ARTICLE

Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem?

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In the endeavour of biobank research there is dispute concerning what type of consent and which form of donor–biobank relationship meet high ethical standards. Up until now, a ‘broad consent’ model has been used in many present-day biobank projects. However it has been, by some scholars, deemed as a pragmatic, and not an acceptable ethical solution. Calls for change have been made on the basis of avoidance of paternalism, intentions to fulfil the principle of autonomy, wish for increased user participation, a questioning of the role of experts and ideas advocating reduction of top–down governance. Recently, an approach termed ‘dynamic consent’ has been proposed to meet such challenges. Dynamic consent uses modern communication strategies to inform, involve, offer choices and last but not the least obtain consent for every research projects based on biobank resources. At first glance dynamic consent seems appealing, and we have identified six claims of superiority of this model; claims pertaining to autonomy, information, increased engagement, control, social robustness and reciprocity. However, after closer examination, there seems to be several weaknesses with a dynamic consent approach; among others the risk of inviting people into the therapeutic misconception as well as individualizing the ethical review of research projects. When comparing the two models, broad consent still holds and can be deemed a good ethical solution for longitudinal biobank research. Nevertheless, there is potential for improvement in the broad model, and criticism can be met by adapting some of the modern communication strategies proposed in the dynamic consent approach.

Keywords: broad consent; dynamic consent; biobank; research participation; ethics

BACKGROUND

The standing of the ‘biobank donor’ as to what type of involvement and control donors of biological samples should have has been one of the major issues in the ethical debate surrounding the use of biobanks as resources for research. This has been embodied in an extensive discourse on consent and consent processes in biobank research (see for example, Shickle,1 Caulfield and Kaye,2 Otlowski,3 Elger and Caplan4 and Caulfield and Knoppers5). No consensus seems to exist on a theoretical level whether ‘blanket consents’, ‘specific consents’, ‘no consents’ or ‘broad consents’ fit best as a consent model for balancing the interest of donors and research in the best possible way. In practice, however, the model termed ‘broad consent’ has been adapted by many current biobank projects, like UK Biobank, CARTaGENE (Montreal, QC, Canada) and the Norwegian HUNT study.6

Broad consents are not open nor are blanket consents. To give a broad consent means consenting to a framework for future research of certain types.7–10 Included in this framework is ethical review of each specific research project by an independent ethics committee as well as strategies to update regularly the biobank donor and ongoing withdrawal opportunities. If anything in the framework changes, the participant should re-consent.8 In that sense, broad consents still claim to be informed consents.

However, this is opposed by some scholars. They reject labelling broad consents to biobank research ‘informed’, as aspects of future research projects are today often unspecified and to some extent unforeseen. The promoters of this view render ‘informed broad consent’ to biobank research a contradiction in terms.11–14 Taken even further, some claim that broad consents ‘... hinder donors from exercising fundamental rights and freedoms’.15 Based on arguments like these and technological developments enabling easy, two-way, cost-efficient, real-time contact with individuals, it is not surprising that the use of broad consent processes in biobank research is revisited.

‘Dynamic consent’ has recently been proposed as a model to resolve the alleged consent problem within biobanking.16,17 These are Internet-based, 2.0 type and interactive consents. Herein lies hope of solving the problem of participants not being appropriately informed. In addition, an essential shift in the standing of the donor is envisioned by being a participant-centred initiative, which locates ‘the research patient in the centre of decision-making as equal partners in the research process’.18

Dynamic consent intuitively sounds like a beautiful idea. It is a strategy that first of all involves a more active and potentially more interactive follow-up process of biobank contributors (compared with today’s broad consent). Obtaining specific consent from individual biobank participants for each subsequent research proposal after the initial broad consent has, up until now, in general been deemed unachievable.1,16,17,19 Dynamic consent employs features of web-based technology to solve the perceived problem of lack of ‘real-time’ specific information about individual research projects seen in the broad consent procedure used in many research biobanks today.20

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A dynamic longitudinal consent strategy for biobank research is promoted by some leading ethical and legal scholars. Kanellopoulou et al.\(^\text{16}\) anticipate ‘that dynamic consent’ will become an essential and sustainable component of research infrastructure.\(^\text{16}\) As this proposal immediately seems appealing, it is, from an ethical perspective, important to investigate that there are no hidden challenges related to the model. As a matter of fact, we will argue that there are.

**WHAT IS DYNAMIC CONSENT?**

Different proposals for dynamic consent or patient-centric initiatives have been launched over the past decade.\(^\text{1,16,18,21–23}\) And although they all utilize information technologies, their solutions vary when it comes down to the core issues of re-contact and re-consent.

A recent and interesting proposal of dynamic consent, and manifestation of ‘dynamic’ as a unique concept, comes from the Ensuring Consent and Revocation (EnCoRe) project, an interdisciplinary project with actors both from academia and the business sector.\(^\text{24}\) The EnCoRe ‘dynamic consent’ is a web-based platform with an interface that allows research participants to have an ‘interactive relationship with the custodians of biobanks and the research community.’\(^\text{25}\) Here a dynamic process is promoted, which emphasizes continuous re-contact with biobank donors, giving them ‘real-time’ information on specific research projects, and enabling the participants to easily provide or revoke their consent.\(^\text{20}\)

Contrasted to today’s broad consent model, a dynamic consent entails narrower, more specific consents with active opt-in requirements for each downstream research project. (From the EnCoRe proposal, it is unclear whether an initial broad consent with downstream opt-out solutions is a viable option;\(^\text{16,18,20}\) however, they clearly point out shortcomings in a broad consent model. We also acknowledge that the EnCoRe project has for the most part focused on biobanks derived from patients, especially those generated in university hospital settings. Here, for the purpose of the argument and the larger picture we are not limited to biobanks derived from patients but include all research biobanks with a longitudinal design, including the large population-based biobanks in this dynamic consent discussion.) In this article, it is the proposal of dynamic consents with active opt-in re-consent strategies that we will address, as this model clearly illustrates the moral differences between the broad and dynamic consent.

Proponents of dynamic consent claim that the dynamic consent approach is something essentially different, thus better, compared with broad consents: ‘In this model, consent is not a mere communication exercise but a bidirectional, ongoing, interactive process between participants [research participants] and researchers.’\(^\text{16}\) The implication is that broad consent results in passive participation, and that this is ethically problematic. Based on this there are at least six claims, which trigger us to examine whether dynamic consent is superior, ethically speaking, to broad consents.

**DYNAMIC CONSENTS RESPECT PARTICIPANTS’ AUTONOMY FAR MORE THAN BROAD CONSENTS!**

Dynamic consent is argued by its proponents to better meet the specifications of autonomy embedded in informed consent requirements compared with broad consent. Kanellopoulou et al.\(^\text{16}\) explicitly express this as they write, ‘The benefit of … [Dynamic consent]… is that it enables individuals to exercise their autonomy by giving informed consent for new types of research in real time rather than being asked to give a broad consent at the beginning of the research process when they are recruited into a biobank.’

However, both consent models can be said to respect autonomy as they both provide information about biobank endeavours and leave it up to the individual to decide if he or she would like to take part or not. The fundamental difference between the two is disagreement on whether consent to ‘unknown’ future activities, can be labelled ‘informed consent’ and be viewed as an expression of an autonomous will. As Sheehan\(^\text{26}\) and Steinsbekk and Solberg\(^\text{8}\) have argued, we regard many ordinary decisions people make as properly informed without having all the specifics — thus they are still ‘perfectly acceptable autonomous decisions’ in most people’s minds. The model of broad consent follows such decision patterns.\(^\text{8,27}\)

In the dynamic consent model, participants should always make an informed consent to both primary and secondary use of their data. It does not matter whether a new project Y is only slightly different from an initial project X. And it does not matter whether it is possible or impossible to find any kind of ‘rational’ justification for taking part in X and saying no to Y. As such, dynamic consent takes people’s preferences as the point of departure.

In the broad consent model, on the other hand, people are asked to re-consent only when there may exist an ethically relevant difference between X and Y.\(^\text{9}\) Participants in such situations are asked to re-consent, because a research ethics committee or the biobank institution believes there is something to ask them about, something that matters.

The difference between dynamic consent and broad consent is then made clearer: In a dynamic consent model, participants will be asked for consent continuously, simply because each new project is a new project. Thus, they will be asked to re-consent both for trivial and essential reasons, and often the former. In a broad consent model, participants will seldom be asked to re-consent, but when they are asked, they are asked for a non-trivial reason. When described like this, it is not obvious that the dynamic consent model respects the autonomy of participants in a better way than the broad consent model.

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**THE DYNAMIC CONSENT MODEL KEEPS PARTICIPANTS BETTER INFORMED COMPARED WITH THE BROAD CONSENT MODEL!**

Being able to inform research participants about the research they are involved in is essential in all types of research consent processes and has been the crux in the debate surrounding the legitimacy of broad consents. By continuously sending out updated information about specific research projects via SMS’s, e-mails or websites, dynamic consent can better fulfil the ideals of distributing detailed information compared with broad consents. According to Whitley et al.\(^\text{20}\) While it [broad consents] offers a pragmatic solution to the current problems faced by biobanks, broad consent arguably fails to meet the tenets of informed consent as provided by the 1964 Helsinki Declaration of the World Medical Association. Based on this, proponents of dynamic consent emphasize the value of information, that it is important to be properly informed, that is, informed in detail. It is plausible that dynamic consent will provide the research participant with more information than that given by the initial broad consent process in today’s biobank undertakings.

However, large biobanks are already obliged, in some countries even by law, to continuously update their donors about ongoing activities, no matter what kind of consent has been obtained. It is probably true that legitimate criticism may be raised against some biobanks for not fulfilling their ethical or legal duty to inform. However, that is not an argument against broad consents; rather, it is a criticism of an information policy. Several biobank organizations,
like UK Biobank and the Norwegian Mother Child Cohort Study, resting on broad consents keep their donors and other interested parties informed by regularly updating dedicated web pages as well as sending out annual newsletters.\textsuperscript{28,29} Transferring information whether through e-mails or newsletters holds the same potential as dynamic consents to fulfill the duty to inform.

Thus by itself, the information strategies given in the dynamic consent proposals might just be seen as an alternative, although for many a preferable, route of distributing information, but not as something fundamentally new. Nor should it be regarded as the sole option for communication in biobank research: Relying heavily on electronic communication strategies will exclude individuals and groups from taking part in activities like biomedical research, because of what has been labelled ‘the technological and digital divide’.\textsuperscript{30}

More information ultimately appeals to people who want to be in control and people who are uncertain about what it is they are taking part in. However more is not always, morally speaking, better. The core of this debate, as we see it, is what it means to be ‘adequately informed’ and whether giving consent based on broader premises is valid or not. As we have argued, broad consent in biobank research is not merely a pragmatic solution but a morally valid, legitimately informed model when used as part of a framework of research governance.\textsuperscript{8} This also implies that ‘more information’ in itself does not necessarily make a consent more informed. Rather, it is relevant information that makes a consent informed.

There is risk of making it difficult to distinguish between relevant and irrelevant information when faced with the fascinating prospects of informing participants about everything in the dynamic consent model to achieve ‘informed’ decisions before opting in. In the broad consent model, there is nothing that prevents availability of detailed information on web pages, but the participant is not contacted to become ‘informed’ unless some kind of fundamental issue is at stake. So even based on the relation between autonomy and information, it is not clear to us that dynamic consent is superior.

MORE PEOPLE WILL TAKE PART IN BIOMEDICAL RESEARCH BASED ON A DYNAMIC CONSENT MODEL!

Proponents of dynamic consent also propose this as an exercise that can increase trust and willingness to participate in research. The aim of dynamic consent is to be more inclusive compared with regimens based on broad premises and to involve people in ‘proposing, drafting and amending biobank digital governance structures, protocols, strategies and policies’, thus giving ‘power to the people’ by adopting a wiki-governance model for biobanks.\textsuperscript{17,38} Thus, it can be part of a model that meets ideas of participatory democracy or deliberative democracy as promoted in the context of biobanks and biobank research.\textsuperscript{38} This can foster, as Dove et al\textsuperscript{38} advocate, publics to engage in ‘proposing, drafting and amending biobank digital governance structures, protocols, strategies and policies’, thus giving ‘power to the people’ by adopting a wiki-governance model for biobanks.

Providing individual biobank contributors with tools that give them increased control and maybe new rights over their contribution is probably the strongest argument for a dynamic interactive consent model. Addressing and involving participants more as active partners than passive contributors seems a good way to treat participants and it has the potential to give participants a possibility to express their preferences and protect their interest over time, as called for by scholars like Saha and Kaye.

However for biobanks, such argument assumes that it is an important task to empower and engage people to achieve good governance – an assumption, we claim, is not necessarily true. The reason why ‘user participation’ in health care in general is seen as important is basically because we believe that we should be engaged in the process and participate in decisions regarding our own health.
Biomedical research, however, is not primarily about our own health but rather about potential health benefit for future generations. An important reason for active engagement and participation in biomedical research is thereby lacking compared with general health care.

Of course, one could argue that it is rather the important research contribution by each and every one in biobank research that justifies 'user participation' and 'power to the people'. However, this way of arguing also seems odd, taking into account that biobank research is probably one of the least invasive research forms that exists with minimal efforts on the part of participants.

In general, responsibilities for various functions in our society are handed over to experts and their framework negotiated within political and expert systems. This has also been the tradition within research at large. Both the funding and ethical approvals are mostly handled by experts. However, this has been criticized as insufficiently robust. Scholars like Nowotny\(^3^9\) argue for a broader involved deliberation and decision-making due to the changing nature of scientific knowledge production. Especially in areas where there are uncertainties surrounding the consequences or outcome of the scientific activity or where values are at stake.\(^4^0\) Now, a true democratic and participatory model of medical research in general would be a model where citizens were allowed to impact on what kind of research initiatives they thought would have the biggest effect on promoting health and reducing the burdens of disease in a society. In such a model, they would have power by being able to say yes or no to, for instance, large-scale biobank initiatives in a society. However, such a model is far from the model described in relation to dynamic consent. The 'participation' here is participation inside an already established research arena where only minor changes of policy are up for discussion. We do not deny that increased user participation is possible to achieve. However, we doubt that there is a moral imperative to try to achieve this within today's framing of biobank research.

**DYNAMIC CONSENT IS GOOD BECAUSE IT TRANSFERS ETHICAL RESPONSIBILITY FROM COMMITTEES TO PARTICIPANTS!**

In addition to giving biobank donors direct charge over their 'deposits', the dynamic consent strategy has the inherent potential to shift the control and responsibilities from research ethics committees and researchers to research participants, and thus it constitutes a moral difference. This can then be a part of a move towards more open and democratic processes in science, ensuring a socially robust knowledge production. This will ensure, it is believed, a qualitatively better research and technology development. In such a system, new consents will be asked for, for each new project, which eliminates the need for review boards or ethics committees to reassess the validity of a previously given consent. From this follows that if there is lack of support – not enough participants consent to the specific project in question – it will not be realized, meaning that the project is not socially robust.

Nevertheless, one may find problems with such reasoning. Especially since the lack of support does not necessarily imply that many people find the proposed research wrong, controversial or even unethical. It can merely be it is not sufficiently spectacular or populist to attract enough support.

It is also possible to see hopes of reduced ethical review for secondary research, as Kaye\(^1^7\) explains when advocating the EnCoRe dynamic consent model: 'The current research governance system [including broad consents] … has the potential to place the ethical burden for secondary research on researchers'. In another paper she writes that the dynamic consent strategy 'could be used as a basis for cutting down on research ethics oversight for secondary research'.\(^2^5\)

Our major objection here is the risk of an 'adverse effect' of trying to take away the ethical burden for secondary as well as primary research from researchers and research ethics committees, and put participants in charge. The possible adverse effect is that of weakened ethical assessment. In a participatory dynamic consent model, you as the participant are required to raise your guard, get involved and evaluate every project instead of placing trust in research ethics committees and researchers. Trust in research ethics committees could seem to be understood as blind or misplaced trust, according to this model, and in that sense the request is to enlighten yourself and make an informed decision. The problem with such a construction of the 'participation' is that very few participants will probably be able to meet such high expectations. Putting up one's guard seems to contrast intuitions reported form a Eurobarometer study on Europeans and biotechnology form 2010.\(^4^1\) Here it was reported that people, although nuanced, 'do not seem to have particular worries about providing certain types of information to biobanks: blood samples, tissue samples, genetic profiles, medical records, and lifestyle data elicit similar levels of concern' and where '[b]roadly speaking, respondents in those countries that show higher levels of support for biobanks tend to favour external regulation more than self-regulation.\(^4^3\) For most people, we suspect that biomedical research is complex, complicated and rather boring stuff. Patients are often engaged in the whole process through patient organizations. However, we can assume, based on the Eurobarometer findings cited above and several qualitative studies (see eg, Simon et al\(^4^2\)), that healthy individuals and many individual patients who are potential participants do not want to engage in decision-making regarding whether a cardiovascular research project is more in line with their personal preferences for the use of secondary data, than a project on cancer or diabetes. This is not primarily a thesis about public knowledge deficit, as Dove, Yole and Knoppers\(^3^8\) seem to suggest. Rather, it is recognition of the fact that ordinary citizens are expected to engage and participate in a number of different practices in a democratic society. There is no good reason why biobank research should take a prominent place in ordinary people's lives, as such. We assume that many would not be willing to spend the time and effort necessary to fully grasp all aspects of the research that they can consent to; leaving the claim of increased sustainability, entrenched in a dynamic consent model, not so straightforward. If this is correct, the benefit of increased choices may for a majority become a burden of autonomy with negative impact on recruitment.

Of course, in a system of dynamic consent, you are allowed to consent every time without actually using this opportunity of control. However, the 'subtext' has a different message. This message is that in research people ought to have knowledge and competence to make informed decisions. Moreover, the underlying message is that informed decisions, on a detailed level, are important elements of research participation. Our claim here is that this is the embedded 'meaning' of a system with dynamic opt-in consent, even though it is not formulated anywhere. Why else should people continuously be informed, be asked and have to decide, if it was not because the embedded normativity in this model says it is so important to make this type of informed decision instead of transferring that responsibility to researchers and ethics committees?

The consequences could either be that people will become reluctant to participate in this type of medical research or they will participate with a 'bad conscience'. The first consequence is obviously bad for future research, as well as future patients. For the other consequence,
it could be claimed that it is something we have to live with, as long as dynamic consent is the only relevant form of a valid consent. However, we get the opposite of empowered people, namely participants who do not use this opportunity of learning and exercising their potential power, they rather experience that they fall short on the implicit demands of participation. In addition, this is not only a matter of self-esteem, as one of the assumed benefits of dynamic consent is transferral of responsibility for the ethical acceptability of biobank research projects from researchers and ethics committees to participants. If participants do not engage, then the situation is one of weakened rather than strengthened research ethics assessments in a time when evaluating potential impacts connected to this kind of research seems to increase in scope and complexity.

A DYNAMIC CONSENT STRATEGY IS NECESSARY TO ENABLE THE RETURN OF RESEARCH RESULTS AND INCIDENTAL FINDINGS TO PARTICIPANTS IN AN EASY AND TAILORED MANNER!

Right now there seems to be a growing focus on the return of either research results or incidental findings to participants in biobank research.\(^\text{43,44}\) The dynamic consent strategy aims to enable the return of such research results to individuals in an easy and tailored manner. Thus its advocates argue that, to respect the values of autonomy reciprocity and beneficence, return of results is a necessity. This is especially based on the idea that the development within genome sequencing increases the potential for producing data that would be valuable for a research participant to have access to, therefore being informed about them and continuously having choices of receiving them or not are called for.

We do not doubt that a dynamic consent strategy is well-suited for return of results and incidental findings in a tailored manner. However, we doubt that such return of results is necessarily a good thing. There are still important arguments for being restrictive and supporting a non-disclosure policy.\(^\text{45,46}\) The dynamic strategy has the inherent potential to conflate research with health care, especially when it promises the return of individual research results (‘the therapeutic misconception’, see Appelbaum et al\(^\text{47}\)). This can have several effects on research. One is the diversion of resources from the core activity of research, namely that of asking questions and creatively seeking answers towards producing information that is suitable to feed back to individuals. Another is prohibitive restrictions of the types of analysis biomedical research can do, and what types of persons would be allowed to do them; only accredited personnel with diagnostic competence or ‘everyone’ from a learning setting to highly skilled professionals in a biomedical lab? If only the latter, it has the potential to hamper the freedom of research and to reduce its future outcomes. Yet, another will be that research is forced to prematurely translate group-based research into individualized information. This can then lead to further challenges of overdiagnosis and medicalization of those who participate in medical research. As our societies strongly emphasize the health of its populations, there are, as Moynihan et al\(^\text{48}\) have pointed out, evidence that medicine is harming healthy people through its quest for early diagnosis and use of wider disease definitions. Therefore, biomedical research is a balancing act between creating better understandings of disease and disease prevention but at the same time not being overzealous in translating research findings into practical medicine and creating ‘unhealth’ instead of health by mechanisms of medicalization.

A fundamental critique of dynamic consent is thus against its proposal’s implicit value of the primacy of private interests. Population-based biobanks can be seen as a public health research initiative aiming for knowledge that benefits everybody. A disclosure policy may easily shift the focus and expectations of research from no direct personal gain to making return of individual research results the primary motivation for participation. If that should happen, one could also claim a cost to the traditional values and feelings, which lie in acts of altruism and participation towards common goods. This might then enforce ideas of individualism and of ‘what’s in it for me’ even in aspects of human conduct relating to contributing to biomedical research.

CONCLUSION

Proposals of dynamic consent, especially its focus on new possibilities for communication with research participants embedded in Internet and social media, definitely have the potential to sharpen and broaden consent strategies. We concur with the importance of information and that improvement of information strategies should be addressed repeatedly. However, based on the reflections above where we argue that the broad consent model is consistent with the value of autonomy and informed consent, we are not ‘forced’ to accept all aspects of dynamic consent. The dynamic consent strategy with repeatedly opt-in options holds the risk of participants not opting in or opting in with a bad conscience for not making an informed choice, risk of weaker ethical review of research projects, risk of disillusionment based on unfulfilled expectations, as well as the risk of inviting participants into therapeutic misconception. Therefore, we hold that the relatively passive participation implied by broad consent has ethical strengths that outweigh the potential problems suggested by dynamic consent proponents, as long as well-functioning systems for ethical review and information strategies with opt-out arrangements are in place.

Assuming that biobank research carries the potential for important medical breakthroughs, it is morally problematic if consent procedures unnecessarily reduce or prevent these opportunities. As the overall goal of biobank research is beneficial medical inventions, the choice between broad and dynamic consents is not merely a matter of their respective internal merits in protecting the interests of participants. We have a prima facie duty to promote this kind of research. This means that if broad and dynamic consent are considered morally equivalent in protecting participant interests, we should use the one that is least likely to reduce the value of this research.

As we hold that the proponents of dynamic consent have not made a convincing case that their proposal will be better in this respect, under the current circumstances we claim that broad consent combined with competent ethics review and an active information strategy is a more sustainable solution.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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