Genetic privacy versus genetic solidarity: In the field of donation and expectation of benefits in research biobanks

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Introduction

It is certain that medical science during the last decades has been developed more than the last 30 centuries. The intent research effort of the last years and the mainly new directions utilized by the new way of scientific thought, they have added more diagnostic and therapeutical weapons to the inexorable battle between death and life.

One of the most valuable instruments of this effort base on the rapid evolution of biotechnology is biobanks for research purposes. In particular the establishment and the operation of these biobanks have raised expectations for addressing serious problems for human life such as the genesis and the course of specific diseases. The initiation of the interpretation of the human genome has turned attention to the so called 'functional genomics' and has oriented the interest in understanding the links among genes, gene with environment and genotype (the aggregation of the genetic information) with phenotype (the aggregation of the biological characteristics of an organism)[Knoppers and Fecteau, 2003].

It is well known to scientists involved in genetics, that the complexity of an organism is related to the 'different genes' provision, the regulation of the degree of their expression and certainly not to the number of genes. Thus, the discovery by the scientists of the role that genes are involved to the expression of certain diseases, will offer them from the therapeutically point of view, the advantage of proposing efficient type of medications to their patients as well as to develop new methods/tests of diagnosis.

On the other hand, all samples of biological material, stored in a research biobank, contain an archive of genetic information which is unique for every individual. This information concerns not just the individual, but also his/her blood relatives, who share 'a common gene pool' [Mason and Laurie, 2006] and contains a degree of certainty that those persons might be affected by a genetic disease. Thus, through genetic diagnostic tests, it is possible to explore if there is a predisposition to a specific disease or if there is a possibility his or her descendants to face the same medical problem.

Nevertheless is it possible to consider human genome as a 'heritage of humanity' [UNESCO, 1997] and under this point of view the principle of genetic altruism takes precedence, or the right of self-determination of the donor is at stake in the field of research?

The right of self-determination

The right of the self-determination of the donor of the biological material consists on the ability of the individual to decide and determine the time and under which circumstances is possible to accept the process of the information related with him. The self-determination and the autonomy of the individual premise the freedom of decision. In correlation with the genetic data protection, the right of self-determination lies on the individual's ability to decide on which information is permitted to collect, stored and become an object for processing and research.

Additionally the right of self-determination of the donor is associated in a direct way with the consent which should always be voluntary and explicit, surrounded by detailed information.

Under the Universal Declaration of UNESCO in Bioethics and Human Rights adopted on 2005, in article 6.2 indicated that:

'Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned'.

The meaning of this paragraph is summarized in one principle that the donor has been appropriately informed for the purposes, significance and implications regarding the use of the biological material and data. Informed consent founds its moral foundation and documentation on the respect of the individual's autonomy. Autonomous is the individual, who has the ability to take decisions freely and consciously, liberated from any kind of pressure forming a life frame according to his decisions.

Nevertheless respect for autonomy does not mean total self-governance, in case of a decision which affects others [Hansson Dillner Bartram Carlon Helgesson, 2006]. For example the members of a family might not wish their genes mapped, knowing that molecular biology could link genetic information with donor's clinical data and in some cases with relevant non-medical information [Gaulfield Ross Daar, 2003].

The protection of genetic information

According to the research report of Parker and Lucassen [Parker Lucassen, 2004] a central question arises: 'Does the genetic information belong to the donor or to his entire family, in other words are we referring to a 'personal account model' or a 'joint account model'?

More specifically in 'personal account model' the donor has the absolute control of genetic information management. In 'joint account model' the genetic information is accessible to everyone who is related to it and restrictions are in place only if certain reasons exist.

It is obvious from the above that, the collection and management of biological material encounter dilemmas related to the query on who controls the genetic information. In case of 'personal account model' for example, as it has already

mentioned the genetic information belongs exclusively to the donor, on the other hand the 'joint account model' offers this power to the researcher.

The Council of Europe Recommendation No (97)5 in article 9.1 states that:

'Appropriate technical and organizational measures shall be taken to protect personal data- processed in accordance with this recommendation- against accidental or illegal destruction, accidental loss, as well as against unauthorized access, alteration, communication or any other form of processing. Such measures shall ensure an appropriate level of security taking account, on the one hand, of the technical state of the art, and, on the other hand, of the sensitive nature of medical data and the evaluation of potential risks. These measures shall be reviewed periodically'.

As it is easily understood in a European frame a platform is already in place for the establishment of safety mechanisms regarding storage and use of genetic information and depending on the targets of the biobank, the genetic information as well as the information related to the medical status of the patient and his life conditions could related directly with the samples [Caulfield Ross Upshur Daar, 2003]. Thus biological sample collections obtain a discrete role due to this association. Laurie has expressed the opinion that biobanks could become a source of dangers due to the structure, function and aims and not due to the fact that they store genetic data [Laurie, 2002].

In addition the genetic analysis could offer valuable information for populations, such ethnological groups or group of individuals who are vectors of genes related to specific genetic disease. It is logical to have concerns regarding the kind of guarantees and rights which could be offered to third parties with interests that may be affected by the ongoing medical research.

Under the Council of Europe's Convention of Human Rights and Biomedicine covering the broader perspectives of the human rights implications related to the applications of biology and medicine (article12):

'Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counseling'.

The most interesting part of this article is the provision of the 'appropriate genetic counseling', stating the necessity to inform the person involved before processing his genetic information. Besides, the donor has the right to decide whether he wishes to participate in a genetic research or not.

The concept of informed consent and the freedom of research

As it has already mentioned both in terms of bioethics and in terms of personal data protection consent should be obtained after sufficient information. It has been suggested that the practice of giving specific information and asking for specific consent shows respect for patients and donors [Hansson Dillner Bartram Carlson

Helgesson, 2006]. It is indeed difficult to imagine consent on any issue without prior information.

Under the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research (article 13), which illustrates the relevant information which must be offered to the donor in order to participate in a research project. So the donor should be informed about the following:

1. 'The nature, extent and duration of the procedures involved, in particular, details of any burden imposed by the research project;
2. Available preventive, diagnostic and therapeutic procedures;
3. The arrangements to ensure respect for private life and ensure the confidentiality of personal data;
4. The arrangements for access to information relevant to the participant arising from the research and to its overall results;
5. The arrangements for fair compensation in the case of damage;
6. Any foreseen potential further uses, including commercial uses, of the research result, data or biological materials;
7. The source of funding of the research project;
8. The right to refuse consent or to withdraw consent at any time without being subject to any form of discrimination;'

It has been supported the view that informed consent protects individual autonomy by preventing coercion and deception [O'Neil 2003]. Coercion is the case when individual has been forced to consent under the use of threats. Nevertheless there are cases where people may believe that they are being coerced even when they are not. For example people might believe that if they do not cooperate with their doctor in a research project this will have negative impact in their future relationship [European Textbook on Ethics in Research].

On the other hand the oversupply of information might lead the donors in total confusion, resulting as a consequence the provision of uncritical consent or the refusal of consent due to the failure of clarification. For example will the information sheets are written in a research style that donors will understand or will they manipulate donors consent? Also will prospective participants be given an opportunity to go away and think thoroughly their decision and probably to consult other sources of information such as websites or books?

Additional, donor should be able to control to some extend his samples and the related data. This should be ensured by making it possible to drop out the right to withdraw consent to the use of the samples and data at any time. It is also recognized that the protection of data is directly connected with the right to withdraw from the research project [Campon-Thomsen Rial-Sebbag Knoppers, 2007]. It also very important to point out that the donor's right to withdraw at anytime, strengthen people's willingness to participate in research [Helgesson and Johnsson, 2005].

According to the Council for International Organizations of Medical Sciences (CIOMS) it has been suggested in its international ethical guidelines for biomedical research involving human subjects (guidelines 4 and 5) that:

'informed consent protects the individual's freedom of choice and respects the individual's autonomy' and 'the individual is free to refuse to participate and will be

free to withdraw from research at any time without penalty or loss of benefits to which he or she would otherwise be entitled'.

Although there many advantages in the application of informed consent we cannot slight the fact that the deviation of the explicit and specific consent causes serious problems on the grounds that research is not limited in a moment but it constitutes a continuous process. For that reason it is possible to change the purpose of research or the group of researchers. In that case previous informed consent is no longer valid and according to classical research ethics fresh consent should be given for each new research project. Taking in advance the number of donors who might be involved, this would be impractical and also endangers the scientific value of the entire research project.

On the other hand, one obvious prerequisite for the development in the field of genetics is to ensure the possibility of performing scientific research and the related experiments [Βιδάλης, 2003]. It is worth also mentioning that the Additional Protocol to the convention of human rights and biomedicine, in article 7, states that in order to approve the proceedings of research, should be considered:

- The scientific value
- The importance of the scope
- The interdisciplinary acceptance of research in moral terms

Nevertheless the most important is the protection of the individual and preventing the infringement of human dignity.

Is broad consent appropriate for research?

Broad consent is the authorization of the participant to do the researcher something based on information and deliberation. Broad consent is distinguished from blanket consent because it refers to a wide but specified range of uses while blanket consent refers to the unrestricted use of a sample [European textbook on ethics in research, 2010]. Broad consent seems probationary when combined with coding or anonymization of the data. Also broad consent involves the agreement of the research participants to the use of their sample or data in different research projects, or by different researchers or in very different contexts.

On the other hand according to Additional protocol to the convention on human rights and Biomedicine, the persons who participate in a research project before being asked to consent should be specifically informed about any foreseen potential further uses. Thus, we could assume that donor's consent covers at least these potential uses beyond the initial research purpose. The German National Ethics Council [Nationaler Ethikrat, 2004] points out that for reasons who are serving the scientific merit of the process consent should be given indefinitely under the condition of withdrawing from the project unless donors personal data have been destroyed or been fully anonymized.

From another point of view it can be acceptable the fact that sometimes we might 'trade' the rights of one person in order to benefit others [Miola, 2006]. In this case the donation should be considered as generous especially in circumstances where the

donors cannot expect immediate personal benefit from their participation [Mullen, 2009]. Researchers and patients should be seen as a team, each doing their share to promote the common good of improved health [Forsberg Hansson Eriksson, 2009]. European Society of Human Genetics accepts that individuals may ask to give a broader consent and in that case it is not essential to recontact, although individuals maintain the right to withdraw at any time [European Society of Human Genetics, 2003].

Nevertheless before providing broader consent donor should be informed about the possibility of possible future uses for research purposes or for possible commercial use. Additionally if donor had stated in his initial consent that he wishes new information before any other subsequent research this must be respected.

Secondary use of genetic data

The biological material and the related genetic data can be used for secondary use namely beyond the purpose for which it was collected and stored [Μήτρου, 2008] and this is achieved by broader consent. The right of access in this case should be allowed only when the results are of direct relevance to the donor himself and the survey results are confirmed.

So in case of cross-border transfer of data according to Directive 95/46 it is essential to establish that the destination country has a satisfactory level of data protection.

Especially in cases of non research uses like in the field of insurance, employment, detection of crime or in the field of identification of victims, reasons to deviate from the initial purpose or stigmatization reasons of the donor, requiring the exclusion of such uses or exceptional application but with appropriate legislative frame. The potential leak of data and their possible use by insurance companies or prospective employers is of a great concern, since it may lead to discriminatory behavior and create inequality based not on the existing possibilities and perspectives of the individual but on his genetic endowment [Κριάρη-Κατράνη, 2004]

In any case it is advisable to inform the donor of genetic material data on the ability to have settings that will allow the use of materials and data for purposes that were initially prohibited.

Donation for research: An obligation or altruism?

To proceed to this fundamental question it is essential to establish a logical frame so as to examine both possible answers. It should be also decided whether biobanking serves as a project to improve public health and consequently the quality of our life or it should be expected that medical research based on genetic information could harm the individual, although is an obligation as a defensive effort against genetic deceases.

Firstly the research on this topic should focus on individual’s rights in comparison with public health issues. The anonymity of the samples is an efficient approach in reducing risks for individuals [Hansson Dillner Bartraam Carlon Helgesson, 2006].

The anonymity naturally is essential to accompanied from a secure coded recognition and traceability system [Helgesson Dillner Carlson Bartram Hansson, 2007]. This practice possibly will reduce publics concerns, but still is not a 'sufficiently' moral attitude towards donors. The issue becomes more complicated if we accept the hypothesis that these samples could be used for future research without a specified frame of research activities.

The next thing to consider is the obligation or not, from the researchers point of view, to return the results to the donors as an indication of respect to these persons. According to Beskow [Beskow Burke Merz Barr Terry Penchasxadeh Gostin Gwinn Khoury, 2006] this is not exactly the case. Genetic data should not be returned, according to their views, if they are not involved in clinical research. Conclusively it is important not to hide vital information, but also not to confuse the donor, who probably does not have the appropriate scientific background, with irrelevant data.

To become a donor as an idea is an act of altruism and the concept is that a donor does not expect anything in return. The case of biobanking is identical to altruism if the issue of data safety is solved. A biobank first of all is a collection of samples coded according to a specific IT system. Every single sample corresponds to a small piece of information of a larger system related to a population or a group of individuals [Forsberg Hansson Eriksson, 2009]. The several pieces of information will create an overall illustration of the population's genetics.

The above approach is the most effective approach to increase the donor's confidentiality to the Biobank projects aiming to upgrade medical research and quality of human life. Confidentiality could be secured on behalf of donors by third party audits and donors have the moral duty to participate in medical research taking place within the biobank [Harris, 2005]. In this case researches should boost their contribution to medical innovation.

Research stuff and donors are both important elements of the biobank and they have a specific target: to promote research for common good. Advances derived from samples do not produced from the samples themselves but are the result of the scientific effort of the researchers.

The UK Biobank project has a pure altruistic approach. It invites people to participate in the project by donating genetic samples, focusing on promotion of medical research and the intention is not to help the specific person but to provide scientific evidence for the future generations. Under this concept there is no feedback for the participants, and the researchers can focus directly to their intellectual effort.

It is commonly accepted and UK Biobank Project is an identical example, that the importance of public interest may affect in a negative manner the interest of the individual, but if the individual care in an honest way about the interest of his or her co-humans, is essential to give up some of his or her rights.

Conclusion

Genetic research should be directed to the common health profit and synchronously avoid the possibility for humans to become experiment subjects. In the frame of a

democratic society, research scientists should have the appropriate freedom without any bans. The threshold of freedom in scientific research is defined by the threat to human life and value, due to this research. For these reasons, donors should be more tolerate with the idea of their privacy breach for the sake of solidarity, thus a broader consent seems to be appropriate.

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