Bioethics in Iceland

Recent Developments

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Abstract: This article examines ethical issues debated in Iceland concerning population genetic research, specifically methods of collecting biosamples and ways to return clinically relevant results to participants. Also discussed are scientific research in the health sector, a bill on surrogacy, and a policy on consent for organ donation.

Keywords: population genetic research; biosamples; surrogacy; consent for organ donation

Five years ago, I wrote an overview article on bioethics in Iceland in which the main emphasis was on issues related to population genetic research.[1] These issues are still prominent in Icelandic bioethics when new questions are raised and debated. Recently, the focus has been on methods of collecting biosamples and ways to return clinically relevant results to individuals who have participated in database research. In the first section of the article, controversy around the method of biosample collection is described. In the second section, the issue of return of individual information from database research is analyzed in light of international discussion about this issue. In the remaining three sections, other interesting developments in bioethics—a new act on scientific research in the health sector, a bill on surrogacy, and a parliamentary resolution on changing the policy on consent for organ donation—are briefly discussed.

Population Genomics: A Controversial Collection of Biosamples

In early May 2014, the genetic research company deCODE Genetics launched a massive collection of biosamples in Iceland under the title "Urgent Call in the Service of Science."[2] The collection was performed in cooperation with the Icelandic National Rescue Team, whose members collected the samples. The National Rescue Team was to receive a certain sum (approximately US$15 or 13.5 euros) from deCODE Genetics for each biosample collected. The company posted to more than 100,000 addressees in Iceland a package containing a consent form with information about the intended research on the samples and a stick for a collection of the sample from the participant's mouth. The participants were expected to pack the sample and hand it over to a member from the National Rescue Team who would pay them a visit.

This national collection of biosamples was launched suddenly by a well-designed PR campaign in which scientists, academics, politicians, and artists joined hands in appealing to the nation to jump on the bandwagon for a good cause. Among the prominent people who appeared in colorful advertisements were the minister of health and welfare, the mayor of Reykjavik, the dean of the school of health sciences at the University of Iceland, the dean of the medical faculty of the same university, and some popular Icelandic musicians. Advertisements also showed medical staff and members of the National Rescue Team with the logo of deCODE Genetics in the background.

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A small group of academics responded to the campaign with some critical remarks, which were sent to the Icelandic media. These remarks were signed by nine people, most of whom are associated with the Centre for Ethics at the University of Iceland. The main points of criticism of the campaign were the following:[3]

1) The cooperation of researchers and the National Rescue Team created an undue pressure on participants to give their biosamples. The National Rescue Team is a very popular voluntary organization in Iceland. Its members often undertake heroic efforts and risk their own lives in searching for and saving people in dire circumstances—for example, in the Icelandic highlands. Because the National Rescue Team was to receive a payment for each sample collected, many people might find it difficult to refuse participation.
2) The information provided in the consent form that the participants were asked to sign was misleading. The information mentioned only that the biosamples were to be collected for the purpose of having a population with which to compare the previous population genetic research that had been done by the company. As in the company's other research projects, the participants had the option of signing two different types of consent. The first was a limited consent that restricts the use of the biosamples to this particular comparative research, after which they would be destroyed and not stored in the company's biobank for further research. The second was a wider consent that allows that the sample be stored in the biobank as part of the company's database resource for further genetic research, subject to the permission of the National Bioethics Committee and the Data Protection Authority. This "further genetic research" is in principle unforeseen and not discussed in the consent form, except in very general terms. The critics point out that novel research possibilities, such as whole-genome sequencing, that have often been discussed in closed professional meetings are not mentioned in the consent form for the collection under discussion.
   Whereas previous participants had mostly been selected from targeted disease groups, this campaign focused on people who had not participated in deCODE Genetics research before. The critics argued that the ulterior motive for this massive collection of biosamples was to extend the deCODE Genetics biobank as a resource for further genetic research. It should be added here, though, that the critics of the campaign did not mention[4] that this extension of the biobank is likely to increase the value of the company, which was recently acquired by the American biotech company Amgen.
3) The campaign was launched secretly overnight, so to speak, without any public dialogue in advance. Since it would have been impossible to describe future genetic research in a short consent form, the critics emphasize that it would have been appropriate and necessary to prepare for such a massive project by holding an informed public discussion about the population genetic research being undertaken by the company and planned in the future. The PR method chosen by the company aimed at creating a national herd behavior in which people would be infected by the enthusiasm of contributing to "a good cause" under a considerable time pressure. This, the critics argued, is not an appropriate method for collecting biosamples for population research purposes; rather, the aim should be to facilitate an informed and critical public deliberation about the subject matter.

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Iceland—unlike other Nordic countries (see, for example, the Danish Council of Ethics or the Norwegian Biotechnology Advisory Board)—does not have a national ethics council. It is part of the mandate of such national councils to facilitate informed public debate about developments in the biomedical sciences and the moral, social, and policy implications of the use of genetics and biotechnology. Efforts to ignite interest among Icelandic authorities to found such a council have not been successful. The Centre for Ethics at the University of Iceland, in cooperation with professional organizations, tries to put bioethical issues on the agenda, but it does not have a legal mandate to facilitate public dialogue with the aim of informing the legislator about public concerns and principled positions.

4) The way in which this collection of biosamples was performed could undermine trust in scientific research in the long run. The willingness of Icelandic citizens to participate in scientific research is a valuable resource that should be handled with care. Using PR methods that aim at maximizing the collection of biosamples and precluding informed public debate would not be conducive to trustworthy practices.
5) The campaign raises concerns about conflicts of interest. The close connections between the scientific and academic community in Iceland are worrying and can be seen as another threat to trustworthiness. The company deCODE Genetics is comparatively a gigantic player on the Icelandic scene, and it has built up a valuable research resource that cannot be accessed except through cooperation with the company, which also increases opportunities for funding of research. Recently, ties have also been strengthened between the company and the University of Iceland, which has boosted its ranking in international university performance tables. As a consequence, there is little resistance within the scientific and academic community to questionable projects like the national campaign discussed here.
6) To sum up, the critics argued that the method chosen for the campaign for a collection of biosamples was contrary to the spirit of research ethics and good democratic practices. The company should have shown the Icelandic public more respect by addressing people as thinking citizens who would like to be informed and participate in a public dialogue about the relevance of the project, rather than aiming at herd behavior for a quick and maximum gain. Even though there had been a considerable amount of discussion in relation to the Health Sector Database project around the turn of the century,[5] that debate had been polarized and ill informed and was in any event no substitute for a public dialogue preceding the national collection of biosamples.

The main spokespeople of the Urgent Call in the Service of Science campaign, most of whom were medical doctors, responded harshly to these critical points in a declaration.[6] They stated that it was wrong to disturb and stand in the way of such a good cause. It was dangerous, they maintained, to spread seeds of suspicion about the important research that this collection served, which could not be carried out without the support of the Icelandic public. They argued that Icelanders were generally well acquainted with the population genetics research carried out by deCODE Genetics, and they flatly rejected that there was a lack of public discussion in Icelandic society about the project, referring to the extensive debate that took place about the Health Sector Database more than a decade earlier.

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The criticism was seen as paternalistic, showing distrust in the ability of prospective participants to make up their mind in an informed way. The spokespeople of the campaign also emphasized that the project had been approved by the National Bioethics Committee, understandably, because this research project was no novelty. It was simply a continuation of the pervasive population genetics research that had been carried out by the company for several years.

Population Genomics: The Question of Return

When deCODE Genetics started its population database research in Iceland in the late 1990s, the company emphasized that there was no interest in gaining information about individuals. The research was described as genetic epidemiology carried out in order "to create new knowledge in medicine."[7] In light of this, Jeffrey Gulcher and Kári Stefánsson argued against a policy of obtaining restricted informed consent for participation in population database research and for a policy of broad consent. "With broad consent to use the genotypic information to study the genetics of health and disease it would be possible to use the combinatorial analysis systematically to seek the best fit between all regions in the genome and all phenotypic variants recorded in the database."[8] These authors point out that consent for genetic research has three components: first, for the acquisition of the biological material, second, to the genotyping of the DNA, and, third, to the use of the genotypic information that results. In all cases, they argue, "the consent requested is for the use of genotypic data to generate knowledge about the nature of the group, rather than knowledge about the individual person."[9]

Nevertheless, Gulcher and Stefánsson were also aware of the possibility that population database research might bring benefits to individuals, and they address this point specifically: "The Icelandic legislature decided that the protection of privacy was more important than the possibility of immediate benefits to individuals. However, if the appropriate authorities granted permission, it would be relatively easy to identify and contact all persons in Iceland who had a particular risk for disease."[10] The authors state that it would be possible to ask participants whether they would prefer to reduce the emphasis on privacy and "wish to be notified about any association between alleles they carry and specific diseases or predispositions to the development of disease."[11] However, this has never been done in Icelandic population database research. The company deCODE Genetics works only with personally unidentifiable information collected for basic genetic research in cooperation with primary researchers and physicians. According to the policy of wide consent for biobanks research, participants give deCODE permission to store their biosamples in a biobank and use them for medical research in search for causes, improved diagnosis, and treatment of illnesses and/or preventive measures. Until 2007, there was no mention of return of information. In the consent form currently used by the Research Service Center for deCODE, there is a clause to the effect that participants give permission to have information personally identified and that they may be contacted with personal information with the permission of the National Bioethics Committee in order to introduce them to further research with their participation. This option, however, has never been used in order to inform individuals about their particular results and is not intended for that.

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A few years ago, the tide suddenly turned, and the issue of return of results to individuals came on the agenda.[12] This discussion had been taking place in closed circles for some time before it broke out into the open in the wake of reports about Angelina Jolie's decision to undergo a double mastectomy in order to reduce her risk of developing breast cancer and ovarian cancer.[13] Stefánsson, the founder and CEO of deCODE Genetics, used the opportunity created by the Jolie case to inform the Icelandic public about certain kind of knowledge generated in the course of research by the company. He maintains that the company has information about approximately 7,000 Icelanders who have a 75–80% likelihood of getting serious diseases related to genetic mutations. According to Stefánsson, about 1,200 Icelandic women have an approximately 80% risk of getting breast cancer of the type BRCA1 and BRCA2 (the latter being prevalent in Iceland). "If it is not duly detected, they will die from this disease,"[14] he says, and adds that the primary duty should be to save their lives.

Stefánsson points out that researchers at deCODE Genetics could quickly find the individuals in its database if they were granted the permission, but that this has been rejected by the Icelandic health authorities. "I have told them that I find it ruthless not to at least contact these women and offer to keep them under close surveillance. I am convinced that it is possible to prevent premature death in this group of women."[15] In a public meeting held on June 11, 2013, the opinion was raised that the responsible reaction to the situation was to have an informed social discussion, and then the women themselves could take the initiative and inquire whether the information applied to them. To this position Stefánsson responded: "This is what the controversy is about. Is it sufficient that we tell the society that this information is obtainable or should we approach these women? As an old fashioned physician, I am of the opinion that we have to approach them because the likelihood that they will get cancer and die from it is far too high for us to simply stand by and watch."[16]

This suggestion of directly contacting people at risk has not received much support. Critics have pointed out,[17] first, that the population genetic results, which are based only partially on whole-genome association study and largely on statistical imputation, do not provide reliable information about the number of people who carry the BRCA2 transmutation. Second, the penetration and seriousness of the disease varies greatly among families and individuals. Third, the available treatment is invasive and burdensome and provides no guarantee for success. Fourth, experience of genetic counseling shows that people want to receive genetic information of this kind when they are ready for it and can face the consequences. Finally, focus on this particular disease will require resources that are currently unavailable in the national health service, which is already suffering from scarcity of money and manpower to deal with its daily tasks.

Most recently, Stefánsson has proposed that a website be set up where individuals could express their wishes for not receiving information about being a carrier of BRCA2. All carriers of this serious breast cancer gene who would not opt out in this way would be contacted. "I am of the opinion that this is such a serious threat to the lives of those who have the transmutation that it is merciless, cold and irresponsible not to contact these people so that their lives can be saved."[18] This proposal has not yet been publicly debated in Iceland.

Icelandic society is facing an ethical dilemma. Researchers have unidentified information about several participants at relatively high risk of getting serious

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diseases, such as breast cancer, but seem to have no channels for conveying the information to these participants. In dealing with the question of whether information should be returned to individuals from database research, three main options have been discussed.

Option 1

The first option in this situation is simply to do nothing. There are two main arguments for this position. The first has to do with the purpose of population database research: "Seemingly, return of individual fundamental research is impossible and nonsensical as the very purpose of this type of research is not the production of individual but generalizable knowledge."[19] To this one could respond that even though this was undeniably the purpose of the research, it has nevertheless revealed information about participants that could be of clinical significance for them. It seems overly rigid to deny individuals possible avoidance of serious harm simply for the reason that their participation in research had another purpose. One part of this argument against return of individual results is that such practices invite therapeutic misconceptions. The words of deCODE's CEO, that "as an old fashioned physician" he recommends that participants be actively approached, indicate that the roles of fundamental research and clinical activity are being conflated. This argument is certainly an important reminder that we should be most careful in building bridges between fundamental research and the clinic, but it should not be used to trump all attempts in that direction.

Another argument for the do-nothing position is that in those cases in which return of results was not part of the consent for participation in database research, there is no justification for getting back to the participants. "However handled, the issue of notifying (or not) participants of results should be disclosed and agreed to in advance (ie on the consent form)."[20] This is a major issue and raises the question of whether return of results should not even be considered in those cases in which that possibility was not raised on the initial consent forms. Such a rigorous position seems to be unwarranted, provided that all other relevant conditions for disclosure are met. There seems to be a growing consensus in the literature about the conditions for disclosure, which can be summarized in the following way: "Findings that are analytically valid, reveal an established and substantial risk of a serious health condition, and are clinically actionable should generally be offered to consenting contributors."[21]

Let us look at two examples of such conditions. The first lists three conditions that directly reference the ethical principles of beneficence, nonmaleficence, and autonomy, in this order: (1) "the data have been instrumental in identifying a clear clinical benefit to identifiable individuals," (2) "the disclosure of the data to the relevant individuals will avert or minimize significant harm to those individuals," and (3) "there is no indication that the individuals in question would prefer not to know."[22] The second example of criteria for sharing information with research participants marks a somewhat different approach but has similar moral implications:

> 1. The genetic finding has important health implications for the participant and the associated risks are established and substantial. 2. The genetic finding is actionable; that is, there are established therapeutic or preventive interventions or other available actions that have the potential to change

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> the clinical course of the disease. 3. The test is analytically valid and complies with all applicable laws. 4. During the informed consent process or subsequently, the study participant has opted to receive his/her individual genetic results.[23]

In the main criteria for disclosure one can find both a positive formulation of an explicit consent, "the study participant has opted to receive his/her individual genetic results,"[24] and a negative formulation and no requirement of an explicit consent to know: "There is no indication that the individuals in question would prefer not to know."[25] This is an important difference that can guide us in the effort to manage the return of information to individuals who decided to participate in research without expecting return of individual results. The positive formulation is stricter and could be compatible with the do-nothing position. The negative formulation, on the other hand, is more flexible and primarily protects the right not to know of those who have indicated that preference. In all other cases, it could be justifiable to approach participants with individual results if all the other conditions were fulfilled. Although these conditions are not sufficient for contacting the participants, they provide a weighty argument against the do-nothing position. The question how participants could be approached is discussed in the next two options.

Option 2

The second option in a situation in which return of information to individuals was not part of the consent form is to contact participants and give them the option of knowing about findings relevant for their health. As mentioned previously, this approach has been suggested by the CEO of deCODE Genetics, who has appealed both to the benefit to patients, that the information could save them from immediate danger, and to respect for their autonomy, because a person with information has a stronger basis for self-determination than a person who is ignorant about the same. Both appeals raise complex questions. As regards benefit, this is already addressed in the conditions for disclosure, but it requires that, prior to approaching individual participants, there has been a careful selection of the type of information that is returnable to them. The notion of returnability implies a responsible screening of information in the light of accepted conditions or criteria for disclosure before they are returned to individuals.

This requires a framework for responsible return within which the autonomy of the participants can be properly exercised. Receiving information about risk without professional interpretation and possibly against one's wishes is not conducive to autonomy. An important question relating to this framework is, in the words of SusanWolf and colleagues, "to whom the finding should be communicated—the contributor or the contributor's primary care physician (PCP)."[26] In a previous paper,[27] these authors argued "that offering the return of findings to the research participant was ethically justifiable to insisting on return to the PCP."[28] The ethical justification rested on respect for autonomy and concerns for the privacy of the participant. The main problem with communicating such findings directly from biobank research to contributors has been well described by Gulcher and Stefánsson:

> Notifying participants in research of the results as they apply to them as individuals before the results have been confirmed and put in the

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> appropriate clinical context is always problematic. For example, the discovery of a mutation in a gene that is found in 100 percent of patients with a certain disease does not tell us how large a proportion of patients with the mutation the disease develops, nor how reliable the test for the mutation is. A basic discovery should always be validated clinically before it is made known to individuals.[29]

Moreover, it is crucial that the information be communicated in a context of genetic counseling, as will be discussed further below.

Option 3

The third option in a situation in which no consent has been obtained for return of information to individuals is to make it publicly known that this information is available and thus enable individuals to take the initiative to receive the information themselves. Those contributors who would prefer to find out whether this information applies to them could then visit a genetic counselor, who would discuss the information with the individual. A precondition for this is an informative public dialogue and announcements that make it clear that the information is available. From the viewpoint of autonomy and the right not to know, this would be a good way to handle the information. Genetic counseling is conducted in the form of a dialogue, which can provide optimal conditions for individual self-determination in this context. This is because the situation has both epistemological and emotional aspects that need to be properly dealt with. The information is complex and requires professional interpretation if it is to enhance the individual's understanding of her situation. The information can also be sensitive and can have serious implications for the life of the individual receiving it. This requires empathy and emotional support, which can also be provided by genetic counseling. In this way, the communication that takes place can provide freedom both from ignorance and confusion and from the fear and anxiety induced by the information.[30] Massive amounts of information can be bewildering and confusing and do not facilitate understanding, which is a condition for self-determination. Therefore, in addition to the criteria of clinical utility and validity, beneficence, and autonomy, it is a responsible requirement that the information be provided only in a context of clinical counseling.

However, the option of making it publicly known that information that may have relevant health implications for individuals could be made available to them in a context of genetic counseling faces several practical challenges. As one researcher at deCODE says:

> Those most likely to make use of this knowledge already know that they belong to a family where genetic diseases have been prevalent. But these are the people who already visit the genetic counselors. Some of the most serious genetic diseases are so rare that people are not aware of the fact that they are hereditary. These individuals can be detected by using knowledge already obtained in the genetic cancer research at deCODE Genetics, and it is imperative to make them aware of the risk.[31]

Is it possible to word a public announcement in such a way that these individuals' interest is ignited without getting the entire population into the clinic for genetic

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testing and counseling? No public discussion has taken place in Iceland that would legitimize giving priority to these diseases in a health care system that is sorely in need of resources to deal with several health problems.

The three options discussed concern a challenge that we need to deal with in the case of those contributors who decided to take part in genetic research at the time when return of individual results was not mentioned in their consent forms. However, the task is not limited to conveying information to those who donated without expecting return; it is also about designing consent for a responsible return of results from future genetic research. The problem of conveying individual research results generated in research that was intended for generalizable knowledge will only increase in inductive discovery research, which scrutinizes the whole genome rather than being driven by a concrete hypothesis.[32] Such research has increased in Iceland, and with statistical imputation, deCODE now claims to have information about members of the population who have never participated in the company's research projects.

Recently, a committee has been working for the minister of welfare to formulate regulations concerning the management of health-related information to participants. The committee has drafted a proposal in which researchers are obligated to obtain research participants' view regarding whether they want to receive incidental information that is important for their health, regardless of whether or not it is actionable. These proposals are still in the works and cannot be elaborated on here. The committee has not directly dealt with the question of how return should be managed in the case of those who never expected any return of individual information. But its recommendation is that if a researcher has results concerning serious health risk for participants, the responsible primary investigator shall apply to the National Bioethics Committee for permission to have the information conveyed to the participants. In that case, the National Bioethics Committee is to set up an independent expert group to assess if and how the information should be provided.

From a clinical viewpoint, the main task is to translate the genetic information being generated in basic genetic research into helpful tools in medical practice, such as more precise targeting of therapies and preventive measures. In the context of clinical counseling, the results of population genetic research can substantially increase the knowledge of genetic mutations and the accuracy of the information provided to individuals who are seeking help, information, or advice in healthcare. A few years ago, a working group composed of scientists from deCODE Genetics and medical doctors and administrators from the National University Hospital of Iceland was set up to propose methods and ways to translate fruits from this genetic research into the public healthcare system. The purpose of this team was also to evaluate the potential of full genome-association studies of the whole population for medical practice, for example, through more precise and personalized genetic counseling. This work has not produced any proposals yet, and the committee has not met for some time. In spite of the emphasis laid by the spokesmen of deCODE Genetics on communicating this information to those at serious risk, they have not found ways to co-operate with professionals at the National University Hospital who would be in the key position to mediate this information to patients. A research company which is not allowed to contact patients needs to build good relations with the health care system if their research results are to have any clinical relevance for their individual participants.

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A New Act on Scientific Research in the Health Sector

The regulation on the return of information to research participants comes in the wake of a new act regarding scientific research in the health sector.[33] The main changes in that act were made to accommodate the changed research environment in Iceland, especially in population database research. The most significant change in this new act is a clause on wide or broad consent for the storage of health data and biosamples for use in further research. This is in accordance with the working guidelines of the National Bioethics Committee, which have been developed as part of its regulation of database research over the years.[34] In addition, an important novel clause about the right of participants was added to Article 19: "Participants who have given broad consent […] shall have access to information on what research is being carried out by the principal investigator, institution or company. Participants may refuse use of their materials in specified studies, in which case their use is prohibited."[35]

In effect, this clause could function as a dynamic consent that reduces the emphasis on the initial consent for participation in database research.[36] Participants now have the opportunity to follow the course of the use of their data and do not have to rely exclusively on regulators acting on their behalf. Participants are then regarded not only as subjects who must be protected or made use of but as citizens who may be interested in research and may change their mind if their data are used for purposes that they disagree with.[37] Furthermore, this clause could contribute to strengthening the trustworthiness of research practices, because it increases transparency and makes researchers aware of the possibility that betrayed or displeased participants might opt out of research projects. However, this clause has not been implemented, and it remains to be seen how it will materialize and affect participants' behavior and research practices.

Reproductive Ethics: A Bill on Surrogacy

In January 2012, a parliamentary resolution about setting up a working group to draft a bill on surrogacy was passed in the Icelandic parliament. The working group finished its task in November 2014, and the bill was presented to the parliament in March 2015.[38] If it becomes law, it will be the first act on surrogacy in the Nordic countries. According to the bill, altruistic surrogacy, subject to strict regulation and oversight, will be permitted, whereas commercial surrogacy is prohibited. The surrogate mother must only receive reimbursement for the costs that are directly related to the pregnancy and delivery of the child.

A special surrogacy committee will handle applications by the prospective parents and the woman intending to be a surrogate. Applicants must meet several conditions. For example, the prospective parents must be between 25 and 45 years old and must be unable, for medical or biological reasons, to have a child. They must consent to the surrogacy and commit themselves to becoming parents of the child. They must provide either the egg or the sperm used for the fertilization. They must not be close relatives of the donor of the other gamete. The woman intending to be a surrogate mother must be between 25 and 39 years old. She must be a mother of at least one child who is at least two years old and was born after a normal pregnancy. She must not donate the egg used for fertilization. She must consent to the surrogacy and so must her partner, if she has one. It is also stated

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that the woman must have the mental and physical abilities and health to deal with the pressure accompanying pregnancy and childbirth. Both the woman and the prospective parents must have had legal residency in Iceland for the past five years. Applicants for surrogacy are obligated to seek counseling about the medical, legal, ethical, and social effects that surrogacy may have.

Although several concerns and doubts have been raised about the need to legalize surrogacy in Iceland, the bill has not been heavily debated, and it seems that by setting these stringent conditions, the legislator has succeeded in resonating with the prevailing moral views of the Icelandic people. In 2010, a working group appointed by the health ministry had objected to legalizing surrogacy in Iceland. The working group recommended caution in this sensitive matter and summarized its moral arguments in this way. First, if surrogacy is permitted, there is an increased risk that children will be regarded as commercial objects. This could undermine the intrinsic value of the child. Second, there is a danger that surrogacy creates a context in which the woman who will carry the child to term is used as a means rather than respected as an end in herself. Third, surrogacy increases the risk that women's bodies will be commercialized and objectified and that women who are socially or economically disadvantaged will be exploited. The working group emphasized that much more public discussion was needed and that differences in Icelandic society needed to be settled before a bill could be introduced.

The new bill does not meet all these objections, but the restrictive approach taken attempts to hinder the risk of commercialization and exploitation. A major message from the Parliament to the working committee was to make sure that the interests of children born by surrogacy will be protected. In the explanatory notes to the bill, three major objectives of the proposal are stated. The primary objective is to protect the interests of the child, the second objective is to secure the welfare and autonomy of the mother, and the third objective is to accommodate the intended parents' wishes.[39] Contrary to the act on artificial reproduction, which still protects the right of the donor to anonymity over the right of the individual to know her origin and leaves it to the donor to decide whether or not that anonymity should be lifted,[40] this new bill on surrogacy secures the right of the child to know his or her origin. The parents are obligated to convey this information to the child no later than six years after the child is born. When the individual born through surrogacy has reached the age of 16, he or she has the right to access information about the donors of the egg or sperm and the name of the donor.

It is also emphasized in the explanatory notes to the bill that the proposal is a reaction both to increased demands for surrogacy in Iceland and to the problems engendered by increased cross-border surrogacy. It is the intention of the legislator to reduce the likelihood that childless Icelanders will seek solutions in practices that may be contrary to international agreements about child protection or that could contribute to exploitation of vulnerable women. Presumably, the stance of the Icelandic legislator will be that cross-border surrogacy is unjustifiable if it violates the main principles set forth in the national legislation.

Transplantation Ethics: A Question of Consent

Since 1991, when an act on organ removal was passed by the Icelandic parliament, the policy for deceased organ donors in Iceland has been presumed nonconsent. In recent years, attempts have been made to change the policy to presumed consent.

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The proponents of change have not succeeded. The main arguments for changing the policy are that there is a shortage of vital organs and that Icelanders have been unable to contribute to Scandiatransplant, the organ exchange organization for the Nordic countries. Except for Denmark, the other partners in this project have a policy of presumed consent for organ donation. This position is supported by the moral argument that it is reasonable to assume that people would want to help another being in vital need rather than refusing to do so. Polls show that a majority of people say that they are willing to donate vital organs, but for some reason or other they don't make their position officially known, e.g. through a website at the National Directorate of Health. It is argued that family members are more likely to refuse donation in a policy of presumed nonconsent than when consent is presumed.[41] It is proposed in the bill that family members are to be contacted and that their refusal of the deceased's organ donation must be respected.

Opponents of the change argue that the main principle in medical practice is to obtain explicit consent for invasive procedures and that the shortage of organs is not sufficient to override this right of patients. It is also argued that presumed consent in effect gives the authorities the right to dispose of the bodies of the diseased. This must be done with utmost caution, especially in the cases of vulnerable individuals who for some reason have been unable to make their will known. It has also been argued that the bustle around organ removal precludes the possibility for relatives to make a last farewell to the deceased in a proper way.

It is interesting that, in a country that is very liberal in many aspects as regards bioethical issues, repeated efforts to change this policy of presumed nonconsent for organ donation have not been successful. Icelanders have very permissive reproductive policies, they are on the forefront of guaranteeing the reproductive rights of homosexual people, and in all likelihood they will be the first Nordic nation to legalize surrogacy. For many Icelanders, a major advantage of the surrogacy legislation is that it will enable homosexual men to have children. This is regarded as a matter of equality between the sexes, and homosexual women and single women can already make use of assisted reproductive technology.[42] When it comes to the end of life, however, Icelanders are relatively conservative. The proponents of legalizing euthanasia or physician-assisted suicide have never gained momentum, and the legislator has been reluctant to change the policy of organ donation.

Notes

1. Árnason V. Bioethics in Iceland. *Cambridge Quarterly of Healthcare Ethics* 2010;19(3):299–309.
2. This case is described and analyzed from the point of view of biopolitics in Árnason V. Biological or democratic citizenship. In: Kakuk P, ed. *Bioethics and Biopolitics*. Dordrecht: Springer Verlag; forthcoming.
3. The criticism appeared in two short media announcements. The first, dated May 9, 2014, appeared widely in the media under the title "Gagnrýna lífsýnasöfnun ÍE" (Criticize the Collection of Biosamples by deCODE). This can be accessed at http://www.ruv.is/frett/gagnryna-lifsynasofnun-ie. The second, dated May 13, 2014, was a response to a declaration from a group of supporters of the campaign, "Viðbrögð við yfirlýsingu vísindamanna" (Response to the Declaration of Scientists). This can be accessed at http://www.dv.is/frettir/2014/5/14/sidfraedingar-svara-gagnryni-laeknatilgangurinn-helgar-ekki-medalid/.
4. There was some discussion of this point in the Icelandic media. Some of the media actively supported the campaign, whereas others engaged in critical discussion, mostly based on the critical remarks of the group associated with the Centre for Ethics at the University of Iceland.

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5. Cf. Rose H. The commodification of bioinformation. *The Icelandic Health Sector Database*. London: The Wellcome Trust; 2001.
6. This declaration, titled "Yfirlýsing vísindamanna um Útkall í þágu vísinda í kjölfar yfirlýsingar siðfræðinga og nokkurra annarra fræðimanna" (Declaration of Scientists about the Urgent Call in the Service of Science in the Wake of a Declaration of Ethicists and Some Other Scholars) can be accessed at http://www.mbl.is/media/30/7630.pdf. It was signed by 36 people, most of whom are practicing physicians and researchers at the National University Hospital in Reykjavik.
7. Gulcher J, Stefansson K. An Icelandic saga on a centralized health care database and democratic decision making. *Nature Biotechnology* 1999 July;17:620.
8. Gulcher J, Stefansson K. The Icelandic Healthcare Database and informed consent. *New England Journal of Medicine* 2000;342(24):1827–30, at 1828.
9. See note 8, Gulcher, Stefansson 2000, at 1829.
10. See note 8, Gulcher, Stefansson 2000, at 1829.
11. See note 8, Gulcher, Stefansson 2000, at 1829.
12. The issue of return is further discussed and analyzed in Árnason V. Responsible return: Consent for feedback from biobanks research. In: Bobbert M, Herrmann B, Eckart WU, eds. *Ethics and Oncology: Therapy, Care, Research*. Freiburg: Karl Alber Verlag; forthcoming.
13. Jolie A. My medical choice. *New York Times* 2013 May 14; available at http://www.nytimes.com/2013/05/14/opinion/my-medical-choice.html?_r=2& (last accessed 22 Sept 2015).
14. ÍE vill ná til allra arfbera [deCODE Genetics wants to contact all BRCA2 carriers]. *Morgunblaðið* [Icelandic newspaper] 2013 May 15; available at http://www.mbl.is/frettir/innlent/2013/05/15/e_vill_na_til_allra_arfbera/ (last accessed 22 Sept 2015).
15. 1200 íslenskar konur sem eru með yfir 80% líkur á að fá brjóstakrabbamein [1200 Icelandic women are at about 80% risk of getting breast cancer]. *DV* [Icelandic newspaper] 2013 May 15; available at http://www.dv.is/lifsstill/2013/5/15/ef-thad-er-ekki-greint-naegilega-snemma-tha-munu-thaer-deyja/ (last accessed 22 Sept 2015).
16. Vill láta konur í áhættuhópi vita [Wants to alert women at risk]. *RÚV* [Icelandic state radio] 2013 June 11; available at http://www.ruv.is/frett/vill-lata-konur-i-ahaettuhopi-vita (last accessed 22 Sept 2015).
17. Árnason V, Eyfjörð EE, Snædal J, Hjörleifsson S. Ætti að segja þátttakendum í vísindarannsóknum frá stökkbreytingum í þeirra eigin BRCA-genum? [Should participants in scientific research be told about transmutation in their own BRCA-genes?] *Læknablaðið* [Icelandic Medical Journal] 2015;100(3):178–9.
18. Kullmann K. Die Allmacht des Forschers [Interview]. *Der Spiegel* 2015;36(29.8):108–10, at 109.
19. Knoppers B, Joly Y, Simard J, Durocher F. The emergence of an ethical duty to disclose genetic research results: International perspectives. *European Journal of Human Genetics* 2006;14:1170–8, at 1172.
20. See note 19, Knoppers et al. 2006, at 1176.
21. Wolf SM, Crock BN, Van Ness B, Lawrenz FP, Kahn JP, Beskow LM, Cho MK, et al. Managing incidental findings and research results in genomic research involving biobanks and archived data sets. *Genetics in Medicine* 2012;14(4):361–84, at 361.
22. WHO. Genetic databases: Assessing the benefits and impact on human and patient rights. *European Journal of Health Law* 2004;11:79–84, at 81.
23. Cassa AC, Savage SK, Taylor PL, Green RC, McGuire AL, Mandl KD. Disclosing pathogenic genetic variants to research participants: Quantifying an emerging ethical responsibility. *Genome Research* 2012;22(3):421–8, at 422.
24. See note 23, Cassa et al. 2012, at 422.
25. See note 22, WHO 2004, at 81.
26. See note 21, Wolf et al. 2012, at 376.
27. Wolf SM, Lawrenz FP, Nelson CA, Kahn JP, Cho MK, Clayton EW, et al. Managing incidental findings and research results in human subject research: Analysis and recommendations. *J Law Med Ethics* 2008;36(2):219–48.
28. See note 21, Wolf et al. 2012, at 376.
29. See note 8, Gulcher, Stefansson 2000, at 1829.
30. Cf. Gottfreðsdóttir H, Árnason V. Bioethical concepts in theory and practice: An exploratory study of prenatal screening in Iceland. *Medicine, Health Care and Philosophy* 2011;14(1):53–61, at 57.
31. Private conversation, 2012.
32. See note 21, Wolf et al. 2012, at 364.

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33. Act on Scientific Research in the Health Sector; No. 44/2014; available at http://eng.velferdarraduneyti.is/media/acrobat-enskar_sidur/Health-Sector-Research-Act-No-44-2014.pdf (last accessed 1 Oct 2015).
34. See note 1, Árnason 2010, at 302–3.
35. See note 33, Act on Scientific Research in the Health Sector 2014.
36. Cf. Steinsbekk KS, Myskja BK, Solberg B. Broad consent *versus* dynamic consent in biobank research: Is passive participation an ethical problem? *European Journal of Human Genetics* 2013;21:897–902.
37. Cf. Árnason V. Scientific citizenship, benefit, and protection in population based research. In: Solbakk JH, Holm S, Hofmann B, eds. *Ethics of Research Biobanking*. Dordrecht: Springer Verlag; 2009:131–41.
38. Frumvarp til laga um staðgöngumæðrun í velgjörðarskyni [Bill on altruistic surrogacy]; available at http://www.althingi.is/altext/144/s/1141.html (last accessed 7 Oct 2015).
39. See note 38, Bill on altruistic surrogacy (comment on Article 4).
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