In Defense of Broad Consent

GERT HELGESSON

Introduction

Proper procedures for informed consent are widely recognized as an ethical requirement for biomedical research involving human beings, in particular as a means to respect the autonomy and personal integrity of potential and actual research participants.[1] There is, however, considerable disagreement on how to handle informed consent in research that deviates from the standard case of clinical research, which is also reflected in the lack of uniformity in how informed consent routines are applied within the global research community.[2,3,4,5]

Whereas several authors have argued that any attempt to depart from the requirement that research information be study-specific compromises the ethical justification for these procedures,[6,7,8,9] others have claimed that regarding some kinds of research it is not only acceptable to obtain less specific consent from those participants who are willing to give such consent but also preferable, because it facilitates important research, especially by reducing risk for unfounded dropout and thereby diminished research quality.[10,11,12,13] In this article I argue that broad consent to future research is a legitimate and preferable alternative to specific consent for biobank research. I also critically discuss counterarguments to this view.

Informed Consent: The Standard Case

For decision-competent research participants to be shown due respect, it is essential that their participation is voluntary and based on correct and relevant information. Routines for obtaining informed consent are commonly understood as essential in order to achieve this. Requirements frequently pointed out as necessary for consent to be legitimate are that potential participants receive and understand the relevant information about the research before they make their decision and that their choice about participation be uncoerced and without undue influence. Furthermore, for their inclusion in research to be justifiable, their consent must still be in force when the research takes place.[14]

The requirement to obtain informed consent was originally intended for research directly involving human research subjects.[15] Since then, the most well-established ideas concerning informed consent have been developed around

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an idealization of biomedical research, in which the standard case for informed consent concerns a single, clearly specified study in which everything of importance about the study is decided before enrollment starts, research proceeds according to protocol, and no changes occur. In the standard case the study involves a face-to-face contact between research participant and researcher, and it only includes competent research participants who have the time and actual ability to consider the study information. Furthermore, the study directly affects research participants physically, as in invasive treatment or the testing of drugs.

In real life there is a great diversity of scientific studies, and many of them deviate from these idealizations of what biomedical research is like. For instance, in emergency care research, there is not always time to inform patients properly, if it is even possible to do so. In much research, participants are not competent or otherwise able to decide about their own participation, such as in research involving young children, patients with severe dementia, or unconscious patients. Nor is all research involving human beings invasive or related to drug testing. An ongoing challenge is how to handle informed consent in research that deviates from the standard case.

Biobank Research: Different in Important Respects

Studies based on analysis of biological samples stored in so-called biobanks are one example of research that does not fit the format of the standard case. Such research involves no direct physical risk to sample providers once their samples are obtained. It is therefore considerably less risky than participation in drug testing or invasive research. The risks associated with biobank research concern the potential harm to study participants caused by inappropriate distribution of information derived from the samples or from registers and medical journals used in combination with the samples.[16]

In any scientific study it is important to get as little dropout as possible, due to the risk of selection bias and thereby reduced scientific quality. Therefore it is important to avoid all nonparticipation that depends on other aspects than potential participants' considered choices not to participate, for instance, difficulties in getting in touch with potential participants or eventual refusal to fill in consent forms because they get tired of doing so, even though they in principle are willing to participate. The risk of such nonparticipation is arguably more pertinent for biobank research than for clinical research, in particular due to difficulties in getting in contact with potential participants. These difficulties relate to the fact that biobank studies may be carried out long after the samples are collected; potential research participants may have deceased or may have moved one or several times. The risk that there will be dropouts caused by practical aspects like these, rather than by reflected choices regarding participation, increases with the number of times people are asked to consent.

Because biobank research does not require study participants to actively participate at any time, it is practically feasible to carry out biobank research on a much larger scale than any research directly involving human beings. Large-scale endeavors that include samples from hundreds of thousands of individuals are becoming increasingly common. This development toward large studies that include multiple populations is much needed. Many local and national genetic studies lack statistical power and cannot distinguish relevant traits from

confounding factors.[17] Although smaller biobank-based studies have already been useful on many occasions, for instance in establishing the causal relation between human papillomavirus and cervical cancer,[18,19] to take but one example, large numbers of familial cases and controls are in many cases needed for validation of the biological importance of genes believed to be associated with various diseases. In large biobank studies, the informed consent issue appears on a very different scale compared to most clinical studies. Obtaining new consent from so many participants may not be practically possible. It may also be too costly given restricted research budgets.[20]

Broad Consent to Future Research

Because biobank research is different from clinical research in some important respects, it has been suggested that less specific consent should be allowed for biobank research.[21] Broad consent to ethically approved biomedical research is found on a scale ranging from specific consent to each individual study to blanket consent, that is, unrestricted consent to any kind of use, including forensic and commercial uses (see Figure 1). To allow broad forms of consent means to make it possible for sample providers to submit consent not only to specific studies but also to classes of research, such as cancer research or cardiovascular research. The broadest form of consent to biomedical research would cover all such research. The way I use the term, ''broad consent'' means general consent to ethically approved biomedical research. If broad consent is treated as a legitimate alternative on consent forms, it allows researchers to obtain consent for all kinds of ethically approved scientific uses when the sample is obtained, which means that researchers do not need to return to the sample providers to obtain consent for new studies.

However, as soon as consent concerns a category of research rather than a specific study, it entails consent to ongoing as well as future studies. Broad consent entails consent to a very wide variety of future biomedical research, which means that it entails consent to much research that cannot be specified in detail when consent is obtained because it has not been conceived of at that time. This clearly shows that broad consent is not a legitimate form of consent, its opponents would argue. Because one important purpose of routines for informed consent is to guarantee that potential research participants get relevant information about the study they are about to enter, promoting routines that accept consent to studies about which there is yet nothing of substance to say is clearly unacceptable.

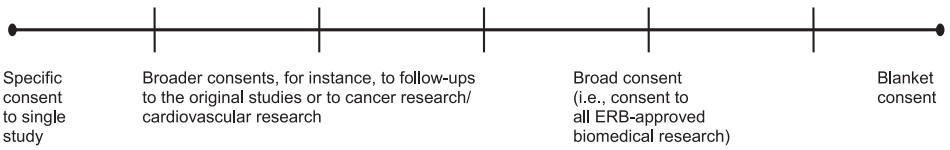

Figure 1. Broad consent on a scale from specific to blanket consent. The further to the right one moves on the scale, the more general the consent. There are, for instance, a number of potential steps to the right of broad consent to biomedical research in which other kinds of uses, such as forensics, are allowed but in which consent is still not entirely unrestricted.

The Core Objection

The core argument against broad consent to future research is that it is impossible to give properly informed consent unless you are informed about the specific study in which you are about to participate. Because those giving broad consent are consenting to participation in research that may not even be conceptualized at the time of consent and about which there is then no specific information to give, such consent cannot be properly informed. Árnason has given a much-cited formulation of this view:

> If we are to preserve a meaningful notion of informed consent for participation in research, it should only be used about specified research where the participants are informed about the aims and methods of a particular research proposal. There is no such thing as "general informed consent." The more general the consent is, the less informed it becomes. It is misleading to use the notion of informed consent for participation in research that is unforeseen and has not been specified in a research protocol.[22]

Similarly, Elger has stated that "following the classical doctrine of informed consent, any consent to future research projects that are not clearly described, is by definition invalid because it is not informed."[23] Basically the same point is made by Caulfield when discussing consent to participation in national biobanks set up as prospective epidemiological resources, like Biobank UK:

> [I]t is impossible to obtain truly informed consent from biobank participants at the time of their recruitment. Of course, one can provide information about the broad purposes and governance strategies for the resource; but the details that are a customary component of the traditional consent process cannot be disclosed. The facts about specific research projects simply are not known.[24]

To some extent these protests can be read as statements about language use that claim that the requirement that information be specific is simply part of the definition of "informed consent," or of being informed in general, and therefore it follows that broad consent is not informed in the relevant way.[25] Because these arguments are used in opposition to certain practices, and not only to the labeling of these practices, it is clear that there is also a genuine ethical issue concerning whether one can be properly informed if one is not given study-specific information. To this question opponents to broad consent to future research answer no, whereas proponents, including myself, say yes.

How to Understand the Concept of Being Properly Informed

The disagreement indeed concerns how "properly informed" is to be understood. According to opponents of broad consent to future research, specific consent is a necessary requirement. This is usually stated with little elaboration, as in the preceding citations. One possible way to elaborate the opponents' position would be to say that being properly informed requires that all information that can be expected to be relevant to at least someone's choice about participation must be given to any potential research participant. Because one may expect that someone would at least like to have study-specific information, such information must be included.

I suggest another approach. Instead of deciding what would be a proper list of information, we should reflect on for what purpose information should be given. The main justification for informed consent in recent years has been in terms of respect for autonomy, and more specifically for autonomous decisionmaking.[26] To the extent that this is correct, the main point of informing potential research participants is to facilitate their autonomous decisionmaking regarding their participation. If they get the information they find relevant for their decision, then they are properly informed.[27] Because individuals differ regarding what information they find relevant for such decisionmaking, a one-size-fits-all approach to study information is inadequate. People are willing to participate in scientific studies on different conditions: some require specific information about the individual study in order to even consider participating, whereas others are satisfied with general information about requirements on biomedical studies involving human beings regarding ethical review, storage and data protection, confidentiality, and so on, in order to be willing to participate with their samples in biobank research. If people in the latter category actually get and understand relevant and correct general information, then, I argue, they are properly informed and their consent is legitimate, because their decision is based on the information they find relevant.

Indeed, the view that participants are properly informed to the extent that they are given and understand the information they find relevant for their decision fares better in terms of respect for autonomy than the view that participants must have study-specific information for their decision to be properly informed, because people may want less information than what the latter view requires. Therefore it is legitimate to have an alternative on consent forms in which the participant gives broad consent to future use for research. Not everyone would be willing to choose this alternative, but that does not disqualify it as a legitimate alternative. Because broad consent not only is legitimate from an autonomy perspective but also is the most convenient consent alternative from a research perspective, it is recommendable that this alternative be included in consent forms regarding storage and use of human biological samples.

It is worth underlining that a person can approve of participation in a study in two ways: either by consenting specifically to participation in that study or by consenting broadly to research of which the individual study is an instance. One may correctly say that a person who, based on his broad consent to future research on his biological samples, has been included in a study that was not conceived of at the time of consent has neither been informed about nor consented to participation in that specific study, yet he has given proper informed consent to this participation. Both types of inclusion rest on legitimate consent after consideration of information relevant to the decision. This is possible because there is no common set of information that is *the* relevant information to every potential research participant. Relevance depends on use.

Arguments against Broad Consent

There are a number of specific arguments against using broad consent, concerning either protection of research participants or the individual's genuine opportunity to choose, or both.

In Defense of Broad Consent

Difficulty of Withdrawal

A standard requirement for proper informed consent is that participants can withdraw from the study at any time and that they are informed of such. The first argument questions that this condition is fulfilled when using broad consent.

1) If you do not know what studies you participate in, it will in practice be impossible to withdraw.[28]

Let me first say that if one gives broad consent, one will have to assume that one's samples might be used at any time for research. If an individual hears about a study with which she strongly disagrees, she may check whether she is included and withdraw her samples if she is. Biobanks should be organized so that this is possible. But what if an individual does not hear about a study that she would feel very strongly against participating in? This is indeed a risk tied to giving broad consent. The sample provider will have to make an assessment of the alternatives beforehand: What are the disadvantages of not giving broad consent to future research and what are the disadvantages of giving such consent? This assessment should be informed by the fact that only ethically reviewed and approved studies will take place.

That this risk exists, however, cannot be used as an argument against broad consent based on respect for autonomous decisionmaking. With a more paternalistic outlook, this situation might seem different, because by prohibiting all alternatives to specific consent, the risk that individuals will be included in future studies of which they disapprove is eliminated. However, a closer look reveals that the individual's interests are peculiarly handled with this approach, because if people are properly informed about what it would mean to give broad consent, this risk should already be calculated. Therefore it could be assumed that participants who give broad consent prefer this alternative even given the risk of being included in a study of which they would disapprove in the future. Having the option of broad consent removed would therefore make them worse off. If people are improperly informed about what it means to give broad consent, then this is an information problem and not a problem with broad consent as such.

Limits of Imagination

Another argument concerns difficulties in imagining what might be done in future studies.

2) Because of limits of imagination, potential research participants cannot make a proper estimation of what interests are in the balance when considering whether or not to give broad consent to future research (this argument has been suggested to me in personal communication on several occasions).

A similar problem exists in relation to consent to specific studies: there is always more to say about the study than what researchers tell potential participants. Because an excess of information might reduce the individual's understanding of the study,[29] researchers have to be selective. It is always possible that they leave out some piece of information that someone would find highly relevant to their decision about participating—and that this person did not think of asking for.

In relation to broad consent to biobank research, there is a greater risk that there might be something relevant to at least some potential participants that they do not think of when they consider whether to give broad consent, because the accompanying information will not say anything about specific projects since a very wide variety of research might use the samples. We cannot exclude the possibility that some participants who opt in with broad consent to future use would decide against participation in a particular study if they were given study-specific information.

The response here has to be similar to the one given to the first argument: this will have to be a calculated risk for those giving broad consent. This risk is not as such unacceptable from an autonomy perspective if it is pointed out beforehand. Nor would it be unacceptable from a participant safety perspective to allow broad consent, because researchers and ethical review boards (ERBs) are obliged to make sure that participation in research does not involve unacceptable risks.

One way to reduce the negative effects of participants' lack of imagination about future research uses of their samples, and to facilitate withdrawal from biobank studies for those who have been included in research they do not want to be part of, would be to have a system in place that provides open access to general information about ongoing studies (for instance, in the form of a regular newsletter) and that makes it possible and practical for one to find out whether one's samples are included in any studies. From an overview perspective it would be preferable if information about ongoing studies could be coordinated at a national level.

The Havasupai Indians Case

Is the suggested approach reasonable when it faces actual cases? The Havasupai Indians case puts ideas about broad consent to the test.[30,31,32] Starting in 1990, members of the tiny Havasupai Indians tribe, living isolated in the Grand Canyon, gave blood samples for genetic research into the tribe's high rate of type 2 diabetes. The consent that was obtained had a much broader application, however; it covered research on "the causes of behavioural/medical disorders."[33] In the following years, the diabetes-related research was carried out—it turned out to be of no help to the tribe—but so were genetic analyses related to metabolic disorders, alcoholism, and schizophrenia, the latter perceived of as a stigmatizing condition by the tribe. One of the papers stemming from this research reported a high degree of inbreeding. Other research traced the tribe's ancestral origins to Asia, whereas its own traditional stories held that the Havasupai had originated in the Grand Canyon. A newspaper later described this as "akin to a scientist asking Christians from Nazareth to give blood for a diabetes study, then producing research to suggest that Jesus never existed."[34]

When the Havasupai Indians learned about all this research, they felt betrayed. They claimed that they were never aware of having given broad consent to research, because the sample collection, in their minds, was initiated solely for the purpose of researching their high rate of diabetes. A lawsuit followed that finally ended with a settlement in which Arizona State University agreed to pay tribe members $700,000 and return the blood samples.

To learn from this example, one must ask what went wrong. Opponents of broad consent are quick to answer: the use of broad consent. But it seems clear that the failure in this case concerned how participants were informed rather than the form of consent, because they formally gave broad consent without

being aware that they did. If information is handled improperly, there is risk of misunderstandings regardless of whether broad or specific consent is used. In this case, in which the Indians' focus was exclusively on getting help with their diabetes problem, researchers should have stressed very clearly that they also asked for consent to other kinds of research.

Perhaps it was also wrong to give ethical approval to some of the studies that were carried out, in particular the one concerning the origin of the Havasupais, because the potential harm arguably exceeded the potential positive value of the study. An alternative for the ERB could have been to insist on specific consent for that study in spite of the existing broad consent, the argument then being that the interest of protecting the individuals concerned outweighed the importance of respecting their (presumed) autonomous choice to give broad consent.

Impossibility of Knowing Future Risks

Future risk is another theme among critics to broad consent.

3) It is impossible to know the future risks of harm beforehand. Therefore broad consent cannot be properly informed.[35]

This argument is similar in structure to the general argument against broad consent that because there is no specific information available on future studies not yet conceived of, it is impossible to give informed consent to participating in those studies. But here the focus is on risk and participant safety, opening up a justification in those terms for only permitting specific consent.

Critics are right that people who consent to future use of their stored samples cannot know what risks participation in specific studies would imply if these studies were allowed to proceed without any assessment. What they do know is that they consent to participate in studies approved by an ERB. It is the job of the review board to assess risks, along with other aspects of the study, as it is submitted to the board for approval. This means that if people are willing to trust the quality of the assessments made by the review boards, then they do not need to predict future risks tied to individual projects. They will know that their samples will only be used in studies with risk levels that the ERB finds acceptable. This is what people who are willing to give broad consent autonomously choose to do.

ERBs may, of course, misjudge the risks associated with a particular study. Studies may therefore be approved due to an underestimation of the risk involved. This risk is, however, considerably smaller in relation to biobank-based research than concerning research with invasive procedures or studies testing new drugs, because the risk in participation in biobank research mainly relates to the handling of data. If researchers handle data properly, risks will be quite similar and quite low across a great majority of biobank studies. Some topics for research may, of course, be more sensitive than others. This is something that the review board has to consider.

Informed Consent Routines Are Not Sufficient Protection

Does this way of reasoning put too much trust in ethical review boards? I think not. We need to acknowledge that routines for informed consent cannot handle

all ethical issues related to research involving human beings or their samples. Some division of labor is needed. For the research system as a whole to work, the ERBs must do their job properly, and the researchers must shoulder their responsibility toward research participants. If they do not, the problems this can generate cannot all be handled by routines for specific informed consent. Requirements on informed consent routines as such cannot guarantee, for instance, that people are properly informed or that research is ethical. What ERBs can do is to specify what information researchers should provide and take a close look at each new study application.

Trust in Researchers and the Research System

Although there is no irreproachable support in the literature for this claim, I would like to suggest that there is a considerable difference between proponents and opponents of broad consent in terms of trust. Whereas opponents tend to mistrust researchers and the general research system, including the practices of ethical review of research, proponents tend to put considerable trust in the research system, not least in the work of the ERBs.

A precondition for my defense of broad consent for future biobank research is indeed that the research projects are properly reviewed by ERBs. Not only should the ERBs have the ability to identify the ethically relevant aspects of the study and properly weigh the different principles, values, and interests at stake, but it is also of utmost importance that they evaluate each study individually and avoid glossing over some studies because they have approved similar studies in the past. In relation to biobank research, attending to risks of stigmatization seems to be a particularly pressing task.

There is no built-in guarantee that any of this will be handled properly, and it has been suggested to me in personal communication by some members of Swedish ERBs, for instance, that studies are not always treated as individually as they should be. The response to indications such as these from opponents of broad consent seems to be that we need strict informed consent procedures in which the individual can shoulder the responsibility of judging the merits of each individual study. However, it is not reasonable to burden potential research participants with such responsibility, because they cannot make the relevant risk assessments, nor can they assess the reliability and quality of research-related information. This also means that those favoring specific consent need to put some trust in ERBs or, if not in ERBs, in researchers. Thus, if there are flaws in the handling procedures of research applications in ERBs, then the most reasonable solution is to try to improve those procedures.

Only Broad Consent?

Let me finally bring up an issue that is closely related to the previous discussion. My concern has been to argue that broad consent to future research use is legitimate and should be included as an alternative on consent forms regarding use of human biological samples stored in biobanks. But what about the practice that is about to be established worldwide in national prospective research biobanks, such as Biobank UK or the Swedish LifeGene, in which the only way to have one's sample included is to give broad consent? Even though such consent is acceptable, as I have tried to show, it could be argued that it should not be the only option.

I am willing to agree that it would be preferable from an autonomy perspective to allow people the alternatives they want when it comes to deciding about personal issues like their participation in research. But it seems to be an entirely different matter to say that respect for autonomy requires the inclusion of the option of specific consent on consent forms. It has to be recognized that certain matters are personal matters that no one else should decide, whereas others are not. Whether or not I should participate in research is a personal matter in this sense. What research should be carried out in my town, my country, or elsewhere is not, nor are questions about what conditions research should meet in order to be permitted. The alternatives to be included on consent forms is not a personal matter that should be up to the individual to decide but is an issue that has to be decided by ERBs after suggestions from the researchers themselves. As Shickle phrases it:

> Providing that there is proper disclosure and so on, then the choice for the individual is to participate on the terms offered or not. There is a ''negative right'' not to be included in the research without consent. . . . There is no ''positive right'' for a biobank to be run in such a way just because an individual would like it to be so.[36]

So including broad consent as the only opt-in option does not imply disrespect for autonomy. If beneficial to research, such a choice can indeed be justified. Besides, to the extent that the large prospective research biobanks make it possible to keep updated on research developments—the Swedish LifeGene, for instance, provides a regular newsletter to anyone who is interested—and to the extent that they provide the option to withdraw, there is little difference in practice between broad and specific consent for the observant participant.

Conclusions

I have argued that although participants giving broad consent to use of their samples for future research are not given specific information about the studies in which their samples will be used, their consent may nevertheless be properly informed. This is the case for those sample providers who want to base their decision about participation exclusively on general information about research requirements—such as the fact that scientific studies will have to be ethically reviewed, the conditions of sample storage, confidentiality, and so on—and who actually receive this information and understand it. It is not only legitimate but also preferable to include the alternative of broad consent to future use for research in consent forms regarding biobank samples, as long as well-functioning ERBs are in place. It further seems fully acceptable to allow large prospective research biobanks to use broad consent as the only opt-in alternative.

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