The Unique and the Universal: Analyzing the Interplay Between Regulatory Frameworks, Researchers and Research Participants in Data Making

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Abstract

Contemporary health research is becoming increasingly data intensive with a dependency on more data, of different types, and on more people. Multiple measures are therefore taken to ensure a variety of data, for example by re-appropriating data collected for purposes other than research. In genetic research, there is a general aim of more personalized diagnostics and treatments. Personalization in many ways depends on access to a universal data pool to gain statistical strength when identifying rare variants affecting unique individuals. If the aim of identifying the unique depends on access to the universal, how are we then to understand the dialectic between these two concepts? Further, if data-intensive research thrives on repurposing data, how does the repurposing affect the interests of the people from whom the data derive? In this article, we explore these questions by comparing two Danish initiatives aimed at making more data available for research through repurposing: one from a screening program of newborns at the beginning of life; and the other through an educational program collecting bodies after death. They both involve reinventing the original collection practices and they illustrate how regulatory frameworks, researchers and research participants reason differently about what can be considered as unique and as universal, as well as the risks and benefits involved in participating in data-intensive research.

Keywords

big data; health data; Denmark; precision medicine; unique; universal; NDBS samples; postmortem body donation

Introduction

Research depends on access to data: big data, small data, new data, recycled data (Borgman 2015). In health research, these data often derive from people, and potentially have implications for people. Researchers employ increasingly data-intensive technologies, such as genetic sequencing. Here interpretation depends on statistical methods: the significance of a variation in an individual is determined in the light of a larger population. To acquire data for this type of research, politicians, clinicians and researchers have embarked

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upon multiple initiatives. Many involve re-appropriating data collected for purposes other than research. During the past decade, the United States has invested more than 30 billion US dollars in digitalization of health records and integration of data sources (Wachter 2015). The European Union has similarly adopted a strategy paper on personalized medicine, prompting member states to standardize biobanks and "promote the interoperability of electronic health records to facilitate their use for public health and research" (General Secretariat of the Council 2015, sec. 29; European Commission 2020a, 9). One of the areas for investment is "health data spaces," and a new regulatory framework has been put forward to facilitate such cross-national data sharing (European Commission 2020b). In short, investments in repurposing data for research are massive and the political hopes are high.

Data are not the same as people, but when interpreted as representing people, data can affect people's rights and entitlements. Repurposing of data can therefore be important for those from whom data derive—as well as other people who data might also be taken to describe. How does work to repurpose *data* (as epistemic representations) interact with and affect the interests and concerns of *people* (as ontological beings with political entitlements and social risks and benefits)? Moreover, do regulatory frameworks address these interests and concerns?

We were drawn to these questions during a research project investigating the remaking of Danish health data infrastructures (POLICYAID 2021). With a long history of data-intensive governance and research, and of transforming administrative data into opportunities for research (Bauer 2014), Denmark has been called "the epidemiologist's dream" and "an entire cohort study" (Frank 2000; ibid 2003). Since 2016, the project has mapped and compared data initiatives in Danish healthcare. These initiatives include 1) a universal screening program of newborns, which is increasingly used also to facilitate research into both mental illness and rare conditions; and 2) a reconstruction of a postmortem body donation program—originally set up to teach medical students anatomical dissection, and now assisting in establishing a biobank for research into rare anatomical features revealed in the course of dissection. In the course of exploring these two data initiatives, we were struck by the very different regulatory frameworks and organizational practices surrounding them and wondered how researchers and the prospective research participants reflect on these differences. The newborns have their whole lives ahead of them, and their contribution to research could potentially have an unforeseen significance for them (O'Doherty et al. 2016), whereas people who donate their body to the anatomical dissection program, conversely, face few, if any, personal risks: they are already dead at the point of their research participation. Still, the regulatory frameworks focus on ensuring the rights of dissection donors while facilitating research uses of newborn samples.

In this article, we investigate the interplay between different forms of reasoning surrounding the two cases with a focus on how each relates to notions of uniqueness and universality. We compare the reasoning across three levels: 1) the regulatory frameworks and organizational practices, 2) the researchers, 3) the people from whom the data derive and who thereby become research participants. While regulatory frameworks, researchers and research participants all reflect on what it means to stand out (uniqueness), and to be a member of a larger population (universality), they do so in remarkably different ways. To address the hopes and concerns of both researchers and participants, we argue how there is reason to rethink regulatory frameworks and organizational practices. Before analyzing the reasoning among regulators, researchers, and donors, we will begin with an overview of our methodology, followed by a presentation of

the two concepts "unique" and "universal" and their relevance for recent scholarship on data-intensive medicine.

Methods

To understand the practices of our first case study—screening through NDBS samples—Nordfalk observed 25 instances of sample procurement at two of the larger hospitals in Denmark, as well as in the homes of some of the parents of newborns. Nordfalk further interviewed 19 parents of newborn babies (in 18 interviews, two being present in the same interview) about their experiences with the sampling and their perspectives on the samples being used for research. As an implication of patterns of parental leave, the parents interviewed were all mothers. During our investigations of the Danish NDBS samples, we were invited to the institute responsible for the samples both in screening and for storage in the Danish Neonatal Screening Biobank. Nordfalk further interviewed the Head of the Danish Center for Neonatal Screening who is also one of the lead researchers utilizing the Danish NDBS samples for research purposes.

In the other case study—which focuses on the postmortem body donation program—Olejaz explored how donated bodies enter into research having revealed interesting physical abnormalities during dissection courses for medical students. The physical abnormalities are photographed, and samples are stored for future gene sequencing, thereby gradually building a database of genetic variations potentially associated with these physical deviations. These data can also potentially be compared to registries containing the biomedical and socio-economic history of the donor. For this case Olejaz interviewed 11 prospective donors and two lead researchers, and analyzed various texts, homepages and other types of material describing the initiative.

All interviews were transcribed and thematically coded (Madden 2010; Attride-Stirling 2001) to compare the two cases across all three levels of reasoning: the regulatory framework, the researchers, and research participants. We have translated all quotations from Danish. This type of research is not subject to ethics approval in Denmark, according to Danish legislation on research and research participation.

Unique and Universal: Recursive Concepts in an Age of Data-Intensive Research

The terms "unique" and "universal" have a range of meanings (Stefánsson 2012). According to the Merriam-Webster dictionary (Merriam-Webster 2021) "universal" means "including or covering all or a whole collectively or distributively without limit or exception." This definition does not define the specific collective, but an example is added: "available equitably to all members of a society"—the latter specification indicating a political criterion of inclusion; citizenship. Merriam-Webster further alternatively defines "universal" as "embracing a major part or the greatest portion (as of humankind)," exemplified as "a universal state." This is akin to a biomedical understanding of a trait characterizing human biology irrespective of political constituency. Another meaning is listed as, "denoting every member of a class," which points to the need for a class (a limit) to declare universality (no limit)—whether in its biomedical or political sense; hence, to think of something as "universal," a form of delineation must be implied. The entry for "unique" begins with the definition "being the only one," but then adds "able to be distinguished from all others of its class or type." Taken together, these definitions imply that in order to be considered "universal," there is a need to define the population of universal coverage, and to be "unique" there is a need for establishing a class or type within which the variation can stand out: to be identified as unique, a

phenomenon must first be seen as belonging to a kind (a member of something universal). In short, unique and universal are recursive concepts.

This recursive enfolding is exactly what epidemiologist Nancy Krieger (Krieger 2012) famously encouraged epidemiologists to tackle explicitly in their research designs. Krieger pointed to the tendency to build research on available data rather than finding the data needed to answer a scientific question. The data needed for epidemiological research refer to "populations" as epistemic classes, (e.g. "all human beings between 20 and 60" or "children with leukemia"). Often, however, research using repurposed data work from data availability and thereby come to refer to a population understood as, e.g., "all Danish citizens." Such a population would mainly be scientifically relevant when the point is to investigate a distribution of a trait specifically in Denmark (which is typically a political rather than a scientific concern). This distinction between population as an epistemic phenomenon and as a political constituency becomes increasingly relevant with the turn to research based on repurposed data, as they are dependent on political, social, and legal modes of inclusion; criteria that might not serve the research question.

What can be considered as "a population" is troubled also by intersectionality (Cruz 2017). Intersectionality means that every individual carries a great number of traits that make each person belong to numerous populations—a "population" here being understood as a group of people having a particular trait in common without otherwise being alike. We therefore suggest that the problems that Krieger pointed to can be seen as springing from a confusion between ontological and epistemological understandings of population and individual. In STS, Mol's (2002) notion of ontological multiplicity has gained significant traction, and intersectionality speaks to the way in which every individual are several things at once, but when we use the term ontological in this paper, we are less concerned with this form of multiplicity and more focused on naming the bio-material presence of persons (rather than epistemic representations of persons). We thereby use the word ontological in the standard meaning defined in Merriam-Webster dictionary as "relating to or based upon being or existence" (Merriam-Webster 2021). People living in a constituency are rights-bearing citizens, and their legal entitlements are universal in the sense of "pertaining to all." In contrast, data are abstractions. They are names of traits. People have an ontological presence embedded in a particular body (and though the body has no clear limits and can be considered multiple it is not this multiplicity we focus on here). When a body becomes ill and acquires a diagnostic code, this code becomes a reference to a patient, but not—physically speaking—the actual person. The code is a representation of the physical experience. It can be present in multiple formats and exchanged across databases without the actual person being involved.

When people receive medical treatment, they do so in light of the entitlements associated with who they are as rights-bearing ontological beings. The data traces they leave in the course of receiving such treatment, however, come to comprise epistemic classes ("everybody with this diagnostic code") and the same person can belong to multiple populations at the same time (e.g., those with "diabetes" and those with "ulcers"). From a legal perspective, people are rights-bearing subjects, while the data they give rise to are merely resources or assets with no entitlements (Birch and Tyfield 2012; Pinel 2020). People can be granted rights with reference to the data that are meant to represent them, but the rights rest with the people as ontological beings; while data hold no independent entitlements. Relevant terms from the two dimensions are presented in table 1.

ONTOLOGICAL	Person	Individual	Subjects	Population
understandings of the terms "unique" and "universal"	a bodily human being	a person with many traits	rights-bearing citizens	pertaining to citizenship
EPISTEMIC	**Data**	**Case**	**Assets**	**Population**
understandings of the terms "unique" and "universal"	an abstraction	a singular trait	research resources	pertaining to research-relevant class

Table 1. Ontological and epistemic terms related to unique and universal.

The reason for summing up these terms in this way, is that in the new data-intensive research paradigm where data are increasingly repurposed, *subjects* become enrolled as rights-bearing citizens accessing healthcare (upper level of table 1) but then their data traces become *assets* (lower level of table). When the regulatory framework, researchers and research participants express what it means to stand out (be unique) and to fit in (be a member of something universal), they tend to move, undetected, back and forth between the two dimensions. Data are used to construct knowledge about *probabilities* for particular diseases or conditions. Probability is an epistemic abstraction. This abstraction maybe used to identify real people and their health outcomes; in which case, in the table, we go back up from the epistemic to the ontological dimension (Holmberg, Bischof, and Bauer 2012; Amelang and Bauer 2019).

When research is successful in establishing particular links, single data points can come to affect people's entitlements and opportunities (Green and Vogt 2016; Pasquale 2015; Vogt, Hofmann, and Getz 2016). When people are identified based on possessing a particular trait (a data point), it is called "profiling." Profiling techniques are the basis of medical screening, but also the basis of very different practices such as marketing and preventive medicine (Cheney-Lippold 2018; Lury and Day 2019; Skolbekken 2019; Lupton 2019). When "unique" is used in the epistemological dimension, it is as a tool for profiling with predictive value. It remains a probability only, but it comes to define the rights and opportunities of the people associated with this data point. Profiling gains ontological traction. "Universal" in the epistemological dimension (building on data analysis), similarly refers to probability being high; it means practically all in a given class. Conversely, "unique" in the ontological dimension pertains to unique individuals, who are unique in the sense of being an individual person. "Unique" can also be used in relation to actual individuals being helped by (or living with the ramification of) profiling tools. "Universal" in the ontological sense is something that pertains to all in a given constituency, for example a political entitlement (such as "universal access to healthcare"). It is not just a high probability, but pertains to rights and experiences.

Entitlements to data are determined through regulatory frameworks enacted through organizational practices. We understand regulatory frameworks as assemblages of legal documents, organizational structures, and clinical routines enacted in practices that produce action: collections of particular samples and data from particular people (Green, Carusi, and Høyer 2019). Such frameworks can be said to uphold and propagate values, beliefs and logics, or what we can think of as a form of practical reasoning (Harman 1976). Earlier studies have pointed to the need for differentiated measures of consent, depending on context and participant group, for instance by applying more dynamic consent models (Holm, Kristiansen and Ploug 2020; Kaye et al. 2015). The reasoning embodied in regulatory frameworks might differ from and construe problems in ways other than the people populating them. As notions of universality and uniqueness typically remain unarticulated and vague, the shifts from the ontological *person* or *people* to

epistemic *data* often go unnoticed. Here we wish to bring these shifts to the fore and explore how notions of uniqueness and universality in both their epistemological and ontological dimensions shape the making of research populations. We thereby highlight what Jasanoff and colleagues have described as a "co-production" of law and research (Hurlbut, Jasanoff, and Saha 2020).

The Reasoning of the Regulatory Framework and Organizational Practices

It takes work to collect and create data, and it takes further work to make them available for research. This work is embedded in regulatory, legal and organizational frameworks, and these frameworks largely shape who comes to contribute to research and thereby form part of research populations. We begin by analyzing the remarkably different regulatory and organizational practices surrounding the two case studies: postmortem body donors have been approached in life as unique individuals determining their own future participation, whereas newborn babies are enrolled as members of a population undergoing newborn screening, with no personal agency as to their participation. Only later do their data traces become used for research, often without the newborns (i.e. in later life) or their parents ever being aware of their research participation.

The collection of NDBS samples for research in Denmark is embedded in an existing clinical screening practice. Denmark, like many other nations, screens newborn babies for congenital diseases (Nørgaard-Pedersen and Hougaard 2007; Statens Serum Institut 2020a). The screening began in 1975 with the screening for phenylketonuria (an inherited metabolic disorder). The current newborn screening program includes 18 diseases (Statens Serum Institut 2020b) and is managed by the Danish Health Authority, officially referring to the Danish Ministry of Health. Newborn screening is offered to all newborns born in Denmark and according to our studies, almost all parents agree on behalf of their children. The newborns are thus enrolled as citizens with a right to healthcare through screening, but not as current or prospective guardians of data. The data dimension is given very limited attention at this point. The Danish NDBS sample is taken within 48 to 72 hours after birth by a medical professional. It involves extracting a few drops of blood from the newborn's heel, collected onto a special filter paper. All samples nationwide are gathered at the end of each day and transported by car or post to the Serum Institute in Copenhagen for screening. After the initial screening, the samples are stored in the Danish Neonatal Screening Biobank. Storing of samples was implemented as routine procedure in 1982 (Nørgaard-Pedersen and Simonsen 1999). In our interviews we were informed that the original purpose for storing the samples was to document that the sample had been taken and analyzed, as well as for quality assurance. Storage was not initiated to meet a research need. However, storage disentangles data from people. Once in store, samples have gradually become conceptualized as a *resource*, potentially for research, especially from 1991 onwards (Nordfalk and Ekstroem 2019). When the parents give consent to having the sample taken for clinical purposes, they also consent to the storage and possible research use of the sample: consent for secondary purposes is embedded in consent for primary purposes. This indicates that in relation to research, newborn babies (or, at least, their data) are considered research assets rather than ontological subjects. They thereby represent a bifurcation in the legal organization between the status of newborn babies as entitled to care, and newborn babies as sources of data. Still, it is possible to undergo screening and subsequently opt-out of storing of the sample and/or having it used for research: this opt-out can be done by actively signing up at the "use of tissue register" (Hartlev 2015; Sundhedsdatastyrelsen 2020). This "use of tissue register" is applicable for

all samples stored, not just the NDBS samples. The Danish Health Data Authority, who are responsible for registering those who have opted out, kindly informed us that as of May 3, 2021, 11,143 people were registered as having opted out from their blood and tissue samples being used for research purposes; and likewise, 7,141 were registered as having opted out from allowing their genome information to be used. In a population of 5.8 million people, with millions of samples in the biobank, these opt-out numbers must be considered fairly small. Further, the re-use of Danish NDBS samples for research is legal under the liberal Danish laws on research participation. According to Danish law (Folketinget 2020), research projects must obtain informed consent from those who participate in their research. However, in §10 of the order, it is stated how the Danish National Committee on Health Research Ethics (Danish National Committee on Health Research Ethics 2021) can dispense from this demand if the project is health-related and register-based, does not inflict health-related risks on the research participant, and if it would be impossible or disproportionately difficult to obtain informed consent. Moreover, biological samples in biobanks are also covered under this legal framework given a Danish amendment to the European General Data Protection Regulation (GDPR) under the legal framework of the new data protection law under §10 (Folketinget 2018). It is therefore possible for researchers to apply for an exemption from the consent requirement when wanting to use the Danish NDBS samples. Taken together, this makes the re-use of Danish NDBS samples for research not only possible, but also manageable. Given the existing organizational infrastructure for screening, this mode of data sourcing has become barely noticeable for the research participants. The legal exemption from informed consent implies that the research opportunities cover practically all citizens. The actual people who provided the samples have lost direct connection to their samples. Their data now form part of a universal epistemic population of research assets.

The legal organization of the postmortem body donation program is an altogether different story. Here, the rights of the donating individual to control their transition into data stands strong. Both in Denmark and elsewhere, the procurement of bodies for anatomical dissection has a contested history, cadavers typically coming from marginalized groups such as convicted criminals, the poor or minority political groups (Richardson 2000; Olejaz 2015; Hildebrandt 2017). Besides a few rare exceptions, bodies were not acquired through donation until the second half of the twentieth century, which saw a rise in the establishment of donation programs across the world. Today, all bodies for anatomical dissection in Denmark come through the donation program. Deciding to donate one's body to the faculty of health sciences in Danish universities is described in the policy documents as a way of helping medical students in their education through anatomical dissection, as well as donating to (University of Copenhagen 2021). In order to donate one's body to science, a person must have reached the legal age of 18 and testify his or her donation through an elaborate declaration, which has to be signed by not only the donor, but also two attesting witnesses or a physician. Participating in the postmortem body donation program is a detailed opt-in to research. The potential donor must actively register to become a part of the research population—in direct contrast to the case of NDBS samples.

The regulatory reasoning in the two cases rests, in many respects, on shifts between ontological and epistemic perceptions of "unique" and "universal." The postmortem body donation program is not tied to a universal right. Instead the legal framework focuses on the donor as a rights-bearing individual (an ontological being) who, through the consent form, sanctions the transformation into data. In contrast, the focus of the legal and organizational framework surrounding the Danish NDBS samples is on a right of access

to the screening through which datafication takes place, but not on a right to sanction the datafication per se. The regulatory framework of the Danish NDBS samples guards the data as epistemic resources. Whereas the participants in the postmortem body donation program enroll as unique ontological individuals, managed as legal subjects, data from the newborns are managed as epistemic resources.

The Reasonings Among Researchers

With almost all children born in Denmark since 1982 having a sample in the biobank, there are currently over two million samples in the biobank. This means that the biobank covers almost every member of the Danish population (the legal population) under 40 years of age, which facilitates the creation of multiple research populations (epistemic subgroups of disease categories and control groups). This makes the biobank an important research resource (Nørgaard-Pedersen 2016). With this many samples, it becomes possible to study rare disorders. Further, with the very low opt-out level, enrolment bias causes limited problems (though Krieger would see "only Danes" as an enrolment bias for many research questions because of the limited diversity in Denmark). This is what makes the biobank so interesting for researchers. iPSYCH is one of the largest studies using the Danish NDBS samples, and focuses on mental disorders (Pedersen et al. 2017). In an interview with Nordfalk, David Hougaard, the principal investigator of one of the subprojects in iPSYCH and the head of the Danish Center for Neonatal Screening, explained how they, when acting as researchers in genome-wide association studies, are not interested in the person behind the sample. Instead, what they focused on was the "swarm" as he puts it:

> When you do these studies, you don't go and look at Peter Brown's gene. You look at the greater [number], several thousand, genes, and study how they form groups. From thousands of people and how they group in comparison to those who are not sick. . . . You have no interest in diving into one single person. Really, it has to be the whole "swarm" you are looking at. (David Hougaard, Head of the Danish Center for Neonatal Screening)

This quotation illustrates how the biological-material uniqueness of a person (the actual ontological being) is not of interest for the researchers using the NDBS samples. They focus on the epistemic dimension of universality—a swarm. Researchers study how they form groups, or epistemic classes, defined by traits. Similarly, when looking for rare mutations among the NDBS samples, researchers seek something unique in an epistemic sense:

> You only take some point mutations or point variants. Single nucleotide polymorphism. That is, single points, bases really, that vary a little bit for all of us. And together they paint a picture of how we differ. And given that we only have very few points, which in themselves do not cause a disease, it is still possible to use those together with other studies to say that there is a possibility of something causing a pathogenic mutation. (David Hougaard, Head of the Danish Center for Neonatal Screening)

The researchers use data points to estimate probabilities. It remains an epistemic task. Still, they take care to justify this epistemic pursuit with the potential for using probabilities to help guide the diagnosis and treatment of future patients. This involves a shift back from the epistemic perspective to the ontological: actual patients with individual disease trajectories.

Returning to our case of the postmortem body donation program, the new addition to the existing program is the collection of data in a biobank. It is a biobank of anatomical abnormalities. In the dissection

lab, the donated bodies are interesting for their fleshy and particular "realness," teaching students how every universal feature of human anatomy has a unique expression. The bodies are troublesome when they are too particular, when they divert too much from the bodily norm the students are supposed to encounter. Medical students also learn how to show respect to bodies, while using them instrumentally; in other words, to approach the dead people as both object and subject (Olejaz 2017). The repurposing of the body begins when a donor is dissected and some sort of abnormality is detected (this could, for instance, be a vein running in an unusual position). The student and the instructor examine the abnormality and thereby start a process of datafication. The abnormality is first described and photographed. Afterwards, a tissue sample from the donor is taken and stored in a biobank at the university. In this practice lies a shift from the ontological subject who donated their body to the sample as data. There is a special interest in gathering information on anatomical atavisms—the reappearance of biological traits that had otherwise been lost in evolution. This biobank of anatomical abnormalities was initiated in 2013, and it is still a biobank in-the-making. The researchers in charge of the project explain the aim of their project this way:

> That is really the point of it, to see if we can find a genetic background behind some of the different anatomical variations. And those that are especially interesting, that's probably those atavisms, if we find some. Because those are probably rarer. (Professor Jørgen Tranum-Jensen)

> . . . So the chance of finding the same hit in a gene or regulatory with a given phenotype is not great, so you have to examine a lot [of donors] (. . .) to get a sense of something being significant enough. It's somewhat of a puzzle, but that's what makes it so interesting. (Professor Niels Tommerup)

The point of the research component (the repurposing of data from dissection) is to find enough bodies with "unique" variations, especially variations that cannot be detected without dissection: atavisms that are hidden under the skin; a singular trait that differs from the epistemic understanding of "normal" anatomy. The rarer—the more unique—abnormalities, such as atavisms, are the most interesting ones. The researchers are trying to solve an epistemic puzzle, pursuing that abnormal piece that does not fit. Importantly, the epistemic puzzle is not one that living people will necessarily have discovered or felt, exactly because it is hidden under the skin. It is interesting for researchers, not because it affected the individual donor, but because it may say something about the shared history of humanity. It tells a story about universal biology, in an epistemic sense, but not in an ontological sense as something affecting all members of society.

In both cases, researchers justify their research with its relevance to people in the ontological sense, but their actual work revolves around the epistemic dimension. They work with data to construct knowledge. Researchers studying NDBS samples use the high numbers of samples to find rare cases, and postmortem body donation researchers study atavisms in the uncovering of hidden traits to similarly find rare cases. Still, in both cases, the search for the rare and the unique aims to inform a general understanding of human biology as a universal condition. Their insights may help guide the medical treatment of ontological individuals based on statistical probability, but this goes beyond the present research task.

The Reasonings Among Donors

Above, we have shown how the legal organization in relation to NDBS samples makes the enrolment of the samples into research a seamless practicality by embedding it in universal access to care (a population in the ontological sense), and then subsequently construes the samples as assets (a population in the epistemic sense). It helps scientists in their search for unique—or, rather, statistically rare—variants. In contrast, the regulatory framework fiercely guards the autonomy of the individual postmortem body donors as rights-bearing citizens making unique choices. Scientists here use the chance to go under the skin to search for unique atavisms, to better understand universal human biology. What, then, do the people from whom the data are derived think about uniqueness and universality? What do they think about the risks and benefits of participating in research? While we will show that they do not understand the research in the same manner as the regulatory framework or the researchers, it is important not to overemphasize this deficit of information. We know from earlier studies that *information* seldom is the reason for research participation (Felt et al. 2009; Høyer and Lynöe 2006; Høyer and Hogle 2014). Instead of criticizing an information deficit, we are interested in what matters to the people who become donors of samples to research.

In relation to NDBS samples, the newborns are for obvious reasons unaware of their donation, while their parents tend to focus on the screening itself, rarely realizing that their newborns are donating to research. When Nordfalk has observed samplings, parents almost never question why samples are taken or whether it is the right thing to do; nor do they tend to notice the information provided about the sample being stored and potentially used for research, and remain unaware of the possibility of opting out. In subsequent interviews with the parents, we quickly realized how none of the nineteen parents we talked to were aware that their baby's sample might be used for research purposes. When we offered this information, the majority of the parents gave us answers like Sandra's:

> . . . it doesn't bother me really. If it can do something good for the Danish people in general, humanity in general, that they have a blood sample from me [and my child], well then by all means. . . (Sandra, parent of a four-month-old baby boy)

Sandra's altruism in this quotation suggests a gift to humanity, a universal community. Sandra welcomes the notion of a research resource (in the epistemic sense), because it may "do something good" for others (i.e. "population" in the ontological sense). The treatment aim motivates the embrace of research. Another parent we interviewed, Simone, similarly endorsed the research, and gave an even stronger indication of being motivated by the idea of being a member of a population also in the ontological and political sense, already receiving care, belonging to a healthcare system:

> It's the same as something like organ donation, consent and the healthcare system. It's just something you do. (Simone, parent of a six-month-old baby boy)

Simone furthermore expressed a sense of security in the fact that everybody donates ("it's just something you do"). These statements echoed what we heard from other parents we interviewed. In general, they felt a protective herd effect of just doing what everybody else does. Participation is a way of being a member of a community and as long as other members of the community do the same, it is safe. Well in line with Mercier's argument about the wisdom of the crowd, they feel protected by being one of many (Mercier 2020).

However, thoughts about the uniqueness of every sample sometimes instigated a shift in the parents' attitude. The concern that someone might gain unwarranted information about their child, made some reevaluate their participation. As Barbara reflects about the sample and her son:

> If that information was somehow traced back to him, I think I'd feel unsafe. Because in general you can find out all sorts of things from genes. It might be, now he is a redhead, that you find out that redheads have this red hair gene, and you realize that this particular gene also makes people less empathic, and that might put him in a bad situation when he has to apply for a job or something. (Barbara, parent of an eight-month-old son)

Even though Barbara laughed a bit at her own example, it illustrates a point that several of the parents expressed. When considering information about their child or themselves as unique, they began to sense a risk. This risk refers to ontological uniqueness, where actual individuals are profiled and have to live with the implications— a risk that the sample they gave as an epistemic research resource, can shift and be used against them, or their child, as ontological individuals.

In contrast to the parents, dissection donors often donate because of a perception of subjective uniqueness. The postmortem body donors often explicitly motivate their interest in donation with a sense of offering unique opportunities for knowledge (Olejaz and Høyer 2016). As one of the donors, Ellen, said to us:

> And I am kind of interesting. Because I've had my ovaries removed, and I've had fourteen titanium screws put into my back over three times, where I had to be re-operated the first time, because of a hematoma and such. As a child, when I was in fifth grade, I broke both wrists. I think there are also some gold teeth and all sorts of old-fashioned things to be looked at. (Ellen, donor in her 70s)

Ellen suggests that the uniqueness she has experienced in her life might be of interest for the students and researchers. The removed organs, the foreign objects and the old-fashioned gold teeth are all testimonies to situations in her life. Another donor, Herman, similarly explained:

> It could be exciting, if they could go and look at some DNA, or I don't know, in the genes or something and say, "Aha! He's from the [surname]—family. Well, that's a family with a history of depression. We know that from others and there is the gene!" And then you can go and meddle with that gene, so the next generation can get off a little easier and not be so sad. (Herman, donor in his 70s)

Herman expresses excitement at the thought of being genetically profiled and sees an opportunity for his family in this (contrary to the parents who mostly perceive this as a risk). For Herman, epistemic uniqueness (a genetic probability) conflates with ontological uniqueness (himself and his family) and makes his contribution to science even more meaningful. Another donor who expressed a sense of bodily uniqueness was Adam. Adam was born a woman but has transitioned into a man. Moreover, he had experienced a variety of adverse reactions to medicine. Adam expressed how he thinks he might be of interest to the medical students and the researchers, exactly because of these bodily and health-related experiences, which set him apart from the majority:

> However, it could be rather educational, if you took a tissue sample or something and studied it further, with chromosomes or genes. What makes me so completely different? Not just bodily and mentally. I've

> always been like this mentally, right from birth, it was just the body that had a mistake in the packaging. But also, the way I react to medicine. (Adam, donor in his 60s)

Like in Ellen's and Herman's cases, the reasoning behind Adam's donation reflects a sense of ontological uniqueness. He believes the uniqueness of his body and his lived life can educate students and researchers. Other donors repeated this kind of reasoning, detailing the kinds of lives their bodies had gone through and how the marks of lived life on their bodies might be more relevant, if data about their lives were put to use in dissection labs (ibid.). The donors and researchers thus share an interest in unique features, but whereas researchers look for hidden atavisms (unique features unknown to the donor), donors are interested in known deviations (but with unknown causes).

A few donors did voice concerns related to the prospect of genetic testing on their dead body. Specifically, this related not to consequences that this might have for themselves (they would be dead) but for their families. It was not all benefit; profiling could also involve risk. At the center of this is the dilemma of what to do if the genetic sequencing of a donated cadaver reveals an unknown hereditary disease or condition, which might affect the family of the deceased. While some donors, like Herman above, believed that such information should be released to the family, others felt that it would be unethical to release any such information, especially if the condition is not life-threatening or if it is untreatable. As Alfred, a donor who was interviewed with his wife present and serving cake, said:

> I don't think it's right, that they are told. That I had a gene that could cause something for my descendants. It could be relevant if I was alive and could tell them myself, but they should not be told anything after [my death]. (Alfred, donor in his 70s)

Alfred's concern is that he cannot himself control who finally is told what. Like the parents, Alfred expresses a fear that research generates knowledge that may negatively affect individuals he cares about. While researchers work with populations in the epistemic sense, the donors mostly think about concrete populations, people they might know. Similarly, some dissection donors expressed concern over the loss of control over what these data might be used for in the future, when times may have changed, or technology may have advanced. At the same time, they voiced how it was difficult to know in the present, what one would have wanted to consent to in the future. The regulatory tool of providing these donors individual control thus seems unfit for research that takes place after they are dead.

The donors of NDBS samples and the dissection donors differ in their mode of enrolment, but are remarkably similar in their perception of risk; except that with the NDBS samples parents fear the donating child might face risks, while dissection donors contemplate risks that their relatives might incur after the donors' own deaths. In this light, it is ironic that the legal organization emphasizes the autonomy of the dissection donors, but not the NDBS sample donors. Dissection donors are, after all, dead when the research takes place, while the newborn donors must live with the consequences.

The Unique and Universal in Research Participation

Ontological and epistemic notions of the unique and the universal shape research participation. In this study we have compared a biobank of NDBS samples, and a biobank of anatomical abnormalities found in the postmortem body donation program. With these two case studies, we have illustrated two very different

practices for creating data from people. The two cases represent two ends of a spectrum. Based on our comparison, we believe that the interplay between ontological and epistemic notions of universality and uniqueness is equally relevant for other biobanks and research done with genetic samples, by bringing about an awareness of the shifts between different understandings of "unique." We have gathered our findings in table 2, comparing the two cases across the three levels.

		The Danish NDBS samples	The postmortem body donation program
Regulatory framework and organizational practices	Ontological	The legal organization enrolls newborn babies through universal access to screening, but newborn babies (or their parents) are not subjects with respect to decisions on research participation.	Donors have no universal right to be dissected, but their right to sanction research is fiercely protected, setting them as unique subjects.
	Epistemic	Samples transition into epistemic assets is authorized by state institutions.	Samples transition into epistemic assets is authorized by the donor.
Researchers	Ontological	Researchers legitimize their research with the potential benefit for future individuals, but the newborns delivering the samples are of no interest to them.	Researchers take great care to express respect for the bodies of postmortem donors, but the donors remain anonymous as ontological beings.
	Epistemic	Researchers use access to many samples to find rare cases. Their interest is epistemic and aims at furthering general understandings of human genetics.	Researchers search for rare variations hidden under the skin. They see atavisms as informing our understanding of universal human biology.
Donors	Ontological	Parents rationalize their children's becoming donors because of a sense of being members of a large community. Some parents fear risks associated with profiling affecting themselves or their child in their future lives.	Donors donate because of an experience of uniqueness that they can phenomenologically experience. Some fear risks associated with profiling affecting the living family members left behind after their own deaths.
	Epistemic	Parents endorse research as a benefit to humankind or ontologically universal Danish healthcare. They rarely see their children as having unique features in need of investigation.	Donors endorse research, not least as an opportunity to learn more about something unique that has marked their own life (whereas researchers are looking for uniqueness hidden beneath donors' skin).

Table 2. Summary of the analytical findings.

Notions of the unique and the universal vary across both sample source (NDBS samples and postmortem donation) and context (regulatory framework, researchers and donors). Large datasets are necessary to identify statistically relevant variations affecting individuals. Such knowledge may help individuals receive better care—it is a matter of probability; the best research can offer. Repurposed data is a way to build research populations based on political and legal conceptions of community and entitlement, rather than

based on scientific rationales. It is a research task to build a population (in the epistemic sense) that fits researchers' purpose. Researchers are trained to reflect on the adequacy of various populations for different research questions (though Krieger questions how often they do so adequately). However, nobody seems be tasked with assessing whether the social, political and legal processes of enrolment ensure the interests of the people who participate in research. Indeed, considering who has what at stake, it seems arbitrary to assign more rights to the dying than those commencing their lives. Svendsen et al. (2018) have argued that in Denmark, rights to life are fiercely guarded for the elderly, whereas the life-worth of newborns is more often questioned (ibid, 30). It might have to do with a sense—within the regulatory and organizational framework—of ontological uniqueness being a quality acquired through life.

For the researchers, the legal framework, at least superficially, seems to work as they gain access to data. Still, they are dependent on a socially sustainable organization. This is where our analysis of different conceptions of risk suggests some challenges. How do we design and implement the right legal organization, if regulators, researchers and donors are not aligned in their ontological and epistemic understandings? How do researchers gain a sense of guidance on what donors find legitimate? It is not uncommon for researchers to experience some form of "data anxiety" (Cool 2019) and recent cases in Denmark have further stimulated the fear of public criticism (Fischer and Friss 2020a; ibid 2020b). Who, then, guides researchers?

Communicating with donors who think of uniqueness in an ontological sense as pertaining to probability—an epistemic uniqueness—could prove relevant for preserving social sustainability. However, it might never be possible to completely transmit a research conception to donors. It is probably more useful to turn things around and consider how researchers and regulatory frameworks and organizational practices can come to respond to the concerns raised by donors. These concerns relate to studies of the epistemic understandings of ethics and research data in the field of precision public health (Khoury et al. 2018). Moreover, concerns among donors often relate to profiling, where the data used for research is used against the people who gave the data. Taylor and colleagues suggest that those affected by identification of special traits might be people other than those on whom the research is conducted (Taylor, Floridi, and van der Sloot 2017). Profiling targets everybody with a particular trait, not just those on whom the research was conducted. Taylor therefore argues that there is a need to protect people against harmful profiling, not just unsolicited data sourcing. Consent does not solve that. Prainsack and colleagues suggest harm mitigation foundations to help those affected negatively by profiling (McMahon, Buyx, and Prainsack 2020; Prainsack and Buyx 2017). For the donors we have interviewed, what matters is how the health services use and share insights into unique traits. As massive investments are made into integration of data infrastructures to facilitate repurposing of data for research, it seems timely to also invest resources in the organizational capacity to deal with how to use the findings. However, such decision-making is scattered. No organizational unity is tasked with a responsibility for following and analyzing shifting perceptions of risk and benefit in the populations giving rise to all the data. The Danish health services have agencies that prioritize drugs, and assess user experiences with medical devices, but no one is responsible for analyzing and prioritizing the use of data predictive tools (profiling) and how people experience these tools. Perhaps it is time to recognize that it is not enough to build data infrastructures without caring about their social sustainability?

Conclusions

In conclusion, we have found how "unique" and "universal" are not only epistemological concepts relating to research opportunities; they are politically and socially mobilizing concepts working on the people who give rise to data. Increased awareness of the effects of the different notions about being unique might facilitate a more constructive debate about priorities—both in new data sourcing research initiatives and when re-using for research data, which were originally collected for clinical or educational purposes. Understanding how to comprehend and handle these notions is crucial to ensure sustainable research recruitment. Focusing on the two cases analyzed in this paper, we wonder if perhaps those who remain alive, the NDBS sample donors, should be given more nuanced tools than a single one-time "opt out" to manage their preferences as they grow up (Holm, Kristiansen, and Ploug 2020; Kaye et al. 2015; Ploug and Holm 2017)? And conversely, those donating their bodies after death have, with their donation, expressed a convincing interest in supporting and participating in research and medical teaching, which makes us wonder if the elaborate protection could hinder, not only research possibilities, but also the true wishes of the donors?

Just as importantly, informed consent gives little power to people when it comes to possible future profiling. Therefore, we need to consider if people can be protected through means other than informed consent. Could there be forms of population consent that fit the way some donors are enrolled—as part of a large group? A possibility for doing this could be through data custodians. Inspiration might be found in the British Caldicott Guardian Council (GOV.UK 2020). We could similarly consider new solutions to help people with handling downstream uses of data, as in designing tools to allow people a say in when and how they wish to be subjected to profiling.

By analyzing the two cases across the three levels; the regulatory framework and organizational practices, the researchers, and the people from whom the data derive, we have revealed how the understanding of what is considered universal and especially what is considered unique, is not the same across the different levels. The uniqueness desired by the researchers is not the same nature of uniqueness that motivates donors to participate in research or that makes them fear the implications. This is not necessarily problematic, but what is key is that the regulatory frameworks, set to protect donors and research participants, are aware of what kind of uniqueness the donors find important to have protected as well as what kind of uniqueness is of interest to the researchers. Thereby it could be possible to design a regulatory framework and implement organizational practices where both the wishes and concerns of donors and the possibilities for researchers are taken into consideration.

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References

Amelang, Katrin, and Susanne Bauer. 2019. "Following the Algorithm: How Epidemiological Risk-Scores Do Accountability." *Social Studies of Science* 49(4): 476–502. https://doi.org/10.1177/0306312719862049.

Attride-Stirling, Jennifer. 2001. "Thematic Networks: An Analytic Tool for Qualitative Research." Qualitative Research 1(3): 385–405. https://doi.org/10.1177/146879410100100307.

Bauer, Susanne. 2014. "From Administrative Infrastructure to Biomedical Resource: Danish Population Registries, the 'Scandinavian Laboratory,' and the 'Epidemiologist's Dream.'" *Science in Context* 27(2): 187–213. Cambridge: Cambridge University Press. https://doi.org/10.1017/S0269889714000040.

Birch, Kean, and David Tyfield. 2012. "Theorizing the Bioeconomy: Biovalue, Biocapital, Bioeconomics or . . . What?" *Science, Technology, & Human Values* 38(3): 299–327. https://doi.org/10.1177/0162243912442398.

Borgman, Christine L. 2015. *Big Data, Little Data, No Data: Scholarship in the Networked World*. Cambridge: MIT Press.

Cheney-Lippold, John. 2018. *We Are Data: Algorithms and the Making of Our Digital Selves*. New York: NYU Press.

Cool, Alison. 2019. "Impossible, Unknowable, Accountable: Dramas and Dilemmas of Data Law." *Social Studies of Science* 49(4): 503–30. https://doi.org/10.1177/0306312719846557.

Cruz, Taylor M. 2017. "The Making of a Population: Challenges, Implications, and Consequences of the Quantification of Social Difference." *Social Science and Medicine* 174: 79–85. https://doi.org/10.1016/j.socscimed.2016.12.025.

European Commission. 2020a. *Europe's Moment: Repair and Prepare for the Next Generation*. Brussels: European Commission. https://ec.europa.eu/commission/presscorner/detail/en/ip_20_940.

——. 2020b. *Proposal for a Regulation of the European Parliament and of the Council on European Data Governance (Data Governance Act)*. Brussels: European Commission. https://www.europarl.europa.eu/doceo/document/A-9-2021-0248_EN.html.

Felt, Ulrike, Milena D. Bister, Michael Strassnig, and Ursula Wagner. 2009. "Refusing the Information Paradigm: Informed Consent, Medical Research, and Patient Participation." *Health* 13(1): 87-106. https://doi.org/10.1177/1363459308097362.

Fischer, Astrid, and Mathias Friis. 2020a. "Blood Samples from Danish Pregnant Women was Flown to the US Contrary to the Rules: The Government will Examine Reviled Research Project at the State Serum Institute" [Blodprøver fra danske gravide blev fløjet til USA i strid med reglerne: Nu vil myndighed undersøge udskældt forskningsprojekt på SSI], trans. *DR.DK*. Accessed January 29, 2021. https://www.dr.dk/nyheder/indland/blodproever-fra-danske-gravide-blev-floejet-til-usa-i-strid-med-reglerne-nu-vil.

——. 2020b. "Documents Reveal: The State Serum Institute Have Passed on Danish Samples for Six Years, Without Permission" [Dokumenter afslører: Statens Serum Institut har i seks år videregivet danskeres blodprøver uden tilladelse], trans. *DR.DK*, December 1, 2020. Accessed January 29, 2021. https://www.dr.dk/nyheder/indland/dokumenter-afsloerer-statens-serum-institut-har-i-seks-aar-videregivet-danskeres.

Folketinget 2018. *Law on Supplementary Provisions to the Regulation on Protection of Physical People when Handling Personal Information and on Free Exchange of Such Information (Data Protection Law)* [*Lov om supplerende bestemmelser til forordning om beskyttelse af fysiske personer i forbindelse med behandling af personoplysninger og om fri udveksling af sådanne oplysninger (Databeskyttelsesloven)*, trans. Copenhagen. https://www.retsinformation.dk/eli/lta/2018/502.

——. 2020. *The Legal Act on Scientific Ethical Handling of Health-Related Research Projects and Health-Data Research Projects* [*Bekendtgørelse af lov om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter og sundhedsdatavidenskabelige forskningsprojekter*], trans. Copenhagen. https://www.retsinformation.dk/eli/lta/2019/1436.

Frank, Lone. 2000. "When an Entire Country Is a Cohort." *Science* 287(5462): 2398–99. https://doi.org/10.1126/science.287.5462.2398.

——. 2003. "The Epidemiologist's Dream: Denmark." *Science* 301(5630): 163. https://doi.org/10.1126/science.301.5630.163.

General Secretariat of the Council. 2015. *Council Conclusions on Personalised Medicine for Patients*. Brussels: Council of the European Union. (2015/C 421/03). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015XG1217(01)&from=FR

GOV.UK. 2020. "UK Caldicott Guardian Council." *UK Caldicott Guardian Council*. Accessed January 29, 2021. https://www.gov.uk/government/groups/uk-caldicott-guardian-council.

Green, Sara, Annamaria Carusi, and Klaus Høyer. 2019. "Plastic Diagnostics: The Remaking of Disease and Evidence in Personalized Medicine." *Social Science & Medicine* 112318. https://doi.org/10.1016/j.socscimed.2019.05.023.

——, and Henrik Vogt. 2016. "Personalizing Medicine: Disease Prevention in Silico and in Socio." *Humana.Mente Journal of Philosophical Studies* 9 (30): 105–45.

Harman, Gilbert. 1976. "Practical Reasoning." *The Review of Metaphysics* 29(3): 431–63. http://www.jstor.org/stable/20126812.

Hartlev, Mette. 2015. "Genomic Databases and Biobanks in Denmark." *The Journal of Law, Medicine & Ethics* 43(4): 743–53. https://doi.org/10.1111/jlme.12316.

Hildebrandt, Sabine. 2017. *The Anatomy of Murder: Ethical Transgressions and Anatomical Science During the Third Reich*. New York: Berghahn Books. https://doi.org/10.1017/S0008938916000984.

Høyer, Klaus, and Linda F. Hogle. 2014. "Informed Consent: The Politics of Intent and Practice in Medical Research Ethics." *Annual Review of Anthropology* 43(1): 347–62. https://doi.org/10.1146/annurev-anthro-102313-030413.

——, and Niels Lynöe. 2006. "Motivating Donors to Genetic Research? Anthropological Reasons to Rethink the Role of Informed Consent." *Medicine, Health Care and Philosophy* 9(1): 13–23. https://doi.org/10.1007/s11019-005-5067-1.

Holm, Soren, Thomas Birk Kristiansen, and Thomas Ploug. 2020. "Control, Trust and the Sharing of Health Information: The Limits of Trust." *Journal of Medical Ethics*. 25 August 2020. https://doi.org/10.1136/medethics-2019-105887.

Holmberg, Christine, Christine Bischof, and Susanne Bauer. 2012. "Making Predictions: Computing Populations." *Science, Technology & Human Values* 38(3): 398–420. https://doi.org/10.1177/0162243912439610.

Hurlbut, J. Benjamin, Sheila Jasanoff, and Krishanu Saha. 2020. "Constitutionalism at the Nexus of Life and Law." *Science, Technology, & Human Values* 45(6): 979–1000. https://doi.org/10.1177/0162243920921236.

Kaye, Jane, Edgar A Whitley, David Lund, Michael Morrison, et al. 2015. "Dynamic Consent: A Patient Interface for Twenty-First Century Research Networks." *European Journal of Human Genetics* 23: 141–46. https://doi.org/10.1038/ejhg.2014.71.

Khoury, Muin J., M. Scott Bowen, Mindy Clyne, W. David Dotson, et al. 2018. "From Public Health Genomics to Precision Public Health: A 20-Year Journey." *Genetics in Medicine* 20(6): 574–82. https://doi.org/10.1038/gim.2017.211.

Krieger, Nancy. 2012. "Who and What Is a 'Population'? Historical Debates, Current Controversies, and Implications for Understanding 'Population Health' and Rectifying Health Inequities." *Milbank Quarterly* 90(4): 634–81. https://doi.org/10.1111/j.1468-0009.2012.00678.x.

Lupton, Deborah. 2019. *Data Selves: More-Than-Human Perspectives*. Cambridge: Polity Press.

Lury, Celia, and Sophie Day. 2019. "Algorithmic Personalization as a Mode of Individuation." *Theory, Culture & Society* 36(2): 17–37. https://doi.org/10.1177/0263276418818888.

Madden, Raymond. 2010. *Being Ethnographic: A Guide to the Theory and Practice of Ethnography*. Sage Publications.

McMahon, Aisling, Alena Buyx, and Barbara Prainsack. 2020. "Big Data Governance Needs More Collective Responsibility: The Role of Harm Mitigation in the Governance of Data Use in Medicine and Beyond." *Medical Law Review* 28(1): 155–82. https://doi.org/10.1093/medlaw/fwz016.

Mercier, Hugo. 2020. *Not Born Yesterday: The Science of Who We Trust and What We Believe*. Princeton, NJ: Princeton University Press.

Merriam-Webster. 2021. "Merriam-Webster Dictionary." Accessed January 29, 2021. https://www.merriam-webster.com.

Mol, Annemarie. 2002. *The Body Multiple: Ontology in Medical Practice*. Dunham, NC & London: Duke University Press.

Nordfalk, Francisca, and Claus Thorn Ekstrøm. 2019. "Newborn Dried Blood Spot Samples in Denmark: The Hidden Figures of Secondary Use and Research Participation." *European Journal of Human Genetics* 27: 203–210.

Nørgaard-Pedersen, Bent, and Henrik Simonsen. 1999. "Biological Specimen Banks in Neonatal Screening." *Acta Paediatrica* (Oslo, Norway: 1992). Supplement 88(432): 106–9. https://doi.org/10.1111/j.1651-2227.1999.tb01172.x.

——. 2016. "The NDBS Sample and the Biobank" In *The Collected Human: The Raw Material of Medical Science from Cadaver to DNA*" ["PKU-Prøven og Biobanken." In *Det indsamlede menneske: Lægevidenskabens råmateriale fra kadaver til DNA], trans.* edited by Karin Tybjerg 106–7. Copenhagen: Medical Museion, University of Copenhagen.

——, and David M. Hougaard. 2007. "Storage Policies and Use of the Danish Newborn Screening Biobank." *Journal of Inherited Metabolic Disease* 30(4): 530–36. https://doi.org/10.1007/s10545-007-0631-x.

O'Doherty, Kieran C., Emily Christofides, Jeffery Yen, Heidi Beate Bentzen, et al. 2016. "If You Build It, They Will Come: Unintended Future Uses of Organised Health Data Collections." *BMC Medical Ethics* 17: 1–16. https://doi.org/10.1186/s12910-016-0137-x.

Olejaz, Maria. 2015. "The Anatomy of Bioavailability. Making Sense of Donation and Dissection of Bodies for Medical Purposes in Denmark." PhD Thesis. Faculty of Health and Medical Sciences. University of Copenhagen.

——. 2017. "When the Dead Teach: Exploring the Postvital Life of Cadavers in Danish Dissection Labs." *Medicine Anthropology Theory* 4(4): 125–149. https://doi.org/10.17157/mat.4.4.310.

——, and Klaus Høyer. 2016. "Meet the Donors: A Qualitative Analysis of What Donation Means to Danish Whole Body Donors." *European Journal of Anatomy* 20(1): 19–29.

Pasquale, Frank. 2015. *The Black Box Society: The Secret Algorithms That Control Money and Information*. Harvard, USA: Harvard University Press.

Pedersen, Carsten Boecker, Jonas Bybjerg-Grauholm, Marianne Gioertz Pedersen, Jakob Grove, et al. 2017. "The IPSYCH2012 Case–Cohort Sample: New Directions for Unravelling Genetic and Environmental Architectures of Severe Mental Disorders." *Molecular Psychiatry* 23(1): 6–14. https://doi.org/10.1038/mp.2017.196.

Pinel, Clémence. 2020. "Renting Valuable Assets: Knowledge and Value Production in Academic Science." *Science, Technology, & Human Values* 46(2) 275–297. https://doi.org/10.1177/0162243920911974.

Ploug, Thomas, and Søren Holm. 2017. "Eliciting Meta Consent for Future Secondary Research Use of Health Data Using a Smartphone Application—A Proof of Concept Study in the Danish Population." *BMC Medical Ethics* 18(51): 1–8. https://doi.org/10.1186/s12910-017-0209-6.

POLICYAID. 2021. "Policy, Practice and Patient Experience in the Age of Intensified Data Sourcing (POLICYAID)." Accessed Nov 2, 2021. Available at: www.policyaid.ku.dk.

Prainsack, Barbara, and Alena Buyx. 2017. *Solidarity in Biomedicine and Beyond*. Cambridge: Cambridge University Press.

Richardson, Ruth. 2000. *Death, Dissection and the Destitute*. Chicago: University of Chicago Press.

Skolbekken, John-Arne. 2019. "Online Risk Numbers—Helpful, Meaningless or Simply Wrong? Reflections on Online Risk Calculators." *Health* 23(4): 401–17. https://doi.org/10.1177/1363459319826183.

Statens Serum Institut. 2020a. *To Parents: Blood Samples from Newborn Babies*. Copenhagen: Statens Serum Institut.

——. 2020b. "Screening for Medfødte Sygdomme." *Statens Serum Institut.* Accessed November 29, 2021. https://www.ssi.dk/sygdomme-beredskab-og-forskning/screening-for-medfodte-sygdomme.

Stefánsson, Kolbeinn. 2012. "What Is in a Word? Universalism, Ideology and Practice." In *Welfare State, Universalism and Diversity*, edited by Anneli Anttonen, Liisa Häikiö, and Kolbeinn Stefánsson. Cheltenham: Edward Elgar Publishing Limited. https://doi.org/10.4337/9781849805940.00008.

Sundhedsdatastyrelsen 2020. "Vævsanvendelsesregisteret." ["The Use-of-Tissue-Register." The Danish Health Data Authority.] Accessed January 18, 2021. https://sundhedsdatastyrelsen.dk/da/registre-og-services/om-de-nationale-sundhedsregistre/testamenter-og-organdonation/vaevsanvendelsesregisteret.

Svendsen, Mette N., Laura E. Navne, Iben M. Gjødsbøl, and Mie S. Dam. 2018. "A Life Worth Living: Temporality, Care, and Personhood in the Danish Welfare State." *American Ethnologist* 45(1): 20–33. https://doi.org/10.1111/amet.12596.

Taylor, Linnet. 2017. "Introduction: A New Perspective on Privacy." and "Safety in Numbers? Group Privacy and Big Data Analytics in the Developing World." In *Group Privacy: New Challenges of Data Technologies*, edited by Linnet Taylor, Luciano Floridi, and Bart van der Sloot, 1–36. Cham, Switzerland: Springer. https://doi.org/10.1007/978-3-319-46608-8_2.

The Danish National Committee on Health Research Ethics. 2021. "The Danish National Committee on Health Research Ethics." *NVK*. Accessed January 28, 2021. https://en.nvk.dk.

University of Copenhagen. 2021. "Kropsdonation Til Gavn for Videnskab Og Uddannelse." *Department of Cellular and Molecular Medicine, University of Copenhagen.* Accessed January 28, 2021. https://icmm.ku.dk/donation/.

Vogt, Henrik, Bjørn Hofmann, and Linn Getz. 2016. "Personalized Medicine: Evidence of Normativity in Its Quantitative Definition of Health." *Theoretical Medicine and Bioethics* 37: 401–16. https://doi.org/10.1007/s11017-016-9379-3.

Wachter, Robert M. 2015. *The Digital Doctor: Hope, Hype, and Harm at the Dawn of Medicine's Computer Age*. New York: McGraw-Hill Education.