

## ***Biobanks and Informed Consent***

Gabriella Foe

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### INTRODUCTION

Biobanks have added complexity to the idea of informed consent, which is an important ethical component in research involving human subjects. The idea behind informed consent is that each potential participant needs to voluntarily determine whether or not to take on the risks of research in order to take part in producing the benefits. The problem arises because researchers wish to obtain consent for future unknown investigative uses of biological materials. Some have argued that any such blanket consent is not truly informed. Proponents of the typical informed consent document argue on the grounds of autonomy. Those trying to propose the use of broader consent procedures argue from a point of view focused more on public health. This paper will explain that it is unnecessary to place biobank research within the scope of public health to ensure a desired amount of public participation; in fact, this line of argument should be discouraged. The public is willing to participate contribute to biobanks as long as they trust researchers; thus, three ways to increase trust will be proposed, along with consent procedures that will suit both the public and researchers.

### ANALYSIS

#### How Biobanks Complicate Informed Consent

Most scientific experiments do not directly benefit participants. Through informed consent documents, potential participants must weigh altruistic motives against risks of participation. Biobanks have caused research in genomics to proceed with great speed and, as a result, there is hope for personalized medicine sometime in the near future.<sup>1</sup> To work towards personalized medicine, researchers need to create gene maps.<sup>2</sup> Using genetic data along with phenotypic characteristics, environmental factors, and other determinants, researchers hope to understand the causal factors of diseases and work to prevent disease manifestation. Since possible future biobank research is continually evolving and cannot be specified, researchers have questioned whether traditional informed consent can apply to this research field.<sup>3-5</sup>

Biobank research takes place at the population level. And although the ultimate goal of biobank research is personalized medicine, solving public health issues is its immediate concern.<sup>13</sup> Biobank research is designed to explore the connection between genes and diseases, allowing for health services to improve. To increase the statistical power of research, it is important to include a great number of samples. Thus, chances of obtaining better data increase when more participants are willing to donate genetic samples. However, study results may show why certain groups of people are more susceptible to certain diseases than others, which can lead to stigmatization and act as a deterrent to participation.

Some argue that informed consent regarding future use of genetic samples cannot be truly given, while others believe that disclosing current known information is adequate. Failing to consent for future research and having to re-consent each time will hinder research progress by limiting the samples that researchers can use—some participants will be unable to be contacted and others will not respond. In addition, the cost and frequency of re-consenting make it unfeasible. Prospective participants have also said that it would be burdensome to receive a

notice for each future study asking them to re-consent.<sup>6</sup> For these reasons, biobanks have considered opt-out systems and different levels of opt-in procedures.<sup>2,3,7</sup> With an opt-in procedure, the three levels include specific consent, broad or categorical consent, and blanket or open consent.

### Different Types of Consent

Opt-out procedures have been criticized because participants are often unaware that they have been automatically included in a study. An example of an opt-out biobank research project that raised controversies is the deCODE project in Iceland, where the government allowed deCODE to access the nation's health records, with an opt-out option.<sup>8</sup> An opt-in procedure: provides participants with more information about the study; is seen to give participants a more active control in decision-making; and is preferred. However, the opt-in system is a barrier to research progress since it will take more time for researchers to obtain the same number of samples as with an opt-out procedure. Researchers recognize that challenges in acquiring the desired amount of participation will affect the statistical significance of research results.<sup>9</sup> As a result of these concerns, researchers have proposed alternate types of opt-in consent with biobank research.

Specific consent is the prototypical informed consent used in other fields of research. It includes the purpose of the research, risks and benefits, procedures, and other categories that inform the potential participant of exactly how their genetic samples will be used. Broad or categorical consent does not mention specific studies; rather, it allows participants to choose the different fields of studies toward which they would like their samples to contribute (e.g. diabetic research, cancer research). Participants determine their participation by checking boxes beside different categories. Blanket or open consent asks participants for permission to use their samples in various types of research, as the researcher sees fit. Open consent gives participants the smallest amount of control over how their genetic material is used.

### Contributing to Scientific Progress

Informed consent aims to give individuals control over what is done to their genetic material: it allows them the right to self-determination.<sup>3,10,11</sup> However, if research is to benefit society and allow scientific progress, the control that participants desire must be balanced with society's interests; namely, that researchers need to make significant conclusions.<sup>5,12</sup> The public cannot erect too many barriers to research and at the same time expect science to make significant progress.

Members of society are open to making contributions toward research. For instance, when individuals are asked the reason they contribute to biobanks, most refer to altruistic motives and a desire to benefit to the common good.<sup>3,13,14</sup> Participants recognize that they are not likely to gain any direct benefit from biobank research, but they hope that future generations will benefit. A number of studies have shown that participants who are parents and/or older in age are more likely to contribute to biobank research and prefer open consent.<sup>14,15</sup> The public realizes that knowledge in medicine today is a result of past research contributions. Thus, it can be said that through participation, individuals affirm the importance of belonging to society, and realize the necessity of mutual dependence. In order to promote the interests of the individual, the interests of society must also be promoted. Improved social conditions will allow everyone to exercise a higher degree of personal autonomy.

When potential participants are asked which type of consent they believe should be used in biobank research, those participating in phone surveys and focus group discussions have various opinions.<sup>6,9,15</sup> Most are willing to

give either broad or blanket consent.<sup>16</sup> What matters is not the amount of information they are given but the degree of trust they have that researchers will not misuse their samples. Thus, in biobank research, the idea of re-consenting will be to ensure that participants agree with the purpose of the research, instead of protecting individuals against coercion.<sup>17,18</sup>

### Autonomy versus Solidarity

Researchers are working on ways to increase the number of people who are willing to contribute to biobanks by addressing public concerns, and some have tried to appeal through solidarity. While the principle of autonomy exercised through informed consent is important to the public, it is also known that solidarity motivates individuals to participate in biobank research.<sup>17</sup> Hansson refers to this as the patient-donor perspective versus the patient-beneficiary perspective.<sup>19</sup> When the two conflict, it is logical to think that appealing to autonomy will put up a barrier to research, while appealing to solidarity will promote research. Appealing mainly to solidarity entails justifying the good of biobank research from a public health perspective. Furthermore, appealing to solidarity compels people to contribute to biobanks using arguments similar to those used to increase vaccination rates—which some researchers have tried to do.<sup>2,13,20</sup>

To determine the most appropriate type of consent, it must first be decided whether the public interest in scientific progress can trump the individual interest of maintaining control over the use of genetic material. Since medical care today is the result of past research, there has been debate on whether individuals have a right not to participate in research: “There is a question mark over the morality of benefiting from research in general while refusing to take part in it.”<sup>19</sup> Following from this, some say there may be a duty to participate in biobank research, and this duty can certainly be required by a governing body if it is determined to be a compelling public health interest.<sup>13,20</sup> Another question which must be answered is how to determine ownership of biological material. Four possibilities of ownership have been proposed: unowned, owned by humanity, owned by the person from whom it was taken, or owned by the researcher or company who transformed it into a useful commodity.<sup>19,21</sup> The legal system has held that biological material is unowned until someone makes it useful, after which it is owned by the researcher who transforms it into a useful commodity (*Moore v. Regents of the University of California*). An example would be the development of HeLa cells from Henrietta Lacks and the patenting of spleen cell lines obtained from John Moore.

Although arguing from the public health perspective is compelling and could achieve researchers’ goals, it is unnecessary. Researchers and the public are on the same side; arguing from a public health perspective will create a gap and put them on different sides. What is required are ways to produce a better relationship and increase trust between the two parties, since it is essential for the success of biobank research.

The amount of trust the public places in researchers varies depending on social context and historical events that have revealed past unethical research. Presently, at least part of society has remained skeptical towards science, while at the same time wanting to contribute to the greater good done through scientific research. This is one of the underlying reasons so many are willing to contribute to biobanks but want great control over what is done with their genetic material: to ensure that researchers do not intentionally harm them. It is important for the public to perceive that research institutions and researchers see their participation and contribution as a gift, and acknowledge the responsibility that it entails. Many studies have reported that developing a course of action to actively promote a better relationship and build trust is of importance.<sup>1-6,9-12,14,15,18-29</sup> Before participating, participants would need reasons for trusting researchers. They would like to know that researchers will not perform research that will cause stigmatization of specific populations. In addition, they would like researchers to ensure that data are protected so that the risk of informational harm is decreased, and they would like researchers to be transparent to the public.

### Three Ways to Increase Trust

Although most of the research about public perspective on biobanks has involved the Caucasian majority population, a study found that minority groups tend to favor specific consent more.<sup>6</sup> This may be due to a lack of trust in researchers after hearing about or participating in unethical studies in the past, or because minority groups are at greater risk of stigmatization.<sup>23,30</sup> To improve relations and increase trust, researchers should work together with small ethnic and population groups to see whether their proposed research is acceptable. The *Tri-Council Policy Statement*, the ethical code of conduct that is adhered to in Canada, requires that researchers consult leaders of Aboriginal communities or other minority groups to obtain community consent before asking for individual consent.<sup>31</sup> Other reports have also suggested this.<sup>22,32</sup> The leader of the community will be involved in ensuring that the purpose of the research is in line with cultural beliefs, and before publication, the community leader will also read and approve the final document. Adopting extra measures such as this will allow researchers to understand their culture and norms, improving the relationship between researchers and minority groups, thus fostering trust.

Since the genetic profile of a person may reveal individual health status and predisposition to disease, the public is afraid that by making it available to researchers, the information may fall into the wrong hands.<sup>1,22</sup> Some have voiced concerns that insurance companies will gain access to genetic data, and others are worried that the information will become commodified and commercialized.<sup>1,21</sup> Since individuals voluntarily give researchers access to this information, they expect that it will be used to better society in the future, and not for commercial purposes. Using materials for commercial purposes is seen as unfair because researchers will be profiting from data that was not rightly theirs, nor was given to them (i.e. it was “stolen”). Therefore, as the means to ensure greater privacy of these data become available, it is only fitting for researchers to warrant that they do everything possible to ensure they are safe. From the participants’ view, researchers have been entrusted with a precious gift, so they should take great care of it and make certain that they use it responsibly.

The public values transparency in research. When researchers are transparent regarding experimental procedures and how results are obtained and reported, the public can be ensured that researchers are using this “gift” responsibly and are not exploiting them.<sup>14,22</sup> Using databases, such as [clinicaltrials.gov](http://clinicaltrials.gov), and giving general updates online through other websites would not only improve the relationship between the public and researchers, but also ensure that the public has access to more primary scientific results.<sup>29</sup>

### Working with the Public

Building a better relationship between researchers and the general public will ensure that more trust is given to researchers. If researchers are to work with the public, then public perspectives and preferences must be taken into account when it is feasible. By working together, participants will feel more comfortable approving of broad or blanket consent for biobank research. Several studies have found that a great number of potential participants find it a burden to be continually contacted to participate in research when they have given previous consent on a related topic. They would rather give blanket consent provided that they trust the researchers.<sup>3,6,15</sup> Thus, an increase in trust will be beneficial to both parties.

However, some would still want to maintain a certain level of control to ensure their samples do not contribute toward studies with a purpose that conflicts with their beliefs or morals.<sup>6,27</sup> So, using blanket or open consent would not show the greatest respect for everyone’s autonomy. Some have argued that having to check off numerous boxes is time-consuming when people want to get out of the doctor’s office or hospital.<sup>9,15</sup> Therefore, participants can be given the option to sign for blanket consent and the opportunity to opt-out of categories which

they may oppose. But these categories would not be listed; instead, it would be up to participants to mention it on the form. An alternative but similar idea would be to sign for blanket consent, and check if a participant would like to be re-contacted for future research with a chance to opt-out. This is less of a barrier than re-contacting for opt-in consent since researchers would be able to use samples unless they receive correspondence from participants. This option would also ensure that there is an on-going communication between researchers and participants, which some prefer.<sup>15</sup> The latter procedure would put more burden on researchers than the former. However, if we hold that individuals may change their participation status, it is important to give them the means to do so.

## CONCLUSION

Typical informed consent used in other types of research cannot be adequately applied to biobank research. As a result, researchers have proposed alternate types of consent documents that would balance the participants' interest in upholding their autonomy with the researchers' need to conduct research without too many barriers. Different types of consent procedures include opt-in consent—ranging from specific consent to blanket consent—and opt-out consent.

Because the typical type of informed consent document has been critiqued as not meeting the standard, arguments have shifted to justify obtaining broader consent. This has largely been done by the appeal to the public's altruistic motivation of donating to biobanks. When using public health arguments, researchers can justify the infringement on participants' right to autonomy for greater social good. However, this is unnecessary since the public understands the advantages of broader consent from the researchers' perspective, and some are already willing to hop on board. Others who prefer more specific consent to maintain control over how their genetic samples are used say that it is due to their lack of trust in researchers. Nevertheless, they are conflicted because they confess that continual re-consent procedures are burdensome.

Therefore, researchers do not need to go so far as to put biobank research in the field of public health to ensure that an adequate number of participants donate their samples. People want to participate in a way that will allow research to progress as researchers wish, but need to know that they can trust them. To build a better relationship and continue to improve trust, three things can be done: work with minority groups so results of the research will not stigmatize them, ensure that maximal protection of privacy will be given for the samples, and increase transparency in the research procedures.

We can come to a result that will satisfy both parties by working together with the public. It is unnecessary to introduce public health's ethos of the duty to participate in research for the greater good of society. This altruistic motive is already instilled in the public; stressing this duty will create a gap between researcher and the public. When approaching research from a public health perspective (for example, by stressing on the duty to participate to benefit society), we increase the authority of the researcher and diminish the importance of the public, ultimately creating a tension that will not promote trust between science and the public.

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