Value-based Consent Model: A Design Thinking Approach for Enabling Informed Consent in Medical Data Research

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Abstract: Due to new technological innovations, the increase in lifestyle products, and the digitalisation of healthcare the volume of personal health data is constantly growing. However, in order to use, re-use, and link personalised health data and, thus, unlock their potential benefits in health research, the authors of the data need to voluntarily give their informed consent. That is a major challenge to health data research, because the classic informed consent process requires the immense administrative burden to ask for consent, every time personal health data is accessed. In this paper we argue that all alternative consent models that have been developed to tackle this problem, either do not reduce administrative burdens significantly or do not conform to the informed consent ideal. That is why we used the design thinking approach to develop an alternative consent model that we call the *value-based consent model*. This model has the potential to reduce administrative burdens while empowering research subjects to autonomously translate their values into consent decisions.

1 INTRODUCTION

In medical data research an *informed consent* (IC) is a process in which research subjects are given information about specific studies and then voluntarily permits research agents to access and use their health data like x-ray images, clinical history, drug prescriptions, and much more to conduct the study. By informing research subjects in advance about research objectives, potential advantages and disadvantages, funding, and other relevant factors, and by granting them the right to revoke their consent at any time, the autonomy of subjects in medical research is structurally protected (Kleinig, J., 2009).

However, the rise of big data in medical research comes along with two challenges for the IC process. First, it is impossible to inform subjects about the scope, the methods, and the risks of research projects that are going to access health data in the far future. Second, to transfer the classic notion of IC into the medical big data context, researchers would have to repeat the consent process for each new data use and each one of the research subjects would have to repeatedly give their consent. It is easy to see that with increased quantities of research requests both the educational and the administrative burden on the part of the researchers as well as the consent burden on the part of the research subjects becomes impractical (Ruyter et al., 2010; Mittelstadt and Floridi, 2016). To face these challenges, a number of digital alternatives to the analogue IC model have been introduced recently (e.g., Helgesson, 2012; Kaye et al., 2015; Ploug and Holm 2016). All of these models try to find an equilibrium between the data subjects' autonomy

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and potential data efficiency benefits by introducing various interpretations of the research scope that subjects are able to consent to. They also try to consider the various national and international laws concerning medical data privacy like the EU GDPR or the US HIPAA. Whether these IC models are able to adequately preserve the research subjects' autonomy is discussed critically and repeatedly challenged (e.g., Caulfield and Kaye, 2009; Cheung, 2018; Manson, 2020).

In this paper, we will use the *design thinking method* to analyse current IC approaches in the digital health data research context and come up with a suitable alternative IC model. First, we analyse the IC models most commonly discussed in literature and identify both normative and technical benefits and risks for researchers and research subjects. Since some of the identified risks may jeopardise the research subjects' autonomy in real live consent situations, we come up with a new consent model that we will call *value-based consent model* and that is built on the Danish *meta consent model* by Ploug and Holm, (2016), the idea of a *cascade consent model* that was proposed by the German Ethics Council (Deutscher Ethikrat, 2017), and the matrix model, introduced by Christiane Woopen (2020). Its innovation is the possibility for research subjects to express consent preferences for different types of research categories such as research scope, research agent, funding, and many more in advance and, at the same time, to manually introduce exceptions from this setting. We call these exceptions *dynamic categories.* They can be introduced in cases, where settings in the *meta consent* conflict with each other. This modification prevents automated consent decisions that do not match a subjects' personal values. Additionally, we promote the subjects' right to withdraw from its research participation by introducing the possibility to transparently oversee all consent decisions already made for past, present, and future research studies in a so-called *consent history* and to opt out of single studies before they start. This way, the *value-based consent model* promotes *value-based consent* decisions while supressing machine-based consent decisions.

2 STATE OF THE ART

To understand what informed consent actually is and how its elements can be justified, it is best to take a closer look at the status of humans as self-determined moral beings. This status is often justified by the human capability to autonomously set and pursue moral ends (Kant, 2011). In this context, Autonomy is not so much a single momentum of purposeful action as it is a process that comprises the capability to, first, create and reflect personal desires, motives and ideals, second, to form and change concrete behavioural intentions and put those intentions into actions and, third, to assess the foreseeable consequences of actions (Woopen and Müller, 2021). To ensure that subjects in medical research are respected in their nature as morally autonomous beings the IC must consider all three parts of the self-determination process. It must enable people to form and reflect their own preferences and desires (Frankfurt, 1971). That includes the ability to project individual changes in preferences and ostensible choice inconsistencies into the IC architecture. Furthermore, the IC must take the *bounded rationality* (Schlaile et al., 2018) of human beings into account. Due to cognitive and physical limitations as well as constraints in terms of time, economic and social resources, the human ability to assess all foreseeable consequences of one's actions is per se limited. Nonetheless, the quality and quantity of information as well as its medium of communication should enable research subjects to make self-determined decisions. That includes the necessity to receiving detailed information about studies subjects are asked to participate in and the structural ability to easily act on that very information by consenting to, withdrawing from, or rejecting research requests. An IC doesn't serve its purpose if these criteria are not met and subjects are not able to form and change their preferences, retrieve relevant information, and change their consent decisions. Especially in the digital research context, the last issue is most relevant. Jürgen Habermas identifies a threat to autonomy in the pragmatic tendency to replace complex decision-making processes with mere technical processes. In such cases, it is no longer the autonomous citizens within a society who define social meaning through their own decisions and discourses, but the few people who develop a technology that makes important decisions for the people (Habermas, 2004). Decisions about which research projects are covered by a *broad consent* and which studies are rejected due to hierarchical meta structures, are part of that problem. Three criteria can be derived from the discussion so far: an IC model that transfers the ethical and legal reasons to conduct the IC into the realm of medical health data research can be considered to be adequate when research subjects (i) are informed about crucial characteristics of a research project before their participation, (ii) are informed about foreseeable personal and social

consequences of their research participation as well as the limitations to that assessment, (iii) can easily incorporate personal moral developments and social changes in their decision-making process and adjust their consent accordingly.

2.1 Specific Consent Model

With *specific consent*, subjects authorise research agents to access a well-defined set of data for one specific research purpose. In contrast to the confusing perception given by the phrase 'data donation', which is often used in such contexts, participants do not lose their right to authorise or deny data access. They can withdraw their consent at any time, even after research has been conducted. Moreover, any data access and use beyond the specific research purpose needs new consent. The *specific consent model* enables potential research subjects to use the *specific consent* type in a digital format (Ploug and Holm, 2016). The information process can be provided by an interface and support subjects in many ways. For example, information can be made available in many languages, its transfer can be supported audio-visually, and the research subjects' understanding of the research in question can be checked with the help of interactive elements (De Sutter et al., 2020). It is also important to stress that in this model, information can be altered to fit the subjects' needs (Ploug and Holm, 2016). Apart from that, the *specific consent model* does not allow researchers to collect contact data for follow-up studies. Some researchers argue that this characteristic can cause tremendous administrative burdens (Helgesson, 2012). Thus, a consent model that enables subjects to use *specific consent* only would demand a lot of efforts from potential research subjects since it is plausible to belief that the number of *specific consent* requests for medical data research will increase significantly in the near future (Mittelstadt and Floridi, 2016). In consideration of the overwhelming numbers of consent requests, we assume that study drop-outs and blanked rejections have to be perceived as likely.

2.2 Broad Consent Model

In contrast, the *broad consent* can be introduced to widen the research purpose subjects can consent to. The definition of what an adequate scope of research should look like is by no means fixed, but open for debate. It may, for example, refer to the development of different image recognition algorithms only and authorise access to skin cancer images exclusively. But it may also include a consent to grant access to all related files in the EHR for the purpose of cancer research in general. As a result, the *broad consent model* reduces the number of research requests and, therefore, the administrative expenses in correlation to the extension of the research scope (Manson, 2020). However, a serious issue with the *broad consent model* is that at the time the consent is given, the quantity and quality of future studies conducted with this data is unknown. The problem is that it is not possible to inform subjects about the research scope, the personal benefits and risks, the research agents, or the funding of future research studies whose design may not even have been invented today (Caulfield and Kaye, 2009; Caplan, 2009). Consequently, subjects cannot know, how their involvement in research may affect future societies and their future self. Moreover, not every *broad consent* attaches an expiring date to the consents which means that subjects can consent to a broad use of their data and when research methods or governance policies changes in the future, the consent will still hold (Ploug and Holm, 2020). Attached to this problem is the issue, that it is inconvenient to make use of the right to withdraw consent, if subjects do not know in which research projects their data is being used (Ploug und Holm, 2016). Advocates of a *broad consent model* argue that subjects can be well informed about the fact that they do not have all relevant information on future research projects (Taupitz and Weigel, 2012). As long as transparent governance structures are put in place, they belief that the *broad consent model* meet the IC ideal (Manson, 2020).

2.3 Open Consent Model

The *open consent model* was implemented in the Harvard Personal Genome Project, in which subjects were able to consent to the public release of their genome data after passing a very detailed test about the properties of genes, the research areas genes are used in, and all possible disadvantages that might come along with public data use. The complexity of the test gives the impression that the few who are able to pass it are sufficiently informed to make an autonomous decision (Angrist, 2009). The *open* or *blanked consent model* enables subjects to grant everyone the access to a specific set of health data without any limitations regarding access time and frequency, data use, or agency (Wendler, 2013). Thus, the administrative burden of obtaining re-consent is minimal. Because it is difficult to imagine that regular data subjects are able to reach a level of enlightenment where they can overview the most important effects their *open consent* might have on

their personal live and the society, most experts disqualify this model for broad social application (Cheung, 2018).

2.4 Dynamic Consent Model

The *dynamic consent model* as well as the *meta consent model* try to mediate the extremes of the former consent models. The *dynamic consent* enables subjects to repeatedly give *specific consents* to researchers to use their personal health data for medical studies (Steinsbekk et al., 2013). While the subjects' data is stored permanently and does not need to be deleted after each study, subjects can actively oversee all research in which their data has been used. Because the data is stored permanently, subjects can be selected for research based on special attributes like clinical history, blood type, social media use, and so on. Empirical data indicates that people are more likely to grant their consent to research projects if research requests are managed with a *dynamic* rather than a *broad consent model* (Stoeklé et al., 2019). While advocates argue that the administrative burden of the *dynamic consent model* is likely to be smaller than in the *specific consent model*, critics doubt that, because the program constantly sends requests to potential subjects followed by a long waiting period for responses (Manson, 2019). In addition, Ploug and Holm assume that people who are often confronted with consent requests will stop reading the consent information and give their consent or refusal out of habit. The authors call that phenomenon "consent fatigue" (Ploug and Holm, 2016). To the best of our knowledge this phenomenon has not yet been empirically proven.

2.5 Meta Consent Model

The *meta consent model* can be thought of as a filter program. It gives subjects the opportunity to set their preferences regarding the study categories "type of consent" (blanked refusal, broad consent, blanked consent, specific consent), "type of data" (e.g., EHR, gene material, tissue etc.), and "research context" (e.g., commercial or non-commercial research, funding situation, national or international research) (Ploug and Holm, 2015; 2016). *Blanked refusal* means that subjects refuse to consent to a given research category in general. Subjects might, for example, deny commercial agents access to their data. By entering their preference settings in the *meta consent form*, subjects can choose how they are going to be asked for consent in the future. Now, if the same subjects prefer to support all research concerning cancer, they can give *broad consent* to cancer research. This way, a study request on skin cancer research that wants to use skin images to train a skin cancer recognition software can do so without asking for *specific consent*. The same way, a research project on lung cancer can use the subjects' EHR. As the example suggests, in the *meta consent model* subjects can choose alternative consent types for different research categories. Unfortunately, there are cases where consent choices on the meta level contradict each other. If a for-profit organisation wants to do cancer research, it is not obvious how the *meta consent form* of the subjects in the example above can generate a consent. For these cases, Ploug and Holm introduce a prioritisation of consent decisions that automatically solves technical inconsistencies. *Blanked refusal* is prioritised over *specific consent* over *broad consent* over *blanked consent*. For the case above, the *blanked refusal* to private businesses is weighted higher than the *broad consent* to support cancer research. The *meta consent model* has empirically been proven to gain trust among Danish research subjects (Ploug and Holm, 2017).

There are some problems with the *meta consent model* as well. First, the *meta consent model* has a higher administrative burden than the *broad consent model* because the system needs to send consent requests constantly and waits for individual answers (Manson, 2020). Second, human preferences are not as ordered and consistent as the automated conflict solution suggests. Preferences and desires do not need to be complete or transitive to acknowledge the moral autonomy of research subjects (Sunstein, 1996). Subjects might, for example, not consent to value *blanked refusal* over *broad consent* in a specific case. Referring to the introduction of this article, we belief this momentum to be particularly problematic because consent decisions are actively delegated to an automated mechanism that is not controlled by the research subjects. Finally, it is important to note that a meta-consent model can be shaped with a variety of meta criteria to choose from and priority rules to govern conflicts. Ploug and Holm introduced only one of many ways to design such a model.

3 RESEARCH DESIGN

We applied a design thinking approach as methodological framework to our research. The method of design thinking is increasingly applied in various scientific domains, particularly information systems research. It is characterizable as a systematic approach to find solutions for complex issues with the

aid of multidisciplinary researchers (Wylant, 2008; Plattner et al., 2011; Wölbling et al., 2012). In this context, a common model by HPI School of Design Thinking outlines an iterative process encompassing six dedicated steps. These steps are passed iteratively in multiple loops and carried out in a sequential order while allowing to return to previous steps within an iteration. The original process model consists of the steps 'understand', 'observe', 'define the point of view', 'ideate', 'prototype', and 'test' (HPI School of Design Thinking, n.d.). For our research design, however, we performed several adaptations. Similar to the proposed framework, we defined six steps and maintained both the sequential order including the possibility of backward stepping within an iteration and the iterative nature of the overall methodological process. Likewise, our research methodology consists of the steps: (1) awareness building, (2) knowledge base development, (3) formation of opinion, (4) ideation, (5) conceptualization, and (6) validation. Our adapted iterative approach contains an embedded loop from the last to the first step to ensure agility of the research process.

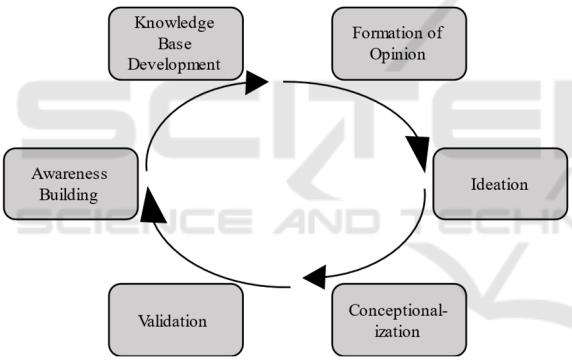

Figure 1: Design thinking Steps.

We carried out the steps depicted in Figure 1 iteratively with a project team of 12 researchers, who contributed their expertise from the research fields ethics, law, economics, social sciences, information technology, healthcare, price and service management, education, and media research. In the first step, *awareness building*, each researcher developed an own understanding for phenomena related to a given domain under investigation. In the second step, each researcher relied on individual and self-selected methods for *knowledge base development*, typically a literature analysis, to acquire comprehensive information about the phenomenon under investigation. Naturally, this step differed among researchers since it is subject to the researchers' expertise in terms of the domains relevant for phenomena elicitations. The creation of a knowledge base allowed each researcher the *formation of an opinion* based on own expertise established over the time of the project. Such expertise was used by the researchers in the phase of *ideation* to generate novel ideas for consent models. In *conceptualization*, these ideas were concretized in several group meetings, five workshops, and weekly small group meetings over a period of nine month. As a result of this step, the first two authors of this article developed first blueprints for consent models, typically emphasizing certain aspects, e.g., legal or ethical issues. The final phase of each iteration, called *validation*, was carried out in plenums with all researchers of the project team. Such plenums took place according to fixed schedules and terminated an iteration. All researchers presented and shared their ideas on state of art consent models and the consent model development. Subsequently, (dis-) advantages, problems, and opportunities were discussed as well as potential (dis-) similarities among model proposals. In a new iteration, the first two authors tried to refine their consent model based on the feedback received by the group. Naturally, this involved further awareness building and an extension of the knowledge base. Our findings generated through this process allowed us to systematically compare the models, which is presented in section 4. Among others, this systematic comparison has led to the further development of Ploug and Holms *meta consent model* into a new meta consent model variation that is the *value-based consent model.*

4 COMPARISON OF THE CONSENT MODELS

As we have discussed in part 2 there are many issues with the current IC models that can either severely limit Big Data research or critically diminish the autonomy of research subjects. The *specific consent model* incorporates the fundamental elements of the classic notion of IC the best. But, compared to the alternatives, it carries the highest burdens for researchers and research subjects. The *broad consent model* and the *open consent model* both reduce or minimise these burdens at the expenses of the research subjects' autonomy. Autonomy can be restricted by inconvenient refusal options and by static *broad consent* types for an unknown number of studies with an unknown quality. The *dynamic consent* and the *meta consent model* try to smoothen this gradual autonomy issues by introducing more convenient choice architectures. Unfortunately, the

Table 1: Benefits vs. risks and burdens of contemporary consent models.

Consent Model	Benefit	Risks and burdens
Specific Consent	-genuine implementation of the IC ideal (Ploug and Holm, 2016; De Sutter et al., 2020)	-huge financial and administrative burden (Helgesson, 2012; Manson, 2019) -burden of being informed numerous times (Steinsbekk et al., 2013) -Risk of study drop outs (Steinsbekk et al., 2013)
Broad Consent	-reduced administrative burden compared to *specific consent* (Manson, 2020)	-subjects are not informed in detail about the studies they consent to (Caulfield and Kaye, 2009; Caplan, 2009) -model may scare potential research subjects away
Blanked/ Open Consent	-minimal administrative burden (Angrist, 2009)	-does not comply with IC ideal in broad public settings (Cheung, 2018) -possibilities to intervene are minimal
Dynamic Consent	-simplified way to contact and re-contact research subjects (Steinsbekk et al., 2013) -reduced administrative burden compared to *specific consent* (Steinsbekk et al., 2013)	-the 'Re-Consent' option might scare potential research subjects off (Steinsbekk et al., 2013)
Meta Consent	-model produces procedurally consistent consent decisions (Ploug and Holm, 2016) -subjects can express preferences comparatively accurate (Ploug and Holm, 2016)	-subjects might give consent to studies that they prefer not to consent to (Ploug and Holm, 2016) -higher administrative burden compared to the *broad consent model* (Manson, 2019)

first one is still burdensome in administration and potentially foster a consent fatigue. The latter might technically generate consents that do not reflect the informed decisions of the subjects. Table 1 summarise the benefits and burdens of all consent models as discussed before. This table relates to the present analysis and is not exhaustive.

Based on the comparison above, we belief that a *meta consent model* approach is the best solution, so far, to realise the IC ideal in the context of medical data research. It enables research subjects to affect the frequency and type of research requests they receive and it also acknowledges their ability to form and express personal preferences concerning research categories like research objectives, research agents, and funding in general.

However, we recognise that the limitations of Ploug and Holms model jeopardise the IC ideal, for it creates the option to generate technical consents that, eventually, do not correspond with the subjects' actual intentions. It does so by providing only technical solutions to resolve conflicting consent types, by allowing subjects to choose between a few categories within the *meta consent form* only, and by not facilitating the subjects' ability to identify and subsequently correct potentially erroneous consents. To overcome those issues and to come closer to the IC ideal without increasing administrative burdens disproportionately, we propose an extended version of the *meta consent model* that we will call *value-based consent model*.

5 THE VALUE-BASED CONSENT MODEL

So far, it has become evident that an exclusive *specific consent model* is too demanding to be used in a medical data research setting and that all the other consent models sacrifice important elements of the IC ideal in their efforts to make medical research more efficient. The *meta consent model* is least affected by this critique. It struggles primarily with the scope of preferences subjects can choose from and the technical solution to conflicts of preference incoherencies. To overcome these problems, we propose to adapt the *meta consent model* by introducing additional consent and refusal options that enables research subjects to translate their values into a fine-grained preference matrix that better reflect their preferences on how to be approached for IC requests.

The idea to adopt the *meta consent model* in a way that better matches the EU General Data Protection Regulation(GDPR) as well as the autonomous decision-making process of research subjects have already been elaborated in political statements elsewhere (Deutscher Ethikrat, 2017; Datenethikkommission, 2019; Woopen, 2020). We also introduce a learning strategy – *dynamic categories* – that enables the *value-based consent model* to favour individual values over technical choice consistencies. The interplay between both mechanisms, the adapted version of the *meta consent form* that we call *value-*

based consent structure, and the *dynamic categories,* enable subjects to autonomously translate their personal values into preferences and IC decisions and to adjust those decisions at any time.

5.1 Research Categories

For the possibility to use broader consent types such as *broad consent* and *blanked refusal*, as it is common in the original *meta consent model*, we propose an adjustment of the *meta consent form* (Ploug and Holm, 2016). In doing so, we also define the term *research category*, which can denote single research fields as well as other characteristics of medical studies such as 'research objective', 'type of data' and 'type of context'. All of those are part of the *meta consent model* by Ploug and Holm (2016). Because every study has a research objective, a source of funding, research agents like hospitals or research groups, and so on, it can always be characterised with a specific set of *research categories*. For example, a study that seeks the data of research subjects to develop an image recognition algorithm for skin cancer can be characterised by its objective (skin cancer research), the type of data that is being processed (images of benign/malignant moles), and contextual parameters (e.g., funded by the Ministry of Health). Each *research category* is composed of many subcategories. For example, the objective 'skin cancer' research is a subcategory of 'cancer research' which has other subcategories as well like 'neoplasms of digestive organs' or 'neoplasm of breast'. The category 'skin cancer' may in turn have further subcategories like 'melanoma' or 'basal-cell carcinoma'. All study requests can be represented as sets of *research categories*. For example, a study dealing with the analysis of skin images with a repeated data query conducted over 5 years in the field of skin cancer research on behalf of the public could look like this:

Study (x) = {…, Virology:false, SkinCancer:true,
DataType-SkinImages:true,
MultipleDataRetrieval:true,
ResearchAgend-PrivateCompany:false,
…}

Now, for a fine-grained adaptation of the *broad consent* and its counterpart the *broad refusal*, research subjects are able to consent to studies that correspond to *research categories* on different super and sub-levels. If *broad consent* is given in one *research category*, the consent affects all subcategories if no other consent decision has been made. In contrast to the classic *meta consent model*, however, subjects have the option of manually consent or refuse to individual subcategories. For example, research subjects may choose to give their consent to all research projects that want to use their

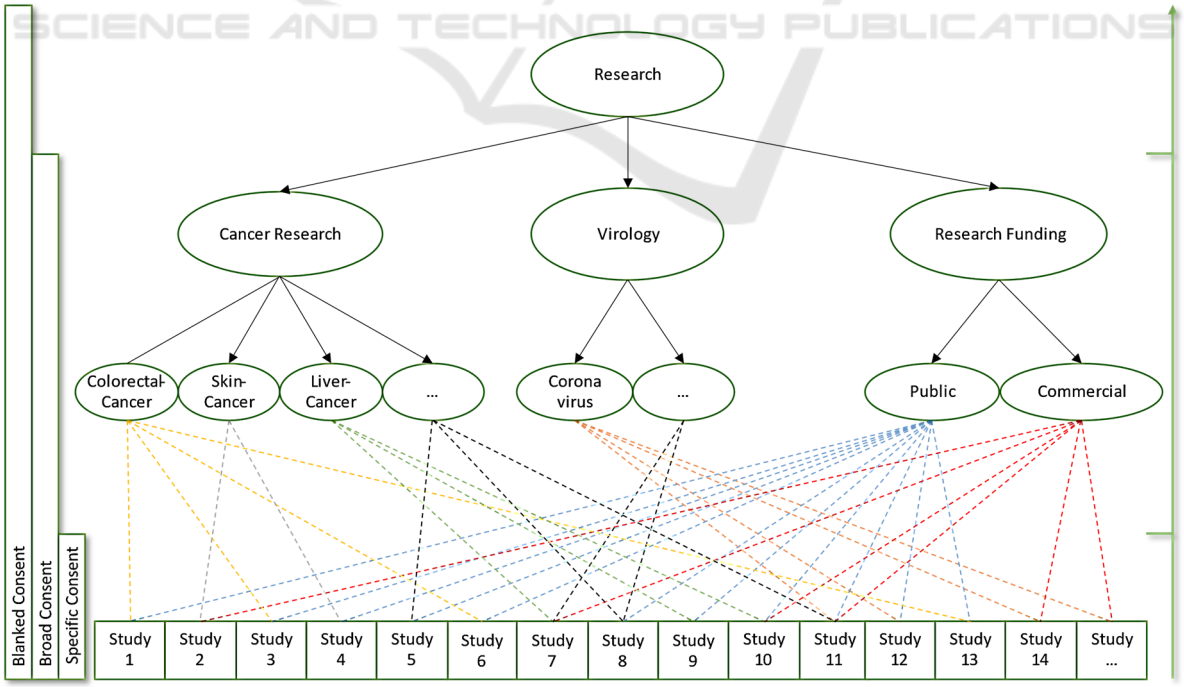

Figure 2: Representation of the linkage between studies and research categories.

data for 'cancer research'. By giving *broad consent* to this research category, subjects also consent to all its associated subcategories. If some subjects like to make other decisions in certain subcategories like 'skin cancer' research, they can select another option in those subcategories. Due to the inheritance of consent decisions to respective subcategories the fine-grained preferences of the research subjects can be represented in a tree structure and all its components.

Figure 2 shows the linkage of different studies to their *research categories* in a tree structure. The *blanked consent* option enables subjects to consent to any research request regardless of the *research category* it belongs to. At this time this option is legally prohibited in the EU and only listed for the sake of completeness.

What level of differentiation of medical research areas, data types, funding models and more can commonly be understood in an IC process and, therefore, what exact set of *research categories* are needed to improve the IC process for research subjects cannot be determined theoretically. We will come back to this issue in the limitations.

5.2 Additional Refusal Types

In order to enable subjects to translate their values into a new fine-grained adaptation of the old *meta consent form*, this subsection explicates some refusal types that have already been in use in other consent models.

5.2.1 Specific, Broad and Blanked Refusal

One new way for subjects to communicate their preferences in the *value-based consent model* is to choose a refusal to certain *research categories* and its subcategories. The *specific refusal* that is already implied in the *specific consent model a*llows subjects to refuse to participate in specific studies and in studies that share certain *research categories*. For example, if subjects are not comfortable to authorise the research team of Google to access their health data in one particular case, they can use the *specific refusal*. If the same subjects are uncomfortable with Google in general using their data for research, they can make a *broad refusal* for Google to use their data in any further studies. Analogously, to the *broad consent*, the *broad refusal* affects multiple studies belonging to that *research category* at once. Likewise, the *blanked refusal* expresses the preference to deny data access to any kind of medical data research, whatsoever. This refusal type differs from the *blanked refusal* option that is known to the *meta consent model* in that it refers to the entire *preference tree* (Section 5.3).

5.2.2 Legal Obligation for Data Processing

For reasons of transparency, it could be useful to communicate legal acts of obliged health data access. For example, when the *Centre for Disease Control and Prevention* accesses its citizens EHR files to count new COVID-19 cases and evaluate counter measures, it is entitled to do so by law. Noteworthy, communicating legal obligations for data processing does not embody a novel governmental power, but rather makes such operations more transparent.

5.3 Value-based Consent Structure

As in Ploug and Holm (2016) original *meta consent form*, in the *value-based consent model* subjects have the option to express their consent preferences for each *research category* and subcategory. In contrast we present the adapted version in a hierarchical tree structure which simplifies the representation of multidimensional *research categories* and allows subjects to combine different consent and refusal types within these dimensions.

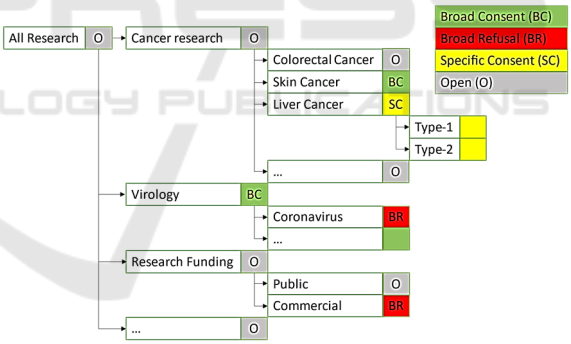

Figure 3: Preference Tree.

Figure 3 shows that some *research categories* are described as 'open'. The term 'open' simply means that the subjects have not made a consent decision in this *category* yet. If, at the time a research agent sends out a study's request, all the relating *research categories* are still 'open', a *specific consent* request will be forwarded to the subjects. Whereby, the subjects are made aware that they could set a consent decision in the *value-based consent structure*. A *specific consent* option means, that requests should be forwarded directly to the research subjects as *specific consent* requests, whereas the *broad consent* option reflects the *broad consent* decision to grant a consent

to all corresponding research requests. In addition, we introduce a prioritisation of consent decisions for subcategories and supercategories in which consent and refusal decisions in a subcategory override the corresponding supercategory. For example, research subjects may choose to give *broad refusal* to the research category 'cancer research' which will mark all subcategories like 'skin cancer research' as refusal. Now, if subjects like to set exceptions, they can choose to give a different consent option to specific subcategories. This makes it possible to express global decisions such as 'All except these' as well as 'None except these' through the consent tree. The opportunity to add exceptions to a *broad refusal* option is actively suppressed by the prioritisation logic of the *meta consent model* by Ploug and Holm (2016).

5.4 Dynamic Categories

In the *meta-consent form* as well as in the *value-based consent structure* it is very likely that two or more preferences conflict with each other on a regular basis. For the skin cancer research case, such a conflict may arise for subjects who have given a *broad consent* to cancer research but *broad refusal* to commercial research agents. Now, if Google wants to conduct skin cancer research, it is not clear whether the consent or the refusal should be more important. The issue of conflicting consent types not only occurs in cases in which *broad consent* and *broad refusal* conflict with each other, but also in those where *specific consent* preferences and *broad consent* decisions preferences contradict each other. To solve this issue Ploug and Holm introduce a prioritisation schema, as described in section 2.5. According to their schema, the leaner decision is preferred and applied as soon as two preference definitions in the *meta-consent form* contradict each other, whereby the refusal is given the highest priority:

Blanked Refusal > Specific Consent > Broad Consent > Blanked Consent

In line with this prioritization logic, the refusal towards commercial research agents like Google would be of a higher priority than the cancer research consent and Googles cancer research request would be denied. This prioritisation does not correspond to the IC ideal, since the subjects cannot decide which of the respective preference they would favour in a conflict. On a more technical level, the scheme will likely generate refusal decisions for research studies in which subjects would have liked to participate. To eliminate this problem, we replace the static prioritization logic with what we call *dynamic categories.*

Dynamic categories enable subjects to individually decide how to deal with conflicting preference choices. In cases in which consent decisions conflict with each other, the affected research request triggers a request for *specific consent*. Subjects are notified that the request has been generated by conflicting preference choices in the *value-based consent structure.* After reading the consent information and approving or rejecting the *specific consent* request, subjects are given the option to give a *broad consent* or a *broad refusal* to all future study requests that trigger the very same conflict. That means that any case of conflict enables subjects to create exceptional *broad consent* or *broad refusal* rules which is the *dynamic category*. For the Google cancer study case, subjects are notified about the conflicting preferences and can choose, either to treat every conflict of this kind as *specific consent* request or to generate a new *dynamic category* that solves the conflict for all studies that share the same *research categories*. In the first case, a different study on skin cancer that is conducted by Google would be brought forward as a new *specific consent* request. In the second case and in dependence to the previous decision, subjects either consent or refuse their participation in forthcoming cancer studies that are conducted by commercial agents like Google, Pfizer, or Nestle without having to go through a new IC process. For the *dynamic categories*, only *broad consent* and *refusal* options are available, since a *specific consent* choice would generate the same effect as the absence of the *dynamic category*.

Since *dynamic categories* can only be generated when consent decisions conflict in the *value-based consent structure,* it is evident that they are deleted when all underlying contradictions cease to exist. As soon as subjects alter the *structure* in a way that the conflicts that establish a *dynamic category* are removed, the subjects are being notified. In addition, subjects can change their consent or refusal decisions or delete the *dynamic category* at any time.

There are two ways in which *research categories* can overlap. First, there are conflict-free overlaps which are overlaps of any number of *research categories* for which the same consent or refusal type has been chosen and any number of *research categories* for which the decision is still *open*. Second, there are overlaps that are characterised by conflicting consent decisions. The following four conflict cases are conceivable:

1. *Broad* or *blanked consent* with *broad* or *blanked refusal*

2. *Broad* or *blanked consent* with *specific consent* preference
3. *Broad* or *blanked refusal* with *specific consent* preference
4. *Broad* or *blanked consent* with *broad* or *blanked refusal* with *specific consent* preference.

The procedure to solve those conflicts is always the same. A *specific consent* request is sent to the subjects who then can give a *specific consent* or *refusal* and create a *dynamic category* by choosing a *broad consent* or *refusal* decision for all cases alike.

5.5 Opt out and Reconsideration Options

We introduced an opt out and a reconsideration opportunity to the *value-based consent model*, that enables research subjects to revoke or change their consent decisions up to the point of data retrieval. We belief this option to be necessary to effectively exercise the right to withdrawal consent in a fast-moving research field that is medical data research. For this purpose, a consent history is available that entails a list of all research requests that have been given a consent or a refusal to. Subjects can use their consent history to modify *specific consent* decisions as well as the *specific consent* or *refusal* decisions that derived through *broad consent* and *broad refusal* settings. For example, research subjects that decide to give *broad consent* to commercial research agents and to skin cancer research at first, might, at a later time, read the list of all research studies that they have given their consent to and realise that they consented to participate in the research of a company that they would rather not have given consent to. In the *value-based consent model* the subjects can opt out in such situations without further ado as long as the data has not been retrieved jet. The other way around it is also possible that subjects have given a *broad refusal* to commercial agents, but by looking on the list of refused research studies they may realise that they want to support a specific skin cancer study by Google. As long as this study is not due, the subjects can alter their former *broad consent* decision in such cases by using the option to reconsider the study for the *specific consent* process. It is also possible to opt out of a *specific consent* that is characterised by multiple data retrievals over a fixed period of time. In the consent history a *specific consent* of such kind is tagged prominently so that research subjects can easily distinguish it from other consent types. To revoke a consent, subjects can simply opt out of the data retrieval that is scheduled next.

The opt out and the reconsider option is a transparency feature that communicates the relation between subjects and all relevant research studies openly. The oversight of the consent history and, thus, the impact of *broad consent* and *broad refusal* options on specific research requests promotes the competence of subjects to translate their values into consent preferences adequately. In all alternative models that offer *broad consent* options, subjects may face the problem of not being able to imagine, which specific research projects may serve an abstract research objection, which specific agents are affected by a *broad consent* decision or which type of data might be risky to share in a given research context. With this transparent structure, the v*alue-based consent model* ensures that subjects will become increasingly better at understanding *research categories*. A remarkable side effect of the opt out feature is, that it excludes the original notion of a *blanked consent* type. Even the broadest consent decision like the decision to give consent to all research objectives, research agents, and all other research categories, whatsoever, does not equal the classic *blanked consent* decision because subjects are always able to change their decision based on transparently communicated research activities and opt out of individual research projects.

6 DISCUSSION

In this article we used the design thinking approach to develop the *value-based consent model*. The *value-based consent model* enables consent requests for the use of personal health data in medical research projects to be answered via the *value-based consent structure* and additional *dynamic categories*. In this process, the *research categories* of each study are matched with the selected consent preferences of each subject. In contrast to the original *meta consent form* by Ploug and Holm, the new structure enables subjects to choose two additional refusal options: *specific refusal and broad refusal*. We believe that representing the super and sub *research categories* in a tree structure (see Figure 2) is also more accessible than the matrix notation used by Ploug and Holm. The *dynamic categories*, then, transfer the power to decide how to deal with conflicting consent preferences from a technical static prioritization logic to the research subjects themselves. By adding a transparent consent history that can be used to audit all former and current consent decisions and to opt out or reconsider consent choices, subjects are also able to increase their

medical and digital literacy and adjust their consent choices to their personal values.

All these changes establish a digital IC process that converges with the ideal presented at the beginning. (i) By informing subjects continuously and transparently about past, current and future studies in a learning friendly environment, the value-based consent model supports the subject's digital and medical literacy, thus, enables them to build their consent decisions on the latest insides and educated assessments. (ii) Based on the easily accessible and comprehensive information provided by the value-based consent model and with access to the advice of medically trained personnel who always needs to accompany consent processes subjects are empowered to understand the risks and consequences of research participation and the limits of that assessment. Finally, (iii) the differentiated choice architecture, the simple to use intervention options, and the consent history give subjects the opportunity to incorporate newly gained experiences and personal value shifts in the IC decision-making process.

However, there is also the issue of the administrative burdens of digital IC models for secondary use of research data. We have referred to empirical studies that indicate that research subjects are less likely to engage in medical data research that is governed by *broad* or *open consent models*. In contrast subjects place more trust in IC processes that are governed by a *dynamic consent model* or a *meta consent model*. Since the *value-based consent model* is comparatively more transparent and does not patronise subjects with priority rules, we assume that subjects would prefer it over other models. If this was the case, the comparatively large number of subjects that would potentially use the new IC model would reduce the challenges of the recruitment process and, therefore, the administrative burden. The hypothesis needs to be proven empirically in future studies.

6.1 Limitations

The effectiveness and the usability of the *value-based consent model* has not been evaluated empirically so far. Since the *meta consent form* is less complex than the *value-based consent structure* and since the new model incorporates a number of new refusal options empirical studies on the application of the *meta consent model* that have been conducted so far cannot substitute the gap. Another limitation is the configuration of the *value-based consent structure*. In their work, Ploug and Holm pointed out that the *meta consent form* can be extended to contain more meta categories to choose from. However, the number and type of *research categories* it should contain in order to allow subjects to make autonomous decisions without being either overwhelming or patronised, has not yet been determined. This issue needs to be addressed in further empirical studies as well.

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REFERENCES

Angrist, M. (2009). Eyes wide open: The personal genome project, citizen science and veracity in informed consent. *Personalized Medicine*, *6*(6), 691–699. https://doi.org/10.2217/pme.09.48

Benke, K., & Benke, G. (2018). Artificial intelligence and big data in public health. *International Journal of Environmental Research and Public Health*, *15*(12). https://doi.org/10.3390/ijerph15122796

Caplan, A. L. (2009). What No One Knows Cannot Hurt You: The Limits of Informed Consent in the Emerging World of Biobanking, in: Solbakk, J. H., Holm, S., & Hofmann, B. (ed.) *The Ethics of Research Biobanking* (*2pp.5-32*). Dordrecht: Springer. https://doi.org/10.1007/978-0-387-93872-1

Caulfield, T., & Kaye, J. (2009). Broad consent in biobanking: Reflections on seemingly insurmountable dilemmas. *Medical Law International*, *10*(2), 85–100. https://doi.org/10.1177/096853320901000201

Cheung, A. S. Y. (2018). Moving beyond consent for citizen science in big data health and medical research. *Northwestern Journal of Technology and Intellectual Property, 16(1)*.

Datenethikkomission (2019). Gutachten der Datenethik-kommission Available at: https://www.bmi.bund.de/SharedDocs/downloads/DE/publikationen/themen/it-digitalpolitik/gutachten-datenethikkommission.pdf;jsessionid=9E1A40B6C43577B2234D8CF241C2241A.2_cid373?__blob=publicationFile&v=6 [Accessed September 9, 2021].

Deutscher Ethikrat (2017). *Big Data und Gesundheit - Datensouveränität als informationelle Freiheits-gestaltung* Available at: https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/deutsch/stellungnahme-big-data-und-gesundheit.pdf [Accessed September 9, 2021].

Frankfurt, H. G. (1971). Freedom of the will and the concept of a person. *The Journal of Philosophy*, *68*(1), 5-20. https://doi.org/10.2307/2024717

Habermas, J. (2004). Freiheit und determinismus. *Deutsche Zeitschrift Für Philosophie*, *52*(6), 871–890. https://doi.org/10.1524/dzph.2004.52.6.871

Helgesson, G. (2012). In defense of broad consent. *Cambridge Quarterly of Healthcare Ethics*, *21*(1), 40–50. https://doi.org/10.1017 /S096318011100048X

HPI School of Design Thinking (n.d.) The six phases of the Design Thinking process. Available at: https://hpi.de/en/school-of-design-thinking/design-thinking/background/design-thinking-process.html [Accessed: September 08, 2021].

Kant, I. (2011). *Groundwork of the metaphysics of morals: A German-English edition* (M. J. Gregor, Trans.) (J. Timmermann, Ed.). Cambridge: University Press. https://doi.org/10.1017/CBO9780511973741

Kaye, J., Whitley, E. A., Lund D., Morrison, M., Teare, H., & Melham, K. (2015). Dynamic consent: A patient interface for twenty-first century research networks. *European Journal of Human Genetics*, *23*(2), 141–146. https://doi.org/10.1038/ejhg.2014.71

Kleinig, J. (2009). The nature of consent In F. Miller & A. Wertheimer (ed.), *The ethics of consent* (pp. 3–22). Oxford: University Press. https://doi.org/10.1093/acprof:oso/9780195335149.003.0001

Manson, N. C. (2019). The biobank consent debate: Why ‚meta-consent' is not the solution? *Journal of Medical Ethics, 45(5),* 291-294. http://dx.doi.org/10.1136/medethics-2018-105007

Manson, N. C. (2020). The case against meta-consent: Not only do Ploug and Holm not answer it, they make it even stronger. *Journal of Medical Ethics*, *46*(9), 627–628. https://doi.org/10.1136/medethics-2019-105955

Mittelstadt, B. D., & Floridi, L. (2016). The ethics of big data: Current and foreseeable issues in biomedical contexts. *Science and Engineering Ethics*, *22*(2), 303–341. https://doi.org/10.1007 /s11948-015-9652-2

Plattner, H., Meinel, C., & Leifer, L. (2011). *Design Thinking: Understand - improve - apply*. *Understanding Innovation*. Berlin: Springer. http://sub-hh.ciando.com/book/?bok_id=232558 https://doi.org/10.1007/978-3-642-13757-0

Ploug, T., & Holm, S. (2015). Meta consent: A flexible and autonomous way of obtaining informed consent for secondary research. *BMJ*, *350*, h2146. https://doi.org/10.1136/bmj.h2146

Ploug, T., & Holm, S. (2016). Meta consent - a flexible solution to the problem of secondary use of health data. *Bioethics*, *30*(9), 721–732. https://doi.org/10.1111/bioe.12286

Ploug, T., & Holm, S. (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*(1), 1–8. https://doi.org/10.1186/s12910-017-0209-6

Ploug, T., & Holm, S. (2020). The ‚expiry problem' of broad consent for biobank research - and why a meta consent model solves it. *Journal of Medical Ethics*, *46*(9), 629–631. https://doi.org/10.1136/medethics-2020-106117

Ruyter, K. W., LÕuk, K., Jorqui, M., Kvalheim, V., Cekanauskaite, A., & Townend, D. (2010). From research exemption to research norm: Recognising an alternative to consent for large scale biobank research. *Medical Law International*, *10*(4), 287–313. https://doi.org/10.1177/096853321001000403

Schlaile, M. P., Klein, K., & Böck, W. (2018). From bounded morality to consumer social responsibility: A transdisciplinary approach to socially responsible consumption and its obstacles. *Journal of Business Ethics*, *149*(3), 561–588. https://doi.org/10.1007/s10551-016-3096-8

Steinsbekk, K. S., Kåre Myskja, B., & Solberg, B. (2013). Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem? *European Journal of Human Genetics*, *21*(9), 897–902. https://doi.org/10.1038/ejhg.2012.282

Stoeklé, H.-C., Turrini, M., Charlier, P., Deleuze, J.-F., Hervé, C., & Vogt, G. (2019). Genetic Data, Two-Sided Markets and Dynamic Consent: United States Versus France. *Science and Engineering Ethics*, *25*(5), 1597–1602. https://doi.org/10.1007/s11948-019-00085-4

Sunstein, C. R. (1996). Social Norms and Social Roles. *Columbia Law Review*, *96*(4), 903. https://doi.org/10.2307/1123430

Sutter, E. de, Zaçe, D., Boccia, S., Di Pietro, M. L., Geerts, D., Borry, P., & Huys, I. (2020). Implementation of electronic informed consent in biomedical research and stakeholders' perspectives: Systematic review. *Journal of Medical Internet Research*, *22*(10), e19129. https://doi.org/10.2196/19129

Taupitz, J., & Weigel, J. (2012). The necessity of broad consent and complementary regulations for the protection of personal data in biobanks: What can we learn from the german case? *Public Health Genomics*, *15*(5), 263–271. https://doi.org/10.1159/000336604

Wendler, D. (2013). Broad versus blanket consent for research with human biological samples. *The Hastings Center Report*, *43*(5), 3–4. https://doi.org/10.1002/hast.200

Wölbling, A., Krämer, K., Buss, C. N., Dribbisch, K., LoBue, P., & Taherivand, A. (2012). Design Thinking: An Innovative Concept for Developing User-Centered Software. In Maedche, A., Botzenhardt, A., & Neer, L. (ed.), *Management for Professionals. Software for People* (pp. 121–136). Berlin: Springer. https://doi.org/10.1007/978-3-642-31371-4_7

Woopen C. (2020). Stellungnahme zum Gesetzesentwurf der Bundesregierung "Entwurf eines Gesetzes zum Schutz elektronischer Patientendaten in der Telematikinfrastruktur. Deutscher Bundestag BT-Drucksache 19/18793. Deutscher Bundestag. Available at: https://www.bundestag.de/resource/blob/698068/d2839c2cc2c1ec321bbb843df38362a3/19_14_0165-26-_ESVe-Prof-Woopen_PDSG-data.pdf [Accessed September 9, 2021].

Woopen, C., & Müller, S. (2021). Die Digitalisierung als Herausforderung für die Bestimmung des Selbst im Gesundheitswesen. In C. Piallat (ed.), *Der Wert der Digitalisierung: Gemeinwohl in der digitalen Welt* (pp. 123–146). Bielefeld: transcript Verlag.

Wylant, B. (2008). Design Thinking and the Experience of Innovation. *Design Issues*, *24*(2), 3–14. https://doi.org/10.1162/desi.2008.24.2.3