The biobank consent debate: why "meta-consent" is not the solution

THE BIOBANK CONSENT DEBATE

Over the past couple of decades there has been an ongoing, often fierce, debate about the ethics of biobank participation. One central element of that debate has concerned the nature of informed consent. The problem arises because biobanks are repositories of biological material, stored and organised in such a way as to make them—and information derived from them—readily available for a wide variety of research purposes, by a wide variety of users in an open-ended way. In order to give valid informed consent for the use of their samples and data participants need to be told the identity of the researcher(s), the nature and purpose of the research, and about the risks and burdens that the research might pose to the participant. The *specific* details about future users and uses are *not yet known* at the time of obtaining the sample. Two broad types of proposal have emerged (with a wide variety of specific variants of each broad type). One proposal is simply that specific informed consent needs to be sought (and obtained) for each separate research project.[1, 2] Against this "specific consent" framework it is objected that seeking specific consent every time a sample—or personal data derived from a sample—is used for a new purpose, or by a new party, poses a considerable financial and administrative burden on researchers and a "drag" on research.[3] Given that samples and personal data can be re-used at points in time remote from the original acquisition, actually contacting the donor may be hard, and become more difficult over time.

An alternative proposal is "broad" consent.[3. 4, 5] Broad consent theories trade on the fact that consent is directed at sets of actions (even when directed at particular individuals). Consent can be given to specified sets of researchers, or research uses (with the proviso that such research and uses are monitored and sanctioned by other, semi-independent parties). Recent broad consent proposals have laid emphasis on the way that broad consent is consent to a complex normative framework that protects the data subjects' interests, with independent monitoring (e.g., via RECs/IRBs) and other aspects of good governance.[6] It may seem that broad consent cannot be *informed* consent:

how can it be, when the future, specific, research uses (or users) are *not yet known*? However, at root, informed consent requirements are obligations to disclose information that allows a consent *decision* to be made in a certain way (knowingly and reflectively, on the basis of adequate, relevant information. There is a contrast between informed and uninformed broad consent, there is a contrast between informed and uninformed specific consent. Provided the donor is truthfully informed about the *kinds* of uses to which her data might be put, and the *kinds* of user who may have access to them, there need be nothing "uninformed" about a decision to give broad consent on that basis to specified kinds of act by any of a specific *kind* of agent, for any of a range of specified purposes.

The biobank consent debate is one with deeply held convictions on both the "broad" and "specific" sides. In recent years the debate has become yet more complex with the development of “dynamic” consent frameworks.[7, 8, 9] A dynamic consent framework utilises formation technology to enable a wide range of continuous, interactive, personalized, channels of communication between researchers and data subjects. Whilst specific consent does involve *ongoing* communication, such communication is grounded in, and restricted to, gaining permission for use of samples and data. Dynamic consent, by way of contrast, also aims to allow public engagement with, and involvement in, research. Dynamic consent also affords data subjects a distinctive degree of fine-tuned control over the use of their data. We shall return to this aspect of dynamic consent later. But, for now, what matters is that both dynamic consent and specific consent frameworks reject broad consent, so our debate has broad consent theorists on one side, with specific and dynamic consent theorists on the other.

Recently, Thomas Ploug and Soren Holm have developed a new proposal: what they call a *meta-consent* framework.[10, 11, 12] Their meta-consent framework is not specifically developed for, or restricted to, biobanks, as it is meant to be applicable more broadly, including secondary research uses of already-gathered health data (including data arising from patient records). But they do hold

that the model is applicable to biobank consent. The aim here is to consider whether meta-consent does provide a "solution" to the biobank consent debate (leaving aside its adequacy as a solution to questions about the regulation of medical data use in other contexts). It is argued here that contrary to Ploug and Holm, there is no moral obligation on biobanks to provide meta-consent, and there are further considerations *against* biobanks offering such a framework. The biobank consent debate remains active as ever.

THE ARGUMENT FOR META-CONSENT

What is meta-consent? Here is how Ploug and Holm put it:

> [M]eta consent" denotes the idea that people should be asked how and when they would like to be presented with a request for consent. That is, people should be asked to design how they in the future would like to provide consent to the use of their personal health data and biological material. By expressing a preference for how and when to provide consent, people can be said to provide consent on a meta level. This is the defining idea in the model of meta consent.[13]

Their central idea is that biobank participants should be offered the opportunity to *choose and design* their own individual consent process, in line with their own preferences. One participant might choose blanket consent for national, public-funded research on non-genomic data; specific re-consent for national public-funded use of *genomic* data; and refusal for international use or commercial use of her sample. Other participants are likely to make different choices from the "menu" of options.

Why should biobanks offer meta-consent? The central consideration that motivates meta-consent is that biobank participants *vary* in their preferences about how they would like to consent:

> Meta consent is a truly individual consent procedure that takes into account the differences in personal interests and levels of trust in researchers among the population.[14]

Both sides of the consent debate have focused on "fixed" consent frameworks where *everybody* is offered the same kind of consent framework and the question is, which type of framework—broad

or narrow—should be offered to all. Meta-consent, by way of contrast, offers participants a *choice*, and allows them to choose, in a fine-tuned way, the kind of consent process that *they* prefer for different users and uses of their samples and data.

COSTS AND BURDENS: WHY ALL THINGS ARE NOT EQUAL

Suppose we accept that a meta-consent framework would better accommodate variation in interests and preferences than a "fixed" proposal.[i] This does not imply that biobanks are thereby under any obligation to *offer* that degree of flexibility? After all, a biobank participant might *prefer* to be given a laptop for participating. It does not follow that therefore the biobank ought to provide it

In response, we might argue that biobanks are going to *have to* offer some kind of consent framework, but they don't *have to* offer a laptop or other payments. All that meta-consent suggests is that the biobank should offer individuals to choose *their* preferred version of the kind of thing that is going to be offered anyway, i.e., a consent framework.

But this line of argument is not strong. A regulatory framework—such as the consent framework for biobank participation—is, or ought to be, designed with a wide range of interests in mind, taking into account the interests, needs, costs, burdens and benefits for many different agents.[ii][12] One core line of argument for broad consent, for example, is based upon two premises: that broad consent is *ethically* adequate; that specific consent poses considerable *burdens* on biobanks, and those burdens, in turn, shift resources from valuable research onto administrative costs. To simply

[i] An (anonymous) referee wonders whether the distinction between preferences and interests might not be of relevance here. It is true that in philosophical writing, especially about the normative basis of rights and obligations, focuses on fundamental interests, rather than "mere" preferences (I might *prefer* one cheese to another but do not have an *interest* here, except the higher-level interest that my preferences be satisfied, all things being equal). Such a distinction does not help Ploug and Holm (who talk of both interests and preferences). The "mere" preference that one have an individually tailored consent regimen is not a candidate for grounding an obligation to provide it, and the discussion below suggests that there is no fundamental *interest* that grounds this positive obligation either.

[ii] Whilst it is possible, that in some circumstances, regulatory systems might only be required to be responsive to only *one* set of interests, in the case of biobank participation it seems plausible (and we shall assume it to be so here) that a regulatory system for biobanks has to balance, at the very least, societal interests in securing the results (and benefits) of biobank-enabled research, against a range of individual interests, such as privacy interests and the interests that underpin rights over the body and bodily materials.

allow people to *choose* whichever framework they wish might seem to be an *irresponsible* way of "solving" the biobank consent debate. By analogy, people have different preferences about taxation systems. But it does not *solve* debates about the proper level of taxation *for all* to allow individuals to *choose* the tax regimen that *they* prefer.

Ploug and Holm do not engage with the fact that regulatory systems should not be decided by individual preferences (of one interest group) alone (especially where the *balancing* of interests is part of the deliberative process leading to a regulatory framework). Instead, we have a weak line of support for meta-consent:

> Although different models of informed consent may lead to informed and deliberated preferences concerning participation in research passing a threshold of acceptability, it seems that we should, *all other things being equal*, prefer a model of informed consent that lead to more informed and deliberated preferences than alternative models of consent (emphasis added).[15]

This line of argument is effectively saying that there is no moral reason *against* providing meta-consent. This seems correct, at least insofar as it does not *wrong* the participant. Accommodating the preferences of participants might be good for recruitment, but such "gifts" have costs. But a regulatory framework that does not wrong individuals may still be the wrong one to have. For example, requiring biobanks to give a new laptop to every participant might be great for participants, but bad for the research budget. Ploug and Holm do put in their qualification "all other things being equal", but this raises the question whether all things are likely to *be* equal. For example, if we compare a broad consent framework with meta-consent, then meta-consent is clearly going to pose many additional costs and burdens. Even if many people choose broad consent, some will not. Worse, the administrative infrastructure needs to be in place to allow specific re-consent for all, even if many choose broad consent in the first instance, because participants might, at any point *change* their consent design. These are costs and burdens that simply do not exist on a one-off broad consent.

The *meta consent* framework also faces most of the problems and burdens of specific consent: maintaining contact with participants, and the problem of what to do when participants fail to reply. Modern ICT may make communication very rapid, but human beings, with their distractions, other interests, emotions and attention, are an essential part of the communicative chain. Suppose 30,000 participants in a biobank have opted for specific re-consent. The technology may be there to communicate in an instant, but the authorisation for the use of each sample depends upon someone being bothered to "click" the appropriate "I consent" response. Worse still, the costs and burdens or meta-consent are likely to be *much higher* than even specific re-consent. It will need to take care to *avoid false positives* where those who chose broad consent are contacted by mistake. The burden here is that administrative systems need to be in place to track, and accurately respond to, individual fine-tuned choices. This is a burden that simply does not exist for broad consent frameworks and is less than that needed on specific consent frameworks where *all* are treated in the same way.

The objection here is not that that we already have reliable, precise, costings for meta consent. We have not *shown* that meta consent has to be more expensive relative to alternatives. There are good reasons to believe that it is likely to be so, given the degree of choice offered to participants. When Ploug and Holm state that *all things being equal* meta-consent is preferable to fixed consent frameworks, they cannot really get away with the "equal" part of that claim, as things—the costs and burdens—are very unlikely to be equal.

THE "PROTECTING AND PROMOTING AUTONOMY" ARGUMENT

However, if there is a strong moral argument in favour of meta-consent, in comparison to its fixed "rivals", then it ought to be introduced and any additional costs factored into the total research costs. But *is* there such an argument? Ploug and Holm, do suggest a more substantive *ethical* line of argument:

> A more flexible model of consent is motivated not only by endeavours to protect research. If we really want to safeguard the individuals' interests—if we want to protect and promote

> individual autonomy—then we should also protect their desire to provide consent in a particular way.[16]

The move here seems to be something like this. Liberal medical research ethics is grounded in respect for autonomy. Respect for autonomy implies a distinctive kind of *positive* respect for the individual as a free agent when interacting with her.

There may seem to be something intuitively plausible about this line of thought. After all, surely we have the *right* to shape our consent as we see fit. We have the right to choose the *target* of consent (the person or persons *to whom* we give permission); we have the right to choose the *scope* of consent (the set of actions are rendered permissible by our consent) and we have the right to introduce *conditions* on permissibility. Take a non-biobank example. If you are going on a long vacation and ask to borrow my camera, I have the discretion to insist that *you* may do so (but others may not) for a certain period of time (scope) but only if you contact me before using it in the rain (introducing a condition). That is, there is a kind of "right to design" built into the right to consent.It would be wrong for you to reply "I don't respect your right to specify *how* you want to consent, *I* will decide that".

But here we need to take care to distinguish two very different ways in which someone might fail to respect an individual's "right to design" her own consent. In our "camera" example above, there is a distinction between the following situations; (a) you understand and accept the terms of my consent "design", take the camera but fail to act within those terms; (b) you understand the terms, but do not want to comply with them, so you do not take the camera, but ask somebody else instead. The former wrongs me, the latter does not. The same is true when we turn to *requests*. Suppose you ask me if you may borrow the camera for a long vacation, but also add the proviso "Look, I'm going to be out of reach most of the time, so it won't be able to get in touch". Here you make a *proposal* about the "shape" of consent that you seek. Even though you do not offer me the opportunity to

shape the consent process as *I* see fit, you do not wrong me. If I don't want to lend the camera on those terms, I don't have to, and if I don't consent on those terms, you may ask someone else.

Biobanks, in general, do not need to recruit any *particular* individual. What is needed is a sufficiently large number of participants of various *types*. It does not *wrong* any particular potential participant to ask her if she is willing to consent in a certain way (provided it meets the appropriate standards—and that is what the ongoing biobank consent debate is about). If this participant does not like the "terms" she does not have to consent to giving a sample. If she does not consent, then others will.[iii]

At this point the advocate of meta consent might argue that these non-biobank examples miss out on some important aspects of biobank recruitment. If biobanks have an obligation to protect and promote autonomy, doesn't it then follow that they ought to respect participants interests' in choosing how to consent? For is that not an important aspect of their autonomy? The simple answer is: no, it does not follow at all. There is a great cloud of confusion within bioethics around the notion of autonomy and the idea of respect for autonomy. A fundamental, and genuine, part of respect for autonomy is to respect the rights and powers that people have: to not force, coerce, deceive or mislead by omission. *Informed* consent requirements reflect a more demanding and specific sense of respect for autonomy. The underlying *ethical* rationale for informed consent is that *if* one party wants to do something that *would* breach the other party's rights, then the requesting part should make sure that the rightholder is able to adequately assess *that proposal*, so that she is in a position to make an adequately informed decision whether to consent to *that* (and thereby knowingly undertake whatever risks and burdens have been disclosed).

But these considerations do not get us anywhere near an ethical argument for offering meta-consent. The obligations to gain informed consent are "tethered", as it were, to the fact that the

[iii] Of course, if the situation were that *almost nobody* would consent *unless* they were offered meta-consent, that would give a strong practical reason for biobanks to offer it; given that there are many well-supported biobanks across the globe, without meta-consent having been offered, this seems not to be the case.

researcher proposes to impinge upon the participant's liberty, or to breach her rights. The reason *why* there are special obligations to disclose facts about the nature of research is because the research would breach rights without adequate consent. Such obligations are restricted in their scope, they extend to making sure that *this particular decision* about what would be a *rights-breaching action* can be adequately made.

There is no *general* obligation upon researchers to "promote" autonomy in an untethered, open-ended, general way. Participants in medical research might have their autonomy, broadly construed, limited in a wide variety of ways. They have low income, low education, or be in an abusive relationship. Their autonomy *could* be protected and promoted by more pay, better education and by a safe route out of the relationship. But clearly it is not the job of a researcher to promote autonomy in *every* sense, or every way.

It might be argued that even if there is no general obligation to promote participants' autonomy, there is a narrower, "local", obligation to promote their autonomy with regard to their decision to participate. But the points made just above apply to the more specific domain too. A participant might be in a better position to make a decision were she more educated, or were she not distracted by worries about her leaking roof. It does not follow that the biobank (or anyone) is under an obligation to the participant to "promote" her autonomy in this way.[17]

An appeal to "autonomy" gives us the sense that there is an argument in play. We may think of areas of research ethics where respect for autonomy is important, we then note that offering *more* choice would, in a broad sense, promote more autonomy, we then flip back to the idea that respect for autonomy underpins obligations, so there must be, surely, obligations to offer choice of consent design. But this is not an argument, this is a cluster of overlapping intuitions and slogans. If the argument for meta-consent is going to be grounded in some kind of obligation to protect and promote autonomy, it cannot be some kind of open-ended general obligation, for then researchers would be obliged to protect and promote autonomy in an open-ended way, and clearly there is no

such obligation. On the other hand, if we turn to a more restricted, limited, set of obligations, it is not clear that there is an *additional* obligation *over and above* the obligation to secure informed consent (whatever that amounts to for the biobank situation), whereby biobanks ought to offer the participant the opportunity to *design* her consent process and to then *abide* by that design and undertake all the obligations and burdens that may go with it.

We noted earlier that the specific consent framework has been developed into *dynamic* consent. Recent formulations of dynamic consent lay stress on the way that an ongoing, interactive, communicative platform makes it possible for research subjects to fine-tune their consent. Indeed, Ploug and Holm acknowledge that a dynamic consent model "could incorporate this 'meta aspect' of the meta consent model, and thereby make their model substantially identical to the meta consent model".[18] Similarly, advocates of dynamic consent have suggested something very like "meta-consent" "Rather than being restricted to the opportunity only to give broad consent to the use of their samples and data, individuals could provide different types of consent depending upon the kind of study".[18] The arguments offered here do not seek to show that dynamic consent (or meta-consent) cannot be justified, it is that the arguments offered by Ploug and Holm do not provide support for the idea that it would somehow be wrong, or remiss, to fail to offer such a framework.

CONCLUSION

In sum, there is no *ethical* reason why biobanks should be obliged to offer meta-consent rather than a "fixed" option. Nobody is wronged by making a non-coercive, truthful proposal, whilst denying the addressee the opportunity to "design" the scope of consent or to shape the nature of an ongoing consent relationship. Although there is no *ethical* reason why biobanks should offer meta consent, there may be contingent, *practical* reasons in favour of meta-consent, both in terms of aiding recruitment and in terms of secondary effects on public trust, levels of "Involvement" and social licence. But such potential *benefits* of meta consent in terms of recruitment would have to be weighed against the considerable costs and burdens that such a complex governance framework

would introduce (we would also need to keep track of *whom* the benefits accrue to). Assessing the relative costs and benefits of meta-consent would require a great deal of empirical work by medical sociologists, research accountants, and many other parties.

The aim here has been modest: to show that there is no *ethical* reason why biobanks should offer meta-consent, it does not wrong potential participants to fail to offer them the opportunity to *design* their own consent process. The biobank consent debate thus continues on, full steam ahead.

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17. For a broader discussion of these issues see Manson, Neil C., and Onora O'Neill. *Rethinking informed consent in bioethics*. Cambridge University Press, 2007.
18. [12] p.732.
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