



## **CRITICAL DISCUSSION ABOUT ETHICAL CONCERNS IN BIOBANKS**

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### **ABSTRACT**

This review critically discussed three ethical concerns of biobanks: consent, altruism, and benefit. Informed consent, altruism, and benefit are issues that must be address in an ethical manner in relation to the operation of biobanks. There are four ethical issues relating to informed consent: withdrawing, feedback, type of consent, and confidentiality. Altruism is another ethical concern with biobanks. It is very important to maintain donors' altruism and the trust through active governance of human genetic banks. There has to be some kind of chain of command that follows the path of each individual specimen collected by a donor so that the altruistic intentions of the donor are preserved. In terms of benefit, Biobanks must balance the responsibilities between donor anonymity and commercial interests. There are ways to try to reduce or eliminate some of the ethical considerations surrounding biobanks. One such suggestion was made about implementing a quality control mechanism in each biobank. This provides a chain of evidence and procedures, so that if a mistake is made, there is a paper trail facilitating ideal solutions. Also, it has been suggested that a conference of professionals from all parts of the medical research field could collaborate for benefit, in order to develop a more formal template for quality control plans in biobanks. Finally, this critical discussion has encouraged the individual medical researcher to take personal responsibility for preserving the integrity of each individual sample, with an understanding that each sample is representative of a human life.

**Keywords:** Biobanks, Consent, Altruism, Benefit

### **INTRODUCTION**

A biobank is place where people can store and receive biological samples of multiple types, while biobank employees may perceive such a place as a collection of individual genomes. One significant aspect of the facilities is the ability to precisely map differences between genomes, accessing a common form of variation which is a single nucleotide polymorphism (Garrath and Schroeder 2004). The objective of continuing research is to relate the resistance or susceptibility to disease with data on genetic variation, while the advancement of preventive medicine is a key role of biobanks. However, the most important reason for maintaining biobanks is to acquire new knowledge related to pathogenic mechanisms. With this knowledge, it is hoped that therapeutic targets will be identified for the purposes of developing new and innovative drugs capable of combating or controlling diseases (Garrath and Schroeder 2004) .

There are many biobanks in existence today (both publically or privately owned), and there are several ethical issues that arise throughout their operation. Informed consent of the donors is the most immediate and obvious dilemma (Elger, 2008). Also, there is a major concern that sample collections will be exploited by standards set by the biobank's commercial partners. As biobanks rely on donor altruism and extensive public funding, these institutions should be accountable for how the specimens are utilized (Garrath and Schroeder 2004). I will critically discuss in this article three ethical concerns of biobanks raised by Garrath and Schroeder (2004) in their article "Human genetic banking: altruism, benefit, and consent" in greater depth, providing details regarding the challenges alongside recommendations for improvement. Ultimately, I will conclude that ethical dilemmas should not overshadow the potential of biobanks, although considerable actions are demanded to minimize lingering ethical issues.

### **Informed Consent**

Many issues are sensitive in biobanks, with most issues stemming from common human expectations and nature. It is naturally difficult for a donor to fully appreciate the extent by which their samples are being used. Initially, informed consent takes place at the beginning of the collection process. The donor then signs a statement that he or she understands that the sample will be used for scientific and medical research. Other than the disclosure that his or her tissue will be used for scientific research, the donors generally have no idea of what each project will entail.

There has been an extensive ethical debate in the medical community concerning full disclosure to tissue donors (Garrath and Schroeder ,2004). Some experts suggest that informed consent does not go far enough, while others say that informed consent is a simple process and should not be complicated by scientific details (as they might actually confuse donors) (Cambon-Thomsen, Rial-Sebbag et al. 2007; Karp, Carlin et al. 2008). The information in informed consent should have specific characteristics. Garrath and Schroeder (2004) claimed that the information should explain purposes of medical intervention, potential benefits, foreseeable risks and its alternatives, and intelligible and relevant to donors. In the same context, the consent should be based on volunteer basis; and it should be documented.

There are four ethical issues relating to informed consent: withdrawing, feedback, type of consent, and confidentiality. Both the Nuremberg Code and the Declaration of Helsinki emphasized withdrawing rights of research subjects. Withdrawing considered a basic right of participants in medical experiments or any other research to withdraw from the research or the experiment at any stage. In terms of feedback, the participants should have feedback as "in return" for their participation. Regarding the type of consent, there are two types of consent: narrow and open-ended consent. The narrow consent used in one, well defined research study while the open-ended consent used for general research which means that this kind of consent can be used for future research without obtaining new consent from research subjects. The fourth ethical issue that relates to informed consent is the confidentiality. It is fundamental principle in medical ethics. There are some situations when confidentiality could be violated, for example, in crime cases and when genetic information obtained by employers and insurance companies.

The general procedure in informed consent issues is to allow the donor to opt out from any further use of his or her specimen deposit (Garrath and Schroeder 2004). The donor must then go through the arduous task of removing his or her name from the system, so that the tissue sample will no longer be used for future scientific experiments. Overall, according to Garrath and Schroeder (2004), very few donors go to the trouble of opting out.

Informed consent is usually a one-time proposition with little to no second thought about the future use of the donated specimen. This presents an ethical problem because people who originally donated tissue samples for a certain research project may not approve of purposes other than those proposed by the initial research project. However, the cost and feasibility of contacting every tissue donor each time a new project was starting up is prohibitive. The man hours and financial resources would present an insurmountable challenge to the directors of the biobanks.

Biobanks are both publically and privately owned and operated; therefore, governmental oversight and regulation can only go so far in regulating the collection and use of human tissue for the purposes of scientific research (Elger 2008). The genetic material and the data derived from that material must be kept confidential. Lifestyle and medical information must also be kept confidential. The reason for this is that disclosure of the data may cause the donor to be subject to stigmatization and/or discrimination.

It is extremely difficult to protect a breach of confidentiality in a biobank. The entire process, from collection to observation can be compromised at any stage. This is especially the case if new and/or revealing information is discovered from a donor's specimen. Confidentiality is in place to prevent research findings from adversely affecting the donor. It is of the utmost importance that biobanks do not succumb to the temptation to release the personal data of a donor who believed that his or her information was supposed to have been kept anonymous.

Since privacy issues are a primary concern of biobanks, the issue has been raised about the ownership rights of the donor's specimen (Elger, 2008). Serious legal questions are raised by this issue including controlling interest. One major question is who has controlling interest of the donor's specimen? There is no given set of rules or regulations governing the operation of a biobank and/or the confidentiality of donor's data (European Agency for Human Genetics 2003). The donor is likely unaware of the legal ramifications involved in providing a specimen for the purposes of medical or scientific research. This is not unexpected because there is no universal legislation that governs the use of specimens or the data collected from them.

The greatest confusion lays in the complexity of policies, which greatly contribute to the nature of ethical issues. A common question regarding what level of data security is most appropriate is especially complex, while various coding procedures must be compared to the code being broken (and thereby compromising the anonymity of the individual donor) (Elger, 2008). Efforts are underway to determine the level of privacy required to protect the privacy of the individual donor, without excessively impeding research (Auray-Blais and Patenaude, 2006) . The main objective here is to determine the most essential ethical issue rather than debate difference over feasibility.

### **Altruism**

Altruism is another ethical concern with biobanks. The donors participate in research projects based on altruism approach, and they trust who is managing these projects. So, it is very important to maintain donors' altruism and the trust through active governance of human genetic banks.

When a donor deposits his or her specimen at a biobank, he or she is under the assumption the specimen will be used to benefit society and the advancement of medical science. The donor gives the specimen to the biobank without regard to his or her own personal interests. The dilemma lies in fact that the donor may not approve of some researches being conducted by the biobank with his or her sample. However, since he or she has provided a specimen, the biobank can use his sample as it chooses. For example, a donor with deep seated religious convictions may have a serious issue with a biobank using his or her specimen for research that goes against religious traditions.

The purpose of biobanks is to develop research that will combat diseases and find cures. Tissue samples are given by participants who wish to advance the cause of scientific and medical research. The donors are providing an altruistic service to humanity in general by giving a part of them to help other people combat the disease (European Agency for Human Genetics , 2003). Their donation may help researchers discover the cure for cancer, HIV/Aids, Parkinson's, leukemia, diabetes, lupus, heart disease and many other diseases (Garrath and Schroeder, 2004). The donors should be applauded for their desire to improve the life of their fellow human beings. Therefore, their specimens should be treated with respect.

Biobanks need to have a set of rules and regulations to follow in order to prevent abuse of the specimens. The abuse lays not so much ending use of the specimens, like a type of entrapment that the donor is drawn into when he or she signs a general, informed consent paper. Most biobanks do not intentionally entrap their donors. Rather, the donors give freely and without reservation because they want to contribute to the field of medical and scientific knowledge.

The main concern is about the use of specimens which are collected in a biobank. Not only is the privacy of the donor important, but the integrity of their research practiced on the donor specimen is also important. There has to be some kind of chain of command that follows the path of each individual specimen collected by a donor so that the altruistic intentions of the donor are preserved. Currently, there is no biobank that documents the path of an individual sample. Samples are used in a collective fashion without regard to where they initially came from (Garrath and Schroeder 2004). There is an ethical consideration with this. Samples could get mixed up, and as a result data will be skewed. This has compromised the integrity of the sample, and there is no way to reconstruct the data by tracing steps made

to gain that data. All the time and effort to ensue creating the data has been wasted. Additionally, the researcher may not even know that the data is incorrect. This data is now passed along to pharmaceutical companies who then create drugs to combat diseases. The drug itself is now contaminated, and if people die as a result of taking this drug the biobank is liable along with the pharmaceutical company.

It has been stated earlier in this discourse that the use of specimens goes beyond the initial informed consent. This use also goes beyond altruism. Biobanks often reuse specimens on other projects in order to provide a benefit to society. This is a commonly held practice. A massive overhaul of the biobank system of intake needs to take place. The actual projects that a donor specimen will be used for is unclear, but all are used to advance the cause of medical science for the purposes of benefiting people stricken with serious diseases. In fact, specimens are used in many projects, and some of these projects take place years down the road. Therefore, there is no way for even the intake specialist to provide the donor with a list of research experiments that his or her specimen will be involved in, which could provide the cure for HIV or cancer.

It is highly improbable and impractical to assume that all the biobanks in the world, and all the countries in the world that use biobanks can come together in common agreement about the issues of informed consent, donor anonymity, and other issues (Auray-Blais and Patenaude, 2006). Sweeping regulation of the biobank industry will not happen because the legal system is different in each country. It would be easy to implement legislation that would regulate biobanks if they were on the system of civil and common law. However, the civil law in some countries is different than civil law and others. Common law is used in countries like Australia, the United States, the United Kingdom, and other countries. There is absolutely no way to regulate biobanks and their collection practices with one regulatory body (Elger, 2008). Many regulators from different countries must come together in order to figure out how to best use donor specimens.

### **Benefit**

As with all industries, money and profit is a primary goal. Biobanks work in a collaborative fashion with pharmaceutical companies in order to provide information for the pharmaceutical companies to create medicine to combat diseases (Elger 2008). Since biobanks rely mainly on the financial contributions of wealthy individuals or businesses, they make a profit and benefit by selling information for commercial purposes. Although one of the goal of the biobanks is to generate research that provides medicine to help combat or prevent disease, it places biobanks in a precarious ethical situation.

Biobanks must balance the responsibilities between donor anonymity and commercial interests (Auray-Blais and Patenaude 2006). For example, if a particular person has a genetic marker that helps determine the cause of Alzheimer's, should that person be personally contacted? The answer in this lies in the fact that the person has signed an informed consent requesting anonymity. The researchers have to deal with the dynamics of their discovery. If the researchers contact the donor about the importance of his or her donation to science and medical research, they are violating that donor's right to privacy. It would seem that this particular donor would want to know that he or she contributed to finding a cure for Alzheimer's. This is especially the case in situation where a family member is affected. The donor may want to be notified if his or her specimen shows a predisposition to Alzheimer's disease. However, this decision is not governed by current legislation, so it is up to the individual biobank to determine the best action in this scenario.

Commercial interests unfortunately are very beneficial in a biobank industry (Garrath and Schroeder 2004). Operating a biobank is an expensive enterprise. Therefore, biobanks are at the mercy of philanthropists. For example, a substantial financial contribution may be given to a biobank for the sole purpose of finding out what causes Parkinson's disease. Another financial contributor may be interested in finding a cure for leukemia. Yet another wealthy contributor may want to find out ways in which drugs can be developed to combat certain diseases in order to make a huge profit. This is a serious ethical

problem. Money is always a motivating factor in anyone's life. One can begin to see how the use of genetic specimens can ignore ethical principles to serve the demands of commercial interests.

Biobanks, therefore, are beholden to the whims and wishes of the pharmaceutical companies who wish to exploit scientific and medical research for the purpose of amassing fortunes (Elger 2008). There is nothing wrong with pharmaceutical companies making a profit. However, that profit cannot and should not come at the expense of donor anonymity. The specimens of donors should be treated with a certain respect. The donor is giving a part of his or her body freely to a biobank for the purposes of advancing the cause of medical research. Biobanks should take this into consideration when deciding on the use of specimens.

Although biobanks should take into account the ethical ramifications of selling out to big pharmaceutical companies, they have little choice because that is why they are in business. Biobanks exist primarily to discovery advances in medicine, and to develop cures and preventative treatment for diseases (Auray-Blais and Patenaude 2006). It takes a tremendous amount of financial resources to keep a biobank operating. The researchers have doctorates and expect a salary commensurate with their education and experience. Operational costs include the electricity it takes to keep the machines and lights on at the biobank, along with all the equipment used in the research process. Biobanks must be answerable to financial contributors and pharmaceutical companies or they will not have the means to operate.

The reliance on outside financial support presents a serious ethical consideration, as was stated earlier. Misuse and abuse of specimens, or the skewing of research results could take place in order to expedite data that can be sold to pharmaceutical companies. The pharmaceutical companies take the tainted data at face value, and proceed to develop drugs based upon that data. There are two issues that are problematic in this situation. Researchers are pressured into finding data that will accelerate the discovery process. In other words, they may be more likely to make mistakes and miscalculations if they are pressured in anyway. Their jobs may be on the line if they do not meet certain deadlines set by the administrators of the biobank.

The second issue that is ethically problematic is that of selling data to pharmaceutical companies that is not completely accurate. The pharmaceutical company creates drugs based on this data. If the data is skewed, the company can produce pharmaceuticals that are not likely to help combat a particular disease, or worse, a person taking the drug could have an adverse or lethal reaction to the drug. This places a legal liability on both the biobank and the pharmaceutical company.

The biobank administrators also have a moral dilemma. They must be able to pay for all the operational costs of the biobank. It is important to realize that this is a way most businesses work. A business must make a profit in order to keep its doors open. A biobank cannot keep its doors open if it has no money to operate. This is an ethical dilemma. It all boils down to money. Since the operation of a biobank takes money, administrators must take into account the fact that at times they may have to compromise their moral integrity in order to keep the biobank operational. It is simply common sense that some concessions on the part of the biobank administrators must be made in order to secure funds to advance the cause of medical research (Auray-Blais and Patenaude 2006). This does not make the practice ethical; it is simply the way in which biobanks are operated. The individual researchers are caught up in this web of ethical dilemmas. The biobanks must concede to wealthy private individual donors, and the researchers must concede to the administrators of the biobank.

## **Discussion**

Biobanks raise many serious ethical issues, and ethical issues are so common in the field that biobanks have become virtually synonymous with ethical challenges (Auray-Blais and Patenaude 2006; Elger 2008). One of the most common scenarios with a high potential for complications relates to donor privacy and informed consent discussed; when a donor deposits his or her specimen at a biobank, he or she is under the assumption that all personal information will be kept anonymous (Malin, Loukides et al. 2011). The donor signs an informed consent form, and this paper allows the biobank to use the donor's specimen for

scientific and medical research. When signing an informed consent document, however, the donor may not realize that he or she is allowing the biobank to use the specimen in later research projects. This is the main, most common, and most significant ethical dilemma. The nature of this dilemma lies in fact that the donor may not approve of the research being conducted by the biobank with his or her sample. However, since he has given informed consent the biobank can use his sample as it chooses. The donor signs a one time, general consent form, oblivious of the ethical ramifications of that action.

The biobank is supposed to protect the privacy of the donor, and the administrators of the biobank take great measures to assure that this privacy is honored (Garrath and Schroeder 2004). Generally, the biobanks uses the donor specimen for more than the initial informed consent covers. That is simply common practice with biobanks. It would not be prudent or efficient to have to contact the donor each time his or her specimen is set to be used in a new research project (Garrath and Schroeder 2004). The anonymity of the donor is usually kept intact. Rarely does the name of the donor become part of public health records. If biobanks can exert such an effort to keep the names of donors anonymous, they should be able to have a quality control process in place to prevent false data from going to the pharmaceutical companies. This is not so much legal issue as it is an operational issue. A biobank might be considered as a type of manufacturing plant. All manufacturing plants have a quality control department, and members of the quality control department oversee the production line. Biobanks benefit by producing data from donor's specimens that is sold to pharmaceutical companies that can create medicine for the purposes of combating disease (Auray-Blais and Patenaude 2006).

Setting in place a program of quality control and biobanks is a process that can help biobanks. There is no law that requires biobanks to implement a quality control plan which would create a framework that would allow samples to be used in a way that is most beneficial to the advancement of medical science. The rules for biobanks are dictated by each biobank (Elger 2008). This is quite unfortunate because there is no logical path to follow in the case of skewed data that result in the death of a person. This does not often happen, but can be the result of labs rushing results in order to accelerate the process of creating pharmaceutical drugs. The production of the pharmaceutical drugs will only provide a benefit to society if the data by which they were created is not tainted. A biobank or a pharmaceutical company should not benefit from data that is skewed for the purposes of making a profit off of the sale of prescription drugs. The person who has died has suffered the ultimate indignity. The victim's fate is a result of medical research. Now the whole of medical research has come full circle.

A donor has given a biological sample to a biobank for altruistic reasons. That donor has given informed consent for the biobank to use his or her sample. The next stage is the research aspect. Researchers are at times under pressure to come up with data for the biobank to sell to pharmaceutical companies in order for the biobank stands to gain a financial benefit. Because the researchers are pressured, so the donors' data will be distributed to other parties and in this case the data will sold to the pharmaceutical companies. The ethical dilemma is that the person who initially donated at the biobank was doing so for altruistic purposes and to save lives, not for making profit to the pharmaceutical companies. At the end, the donor's specimen has been abused; and the integrity and privacy of the donor are violated.

There are ways to try to reduce or eliminate some of the ethical considerations surrounding biobanks. One such suggestion was made about implementing a quality control mechanism in each biobank (Caulfield, McGuire et al. 2008). This is strictly on a volunteer basis because there are no regulations that control biobanks. It is imperative that the scientific and medical community come together across national boundaries in order to create a universal quality control plan (Auray-Blais and Patenaude 2006). An international conference of the researchers, administrators, professors, and regulators should be called to address the ethical dilemmas faced by biobanks. Therefore ethics experts along with legal experts should come together in order to analyze the current situation with biobanks, and ethical considerations should be foremost in routine development (Lin, Owen et al. 2004; Lunshof, Chadwick et al. 2008).

The collection of human specimens is the beginning of the process of understanding human genetics. The purpose of biobanks is to collect and preserve the specimens while retaining the anonymity of the donor source. The researchers that work in the biobanks would be more efficient if they had a formal procedure to follow when dealing with the specimens (Auray-Blais and Patenaude 2006). Supervisory positions could be created to oversee the collection and processing of samples. This is the quality control model that was just mentioned. There must be a chain of evidence from the initial donor collection to that time that the pharmacist dispenses a prescription drug patient, especially when that patient's life is on the line. The scientific and medical community must think outside of the box. There is more to scientific research than research itself. Minus the romantic notion of fighting diseases, the biobank, the individual medical researchers, the administrators of the biobank, the people who work for the pharmaceutical company, pharmacists, and the clerk who rings up a sale at the pharmacy, are all doing what they do to make money. There is nothing wrong with making a profit however; this profit cannot be made because of pressure placed on researchers to provide data without donors' consent or violate donors' informed consent.

### **CONCLUSION AND RECOMMENDATIONS**

Benefit, altruism, and informed consent are issues that must be addressed in an ethical manner in relation to the operation of biobanks. It is very important to earn donors trust in order to maintain the significant increases of genetic banks which will help to promote public good through encouraging research in medical field. The main issue to earn donors trust and to protect from commercial exploitation is through scrutiny of ethical considerations.

Considering all of the ethical issues involved, medical researchers must develop more of 'a conscience,' while taking greater care to consider the negative consequences of existing occurrences (and take appropriate action). Considering the evidence, sensitivity training for medical researchers might be in order in some facilities, either for select authorities or an entire staff. It is imperative that these researchers understand the ethical considerations and human aspect behind their work. This is not to say that medical researchers are not cognizant of the human dimensions and ethical issues. They initially went into the field of medical research with altruistic aspirations of helping humanity, and finding cures for diseases. Somewhere along the way, these researchers may have become so involved in the process they have forgotten why they entered the field of medical research in the first place. They may have allowed the financial benefits overwhelm their original intent for entering the medical research field. If those researchers are trained to be cognizant ethically in the way he or she handles a sample throughout the process of research and experimentation that awareness will be passed onto the others and the ethical issues regarding the donor's sample will be highly considered.

Moreover, personal responsibility on the part of everyone involved in the collection and interpretation of data derived from biobanks is of the utmost importance. This discussion has suggested implementing a quality control plan that is similar to a manufacturing plant's operation. This provides a chain of evidence and procedures, so that if a mistake is made, there is a paper trail facilitating ideal solutions. Also, it has been suggested that a conference of professionals from all parts of the medical research field could collaborate for benefit, in order to develop a more formal template for quality control plans in biobanks. Finally, this discussion has encouraged the individual medical researcher to take personal responsibility for preserving the integrity of each individual sample, with an understanding that each sample is representative of a human life.

### **REFERENCES**

- Auray-Blais, C. and J. Patenaude (2006). "A biobank management model applicable to biomedical research." *BMC Medical Ethics* 7(4).
- Cambon-Thomsen, A., E. Rial-Sebbag, et al. (2007). "Trends in ethical and legal frameworks for the use of human biobanks." *European Respiratory Journal* 30(2): 373-382.
- Caulfield, T., A. L. McGuire, et al. (2008). "Research Ethics Recommendations for Whole-Genome Research: Consensus Statement." *PLoS Biology* 6(3): e73.

- Elger, B. (2008). Ethical Issues in Governing Biobanks: Global Perspectives. Burlington, Ashgate Publishing Limited.
- European Agency for Human Genetics (2003). Data storage and DNA banking for biomedical research: technical, social and ethical issues. European Journal of Human Genetics, European Society of Human Genetics. **11**: S8–S10.
- Garrath, W. and D. Schroeder (2004). "Human genetic banking: altruism, benefit and consent." New Genetics and Society **23**(1): 89 — 103.
- Karp, D. R., S. Carlin, et al. (2008). "Ethical and Practical Issues Associated with Aggregating Databases." PLoS Medicine **5**(9): e190.
- Lin, Z., A. B. Owen, et al. (2004). "Genomic Research and Human Subject Privacy." SCIENCE **305**: 183.
- Lunshof, J., R. Chadwick, et al. (2008). "From genetic privacy to open consent." Nature Reviews Genetics **9**(5): 406-411.
- Malin, B., G. Loukides, et al. (2011). "Identifiability in biobanks: models, measures, and mitigation strategies." Human Genetics **130**(3): 383-392.