual that is marked the owner of the data.[300] However, the anonymisation of data is not without considerable risks. Barocas and Nissenbaum points out that research has shown that it is possible to identify individuals based on the content of search queries:

''*(...) [T]he promise of anonymity is impossible to fulfill if individual records happen to contain information - information that falls outside the scope of the commonly defined set of personally identifiable information - that nevertheless uniquely distinguishes a person enough to associate those records to a specific individual.''*[301]

Specifically, data sets that contain rich and detailed information are at risk of possible re-identification, based on their contents.[302] Medical records in particular have that risk, as they contain a unique, rich, and detailed history of health data. The risk of re-identification is even further exacerbated if an anonymised data-set is overlaid with a seperate data-set that contains identifiable information: the overlap between the sets allows the linkage of data, which facilitates the re-identification of individuals.[303] Moreover, it is possible to deduce the presence of a specific person in a data set by performing a series of searches that shows that only one person in the set has all of the properties that the series of

[297] Barocas, S., Nissenbaum, H., (2015). Big Data's End Run Around Anonymity and Consent. *Privacy, big data, and the public good*. ed. by Lane, J. New York, NY: Cambridge University Press, p. 5.

[298] Ibid, p. 5.

[299] Ibid, p. 7.

[300] Ibid, p. 7-8.

[301] Ibid, p. 6.

[302] Barocas, S., Nissenbaum, H., (2015), p. 20.

[303] Barocas, S., Nissenbaum, H., (2015), p. 20.

searches set out for. [304]

So, anonymized data is at risk of re-identification through the linkage and differentiation of data sets.[305] While there are technological developments aimed to contain the risk of re-identification even further and the actuality of the risk of re-identification is up for discussion, there is also an ethical argument against the use of anonymisation as a legal basis for data processing, as it undermines individual autonomy.[306] One worry is that the more fine-grained and detailed data sets become, the more the actual meaning of 'anonymisation' becomes overturned in the way individuals are treated by institutions.[307] Nissenbaum and Barocas identify that it does not matter if companies know your real identity, because ''what matters are the properties and behaviors that your identity comprises - the kinds of details that can be associated with a pseudonym assigned to you without revealing your actual identity.''[308]

A second worry is the issue of inference, as ''insights drawn from big data can furnish additional facts about an individual (in excess of those that reside in the database) without any knowledge of their specific identity or any identifying information.''[309] Consequently, the anonymisation of personal data becomes meaningless if the data is so rich that the absence of a personal identifier no longer can guarantee non-interference.

Furthermore, the removal of any personal identifiers means that the individual is cut off from making an informed choice on what should and should not be done with his data. The individual is not able to critically reflect and engage on the nature and implications inferred data has for him in the future. Based on the views of the writers mentioned, I point out that it is concerning that the anonymisation of data sets puts individuals at risk of re-identification and inference, and, simultaneously, there is no normative ground for individuals to exercise control over anonymised data, because the removal of any personal

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[304] Ibid., p. 6.

[305] El Emam, K., Jonker, E., Arbuckle, L. and Malin, B. (2015). A Systematic Review of Re-Identification Attacks on Health Data. *PLOS ONE*, 10(4), p. 2.

[306] Kalkman, S. (2019). *Big Data versus de individuele patiënt: hoe verdedigbaar is het algemeen belang? | deFusie*. [online] deFusie. Available at: http://defusie.net/big-data-versus-de-individuele-patient-hoe-verdedigbaar-het-algemeen-belang/. Last accessed 20 June, 2019.

[307] Barocas, S., Nissenbaum, H., (2015), p. 10.

[308] Barocas, S., Nissenbaum, H., (2015), p. 11.

[309] Ibid., p. 11.

identifiers denies people the conditions to a claim to control as an expression of the entitlement to privacy as a condition of personhood.

The anonymisation of data, then, strips individuals from the entitlement to control their personal data as a participating individual within a social contract. The norms and expectations that govern the use of information do not appear to apply to sets of data that contain no personal identifiers. Individuals whose data are anonymised lack the means to govern their expectations within a social contract, such as their interest to restrict third parties from accessing their data and restrain certain processing activities that would undermine individual autonomy.

The Havasupai Indian Tribe case illustrates that the anonymisation of data is not sufficient to mitigate risks for the individual and a collective. It also stresses the importance to consider what values for the researchers and a study population underscore the research objectives and processing of data.[310] In 2010, Arizona State University settled a legal claim with the Havasupai tribe that concerned the improper use of blood samples of tribe members in genetic research.[311] Tribe members filed a claim of fraud, breach of fiduciary duty, negligence, and trespass. Specifically, the tribe objected against three uses of the samples: an evaluative study on the genetic basis of schizophrenia, inbreeding, and migration patterns of the tribe's ancestors.[312]

The basis for the legal claim by the tribe was that these particular uses of the samples fell outside of the scope of consent, as prestudy communications with the tribe's leaders focused on studying diabetes, while the consent form described the project as studying the causes of medical/behavioral disorders.[313] The tribe argued that they would not have provided samples for the non-diabetes studies even if the samples had been anonymised, as they regarded the study as offensive and stigmatising.[314] In particular, the samples were used for studies about the statistical measurement of inbreeding of the tribe, and using data samples for sensitive topics such as inbreeding may appear incriminating to

[310] Mello, M. and Wolf, L. (2010). The Havasupai Indian Tribe Case — Lessons for Research Involving Stored Biologic Samples. *New England Journal of Medicine*, 363(3), p.207.

[311] Mello, M. and Wolf, L. (2010), p. 204.

[312] Ibid., p. 204.

[313] Ibid., p. 204.

[314] Ibid., p. 206.

the participant. The lack of communication on sensitive uses of data left the individuals of the tribe unable to make up their own mind on what they consider an acceptable use of data.[315]

Three issues with consent

Given the current considerations on consent practices in the big data framework, there are three criticisms on consent as a guide to law and policy: ''current consents (1) lack the dynamicity required for modern data, (2) they are not well suited for the education and comprehension components, and (3) they are unable to deal with consent revocation since this undermines the scientific validity of data sets.''[316] Neither is the practice of anonymisation a suitable alternative, as data anonymisation is vulnerable to re-identification, inference, and denies individuals the respect that follows from the conditions to force their attempts to ensure that they are not observed without their permission. Current consent practices and anonymisation techniques cannot meet the obligation to inform the individual about the data-processing activities. It seems as if there are two positions to consider. Either a full commitment is made to the legal obligation to fully disclose all information, which only permits the use of narrow consent.

As a consequence, this would put up a barrier for big data practices. A second option would be to abandon the duty of disclosure altogether and rely on the anonymisation of data. But the anonymisation of data does not guarantee protection from privacy intrusions and does not support the acknowledgement that people are entitled to control the flow of information. These two options do little to establish a mutually beneficial agreement between participants and research institutions. Therefore, the following chapter considers alternatives to meet the challenges that current consent practices pose for the conduct of scientific research.

4: The harmonisation of privacy norms and the public utility of biomedical research

[315] Ibid., p. 206.

[316] Dankar, F., Gergely, M. and Dankar, S. (2019). Informed Consent in Biomedical Research. *Computational and Structural Biotechnology Journal*, 17, p. 468.

The previous chapters illuminated some of the tensions that emerge between big data sciences and the right to privacy, and the tensions between current consent practices and the freedom that is required for scientific progress.A long-term strategy for these issues requires a careful and extensive recalibration of the values and interests that intersect the research, legal, and the ethical practice in the big data biomedical research paradigm. Relevant for this thesis is how to understand the relation between the value of public utility in relation to the modification of certain privacy norms.[317] In the case of the BigData@Heart initiative, the research platform strives to deliver a public good by reducing the 'societal burden' of heart diseases through translational research, personalised medicine, and drug innovation.[318] At the same time, the right to individual privacy also serves a public interest because ''the good of the community depends on [the willingness of individuals] to enter into voluntary cooperation with others under conditions in which they must share private information with confidence.''[319]

Consent as the obligation to fully inform information to data subjects for autonomous decision-making should be reviewed in a broader normative framework that takes into the account the possible social and ethical dimensions of research participation for the individual and society at large. In doing so, the norms of privacy shift from full control by data subjects over how the information is used to norms of confidentiality that govern the flow of information.

Within the broader normative framework, the legal obligations for consent that the GDPR prescribes need to be reconsidered. One option is to find another lawful basis for research data processing activities. Scholars have a proposed a legal exemption from consent for research purposes. I argue that such an approach compromises the respect for individual autonomous decision-making too much. Rather than framing the obligation for consent as a limitation for data initiatives that aim to deliver a public good, it is more constructive to approach the issue in terms of a 'double articulation' ''between the private interest in protecting privacy and promoting the public good, and the public interest in protecting privacy and promoting the public good.''[320] This approach is a compromise

[317] Nuffield Council on Bioethics, (February 2015), xv.
[318] Bigdata-heart.eu. (2019). *BigData@Heart > Objectives*. URL: https://www.bigdata-heart.eu/About/Objectives, last accessed July 2, 2019.
[319] Ibid., p. 56.
[320] Nuffield Council on Bioethics, (February 2015), p. 56.

between the obligations of the social contract that frame the respect for autonomy and the preservation of medical research practices that strive to create a public good. From this perspective, it is possible to reconsider the moral weight of the obligation to respect individual mechanisms of control as an expression of the right to privacy, without compromising on autonomy as the capacity to make an informed decision that underscores the importance of personhood.

Research exemption - legal, ethical, and organisational considerations

A research exemption is invoked as a solution to the burdensome legal requirements of the consent practice. Article 9(2)(j) allows a research exemption in the case if ''processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.''[321] The processing of data is permitted only if there is an exemption clause in national law, which, as stated in Article 89, must provide for derogations from the rights of access of the data subject.[322]

Additionally, 'the exemption clause must ensure that ''that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation.''[323] The exemption in national law must establish a justificatory basis for a derogation of individual rights in the case of scientific research, as it must be shown that ''such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes.''[324] The implementation on the exemption clause via national law depends on the harmonisation of the norms of stakeholders that underlie the interests for the exemption of studies from the data protection regulation.[325] At the moment, there is no clear consensus on the legal and ethical standards that justify an exemption in the interest

[321] *GDPR,* 25 May 2018, Processing of Special Categories of Personal Data, Article 9(2)(J), URL:http://www.privacy-regulation.eu/en/article-9-processing-of-special-categories-of-personal-data-GDPR.htm. Last accessed June 20.

[322] *GDPR,* 25 May 2018, Safeguard and Derogations (...) for statistical purposes. (title abbreviated). Article, 89(2), Accessible at: https://gdpr-info.eu/art-89-gdpr/. Last accessed June 3, 2019.

[323] Ibid.

[324] Ibid.

[325] Mosterd, M. (2019), BigData@Heart Webinar on Privacy, published 29 October 2018, Accessible at: https://www.bigdata-heart.eu/Webinars/WP7-webinar-data-privacy; 4:55. Last accessed June 6, 2019.

of scientific research.[326] Furthermore, there is the legal issue that the standards for a research exemption might be different for various countries in the EU,[327] which would likely to cause a range of organisational, bureaucratic, and privacy difficulties in the case of international research collaborations and data-sharing.

A solidarity-based framework seeks to lessen the administrative and logistical burdens of consent by focusing on people's motivations to participate in research and by emphasizing risk mitigation.[328] The model moves beyond an autonomy-based framework in response to the ethical, legal, and administrative difficulties big data research poses for the governance of public biobanks with a demarcated research focus.[329] A solidarity-based approach makes an appeal to people's motivation to willingly accept costs to assist others.[330]

Solidarity, then, is the dominant perspective that emphasises the development of strategies to mitigate harm as a complementary feature of risk prevention within biobank governance frameworks.[331] The participant agrees to the obtainment of his samples by means of a participation agreement, that sets out the values, goals, information about research studies, and statements for future use, and benefits and risks.[332] The agreement is a statement that the participant ''confirms that she is willing to carry certain potential costs should they arise in order to contribute to the goal of assisting others.''[333]

There are legal, ethical, and practical difficulties with the solidarity model, as research must still be legitimised under a lawful basis. As the solidarity model omits consent, it must either make an appeal for an exemption in the interest of scientific research, or make an appeal that the data-processing acts for biomedical research is in the

[326] Mosterd, M., Bredenoord, A., Biesaart, M. and van Delden, J. (2016), Big Data in medical research and EU data protection law: challenges to the consent or anonymise approach. *European Journal of Human Genetics*, 24, p. 956.

[327] van Veen, E., (2019) BigData@Heart Webinar on Privacy, published 29 October 2018. URL: https://www.bigdata-heart.eu/Webinars/WP7-webinar-data-privacy; 29:08. Last accessed June 6, 2019.

[328] Prainsack, B. and Buyx, A. (2013). A Solidarity-Based Approach to the Governance of Biobanks. *Medical Law Review*, 21(1), p. 1.

[329] Ibid, p. 3-4.

[330] Ibid., p. 7.

[331] Ibid., p. 8.

[332] Ibid., p. 14 -15.

[333] Ibid., p. 18.

public interest, which makes an appeal on Article 6(e) of the GDPR.[334] The difficulties of the former have been discussed earlier. An appeal to solidarity invokes a moral obligation on participants to give up their information for the sake of the greater good, which is problematic in other respects.[335]Crawford et al. argue that an appeal on solidarity in the public interest would introduce a utilitarian perspective of privacy as the mitigation of harm, which threatens to undermine the value of individual autonomy.[336]

The issues on the current grounds that attempt to justify a research exemption point the attention to some of the larger questions that define the scope of the debate on big data. In response to the difficulties with the legal requirements and the ethical aspects of consent, Shona Kalkman raises the question: ''How can we do research in accordance with the GDPR without hampering socially valuable research, while making sure it is undertaken responsibly?''[337] As big data biomedical research holds many promises, and scientific progress benefits society as a whole, ''a revision of ethical standards which strikes a balance between the requirement for consent and the practical requirements of 'Big Data science' may be appropriate.''[338]

Moving past the conflict between big data research and consent

The debate on the research exemption for scientific research frames the issue as if the public value of research practices and the value of the right to individual privacy are in fundamental conflict. While it is clear that current consent practices are problematic for research purposes, Vayena argues that we must avoid the 'collision course' that flows from the seemingly fundamental incompatibility of science with consent practices.[339] Instead, an ethical framework is required that identifies justifiable trade-offs between the tensions,

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334 *GDPR,* 25 May 2018; Lawfulness of processing, Article 6(e), Accessible at: https://gdpr-info.eu/art-6-gdpr/. Last accessed 5 June, 2019.

335 Ibid.

336 Crawford, K., Miltner, M (2014). Critiquing Big Data: Politics, Ethics, Epistemology, *Gray International Journal of Communication*, 8, p. 1666.

337 Kalkman, S. (2019) ''BigData@Heart Webinar on Privacy'', 29 October 2018, URL: https://www.bigdata-heart.eu/Webinars/WP7-webinar-data-privacy; 40:15. Last accessed June 6, 2019.

338 Mittelstadt, B. and Floridi, L. (2015), p. 315.

339 Vayena, E. and Tasioulas, J. (2016), The dynamics of big data and human rights: the case of scientific research. *Philosophical Transactions of the Royal Society A: Mathematical, Physical and Engineering Sciences*, 374(2083), p. 9.

without fundamentally favouring one practice over the other.[340]

Such an ethical framework needs to take the fundamental interests of the individual right to privacy and the public interest in research into account. Individuals have (1) an interest in individual privacy as it entitles them to mechanisms to control over their personal information that enable them become one's own person and be recognised as such, and (2) an interest to maintain and support the infrastructure of research initiatives as a service that benefits society as a whole.[341] Public research data initiatives have an interest to deliver a public good, from which the research platform is dependent on the access to personal information of research subjects. The synthesis of these values is a contractual public interest ''in respecting [people's] privacy because the good of the community depends on [people's] willingness to enter into voluntary cooperation with others under conditions in which they must share private information with confidence.''[342]

Alongside the right to privacy, Effy Vayena introduces the right to science as the idea ''that everyone has a right to benefit from scientific advances, and the idea that people have a right actively to *participate* in scientific inquiry, rather than just to be passive beneficiaries of advances made by professional scientists.''[343] However, the exercise to the right to science is complicated by the fact that data processing activities can limit the actual decision-making options for individuals because data-practices affect the consent procedure by which one forms a decision that corresponds with the ends of the individual. Big data activities distort the traditional line between the private sphere to which the individual is entitled to and the realm of public information, weakening the theoretical and normative boundaries between them.[344]

Consequently, the corresponding duties and obligations are put under pressure, as seen with consent practices. Effy Vayena argues that these challenges must be met by contextualising the ethics of the biomedical research practice in relation to the processing of data which allows the introduction of norms that not only constrain, but also enable the use of big data in scientific research.[345] Vayena suggests that big data practices radically change

[340] Vayena, E. and Tasioulas, J. (2016), p. 2.

[341] Nuffield council.
[342] Nuffield council, p. 54.
[343] Vayena, p. 4
[344] Ford, S. (2011), Reconceptualising the Public/Private Distinction in the Age of Information Technology. *Information, Communication & Society*, 14(4), pp.551.
[345] Vayena, E. and Tasioulas, J. (2016), p. 2.

the social context in which the right to privacy and science play out, therefore changing the content of the corresponding duties.[346] Given the troubles with individual control over personal data and scientific research, Vayena concludes that the privacy interests of the individual ''do not necessarily have to be served through conferring on the right-holder exclusive control over the flow of data (assuming, indeed, that they can always be served by means of consent, which is far from obvious).''[347] The protection of one's privacy is better served in a later stage of data processing flow, which is that of use.[348] The GDPR approach as it places the protection of privacy by means of data protection at the beginning through the management of access to data. Vayena states that ''this approach looks at privacy interests only insofar as they concern certain harms resulting from privacy loss,''[349] which means that the circumstances determine whether interests that fall under privacy norms warrant an actual duty to protect these interests.[350]

Adapting broad consent

Given the moral importance to recognise others as persons through h the process of control, it is undesirable to conclude that consent should be excluded from the process at all. Given the foundational importance of consent as an instrument that acknowledges the value of individual autonomy, it should be not set aside lightly. Given these considerations, what current consent alternatives are there to address the double articulation between the right to privacy and the public interest?

First of all, consent should not be primarily understood as a mechanism that grants individuals control over the flow of information, but as the institutional commitment to the interconnected principles of privacy and public utility by means of the protection of personal data if the circumstances invoke a duty to do so. Second of all, the moral duty to ensure that people participate voluntarily must be preserved. Thirdly, this implies that we seek to mitigate some of the control constraints that follow from the right to privacy (consent as the disclosure of information), while preserving the kind of decision-making

[346] Ibid., p. 10.

[347] Ibid., p. 11.

[348] Ibid., p. 11.

[349] Ibid., p. 11.

[350] Ibid., p. 11.

capacity that an autonomous person is entitled to. This rules out opt-out procedures and blank consent. The latter is not specific enough as it does not impose an obligation to provide any information to the individual. Given that the norm of confidentiality is a cornerstone of the medical research practice and rests on strict rules on what can and cannot be done with personal information as outlined in chapter two, blanket consent lacks the transactional commitment to norms of confidentiality within the social contract. Instead, broad consent would be a potential alternative. Recital 33 of the GDPR permits the use of broad consent but limits its scope ''to certain areas of research or parts of research projects to the extent allowed by the intended purpose.''[351] Thus, we need to further contextualise how broad consent would manage the underlying balance between value in conducting a certain type of scientific research and the right to privacy. In accordance with recital 33, I propose the addition of an exclusion clause to broad consent that limits the use of personal data for certain types of research and limits the sharing of personal data with specific parties.[352] An exclusion clause is a statement added to consent forms that limits the rights of use of the data controller, and its function is to intercept contentious research that could risk the discrimination or stigmatisation of individuals or groups.[353]

The benefits of the use of exclusion clauses is that (1) they are easy to include in a broad range of consent models which include broad and tiered consent,[354] (2) they increase transparency and make it possible to hold researchers accountable,[355] (3) they provide information about the uses of data to participants,[356] and (4), they ''provide guarantees to participants that will likely foster greater trust between participants and researchers, biobanks, research institutions, and possibly the scientific or medical enterprise.''[357]

An exclusion clause should not be confused with the presentation of a set of choices

[351] *GDPR,* 25 May 2018, Recital 33, Accessible at: http://www.privacy-regulation.eu/en/recital-33-GDPR.htm. Last accessed June 3, 2019.

[352] Master, Z. and Resnik, D. (2013), Incorporating Exclusion Clauses into Informed Consent for Biobanking. *Cambridge Quarterly of Healthcare Ethics*, 22(2), p. 203.

[353] Master, Z. and Resnik, D. (2013), p. 203.

[354] Ibid., p. 208.

[355] Ibid., p. 208.

[356] Ibid., p.208.

[357] Ibid, p. 208.

to the participant.[358] Rather, the researchers have the responsibility to decide which areas of research and organisations are excluded.[359] The decisional authority lies with the researchers which implies that the interests of individuals not to have their data disclosed can be set aside if there is a legitimate reason.[360] In the Nuffield Council report, two such cases are identified:

''*The first case is where an aim of paramount public interest can only be achieved by either comprehensive participation (or could not be achieved by a level of participation expected under non-compulsory conditions) or can only be achieved by the inclusion of particular individuals. Such cases as these arise (although not without controversy) in the domain of public health, where individual objections to state intrusion into private life are sometimes overruled in the public interest. (...) The second case is one in which full participation is not necessary, but where it can be argued that 'free riding' (i.e. benefitting from a public good that others have borne the cost of providing) is regarded as morally unacceptable.''*[361]

More can and should be said about how to weigh the circumstances that determine whether the interests of the individual invoke a duty of protection on behalf of the data controller. This is the terrain of governance mechanisms, such as review councils and committees, because such mechanisms ''help distinguish *'bona fide'* and problematic requests for access to data.''[362] Governance mechanisms, such as ethical review boards, can assess under what circumstances there is a ground to exclude or allow some parties from access to data, or if the duty of the protection of privacy outweighs the access of certain parties to data.

An objection against the use of exclusion clauses is that researchers may not know or do not anticipate what participants consider riskful research and organisations.[363]Such considerations are in constant development, which is an incentive for data initiatives to stay

[358] Ibid., p. 206.

[359] Ibid., p. 206.

[360] Nuffield Council on Bioethics, (February 2015), p. 84.

[361] Ibid., p. 88.

[362] Mittelstadt, B. and Floridi, L. (2015), p. 312.

[363] Master, Z. and Resnik, D. (2013), Incorporating Exclusion Clauses into Informed Consent for Biobanking. *Cambridge Quarterly of Healthcare Ethics*, 22(2), p. 209.

in touch with the norms and values that are at the heart of society.[364] The anticipation of these tensions is likely to identify potential conflicts in an early stage,[365] which informs researchers on the permitted scope of future research studies. Researchers, then, are incentivised to involve people 'with relevant moral interests' in the design and governance of studies for the identification of relevant privacy considerations.[366] This adds legitimacy to the research, establishes public trust, and expresses the researcher's commitment to fairness, transparency, and accountability.[367]

Conclusively, big data practices put pressure on the contractual norms and rules that govern the private and public interest in privacy and public utility. A broad consent approach with the addition of an exclusion clause aims to inform the individual, establish voluntary participation, protect the individual from third party interests whose use of personal data would compromise one's autonomy, and acknowledge the importance of a voluntary decision as an expression of personhood. This thesis has aimed to illuminate some of the normative and conceptual big data practices pose for fair information practices, and hopefully made a contribution to enable to meet these issues proactively.

5: Conclusion

This thesis has proposed an approach to consent that seeks to balance the value of privacy in relation to public utility, and is of interest to researchers and policy-makers of research data initiatives. Balancing the interests and values is no easy task in light of the protection of personal data. Big data practices put traditional norms of privacy under pressure by overturning conventional views on what is considered 'private' and 'public' information. This only strengthens the normative value of privacy for the individual and society at large, given the risks that big data practices pose for individual self-determination as the cornerstone of a democratic society.

Consent is the policy that attempts to establish a fair processing of personal data, but current consent practices lack the dynamicity to deal with modern data, which, in turn,

[364] Nuffield Council on Bioethics (February 2015). *The collection, linking and use of data in biomedical research and health care: ethical issues*. London: Nuffield Council on Bioethics., xxii.

[365] Ibid., xxi.

[366] Ibid., p. 84.

[367] Ibid., 154- 155.

fail to inform and educate participants. This obstructs scientific research.
Another, more flexible approach is needed. The scientific practice and privacy norms should not be in perpetual conflict with each other. They are both fundamental cornerstones of societies in Western civilizations, and the erosion of one implies an erosion of the other as well. Therefore, the underlying values of personal data and the scientific research practice should be understood and assessed in conjunction with each other. This adds another layer to the normative basis of a broad consent approach: consent is the expression of an institutional commitment to the protection of the principle of privacy by means of the protection of personal data, if the circumstances invoke a duty to do so. An exclusion clause narrows down the scope of consent in accordance with the circumstances that invoke a duty of data protection. Additional governance mechanisms inform what duties and liberties researchers should have in this process, should strive to educate individuals about data-processing activities, and help to build public trust and legitimacy to the research initiative.

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