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The case of biobank with the law: between a legal and scientific fiction

Judit Sándor,[1] Petra Bárd,[2] Claudio Tamburrini,[2] Torbjörn Tännsjö[3]

[1]Center for Ethics and Law in Biomedicine, Central European University Budapest, Budapest, Hungary
[2]Centre for Healthcare Ethics, Stockholm University, Stockholm, Sweden
[3]Department of Philosophy, Stockholm University, Stockholm, Sweden

Correspondence to
Professor Judit Sándor, Central European University, Nádor u 9, Budapest 1051, Hungary; sandorj@ceu.hu

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ABSTRACT

According to estimates more than 400 biobanks currently operate across Europe. The term 'biobank' indicates a specific field of genetic study that has quietly developed without any significant critical reflection across European societies. Although scientists now routinely use this phrase, the wider public is still confused when the word 'bank' is being connected with the collection of their biological samples. There is a striking lack of knowledge of this field. In the recent Eurobarometer survey it was demonstrated that even in 2010 two-thirds of the respondents had never even heard about biobanks. The term gives the impression that a systematic collection of biological samples can constitute a 'bank' of considerable financial worth, where the biological samples, which are insignificant in isolation but are valuable as a collection, can be preserved, analysed and put to 'profitable use'. By studying the practices of the numerous already existing biobanks, the authors address the following questions: to what extent does the term 'biobank' reflect the normative concept of using biological samples for the purposes of biomedical research? Furthermore, is it in harmony with the so far agreed legal—ethical consensus in Europe or does it deliberately pull science to the territory of a new, ambiguous commercial field? In other words, do biobanks constitute a medico-legal fiction or are they substantively different from other biomedical research protocols on human tissues?

A recent Eurobarometer survey[1] has shown that even in countries where biobanks have already operated for a longer period of time and also on the national level, such as Iceland and Estonia, the approval rate among people is quite diverse. While 92% of the responses from Iceland supported participation in biobank projects, in Latvia the same figure was only 24%. The notion of biobank was defined to the respondents in the following way: '…collections of biological materials (such as blood and/or tissues) and personal data (medical records, lifestyle data) from large numbers of people. Using biobanks, researchers will try to identify the genetic and environmental factors in diseases, to improve prevention, diagnosis and treatment. Critics, however, raise questions about privacy, confidentiality and commercial interests regarding the biobanks and about who is going to regulate them.'[2] Uncertainties about the scope and use of biobanks in the field of biomedical research are even more telling when one looks at the legislative landscape of biobanks in Europe. First of all, there are not too many cases in which legislation focuses on biobanks per se. Instead, a mosaic-like regulation is more widespread, in which the rules of medical research, data protection, the study of genetics, biological tissues and transplantation, together with their interpretation for and application to biobanks are all taken into account.

Using the concept of 'bank' in the field of human tissues, of course, is not entirely new: in a medical context it had already appeared in the 1930s with reference to 'blood banks'. The expression was coined by Bernárd Fantus, an American physician of Hungarian descent, who ran a blood bank[3] before the outbreak of the Second World War. Blood banks later played a major role in the treatment of soldiers wounded in the war. Naturally, the technology of preserving blood has changed a great deal since then, resulting in blood products that last much longer. Although the notion of 'biobank' continues to elicit moral concerns and critical comments now, invariably seizing on the commercial connotation of the word 'bank', the expression 'blood bank' failed to raise similar anxieties at the time: no one seemed to object to the application of a commercial term to a type of human tissue.

While the term 'biobank' is a relatively new one, biological samples were collected for educational and research purposes as early as the end of the 19th century, mainly in the form of pathological or epidemiological samples. Evidently, biological tissue samples and isolated DNA molecules can have extensive use not only in medical research, but also in historical, genealogical and criminal investigations. However, in most cases DNA-based information in itself has very little use and can be evaluated only in a given context. This is also true in the case of biobanks, which, alongside biological samples, cell lines and DNA molecules, also store information relating to patients' health, medical history and lifestyle. Therefore, the key to the success of biobanks usually lies in their ability to link genetic information to any given clinical symptoms and characteristics, and thus to draw conclusions against the genetic background of the medical condition.

Through the utilisation of biotechnological products, biobanks promise additional financial benefits to health institutes with a large biobank.[4] An equally important aspect of biobanks is the mode in which control over the samples can be converted into academic positions and professional advantages, as opposed to direct financial benefits.

Besides having applications in biotechnology, biobanks also form the subject of scholarly research in various branches of the human sciences, most notably ethics and law. First, we witnessed the mass emergence of biological sample collections that had been established in anticipation of future

developments in research. Compared with earlier research protocols, these projects envisaged the involvement of a much larger number of volunteers or occasionally even the total population of smaller communities. Numerous biobanks follow a mixed mode of operation, one that is based partly on a scientific and partly on a business model. While the biomedical sciences relied on the 'fiction of biobanks' in their marketing and scientific utilisation of tissue collections, the legal experts were readily extending the rules of human research to the molecular level, themselves also resorting to some sort of a legal fiction in the process. (Legal fiction is usually understood as a technique developed when a legal instrument accepts a verifiably false legal statement of facts as true. This means that we declare a statement of facts to be identical to another one, even though we know it to be different, in order to apply a certain legal consequence.) The fiction is intended to be a legislative instrument in the aid of the execution of law. The process of extending human rights norms from humans to human tissues has remained largely without reflection. As a result, while the ethical–legal norms introduced after the Second World War were intended to establish legal guarantees to protect individuals from involuntary, risky and painful procedures in human experiments, more recently similar norms have been put in place—often without adequate legal assessment—in relation to tissue sample collection, even when the research is conducted only on someone's DNA, and not the individual.

As it follows, from the moment of conception, the notion of biobanks has given rise to ambiguities and uncertainties in the everyday operation of the biobanks. Although in terms of infrastructure, biobanks are primarily seen as computerised laboratories with substantial cryopreservation and storage capacities, possession of the infrastructure alone is not sufficient for an institution to qualify as a biobank. Biobanks result from the collection of biological samples according to a specified system and protocol, which make them suitable for research. Some banks collect blood, while others collect cell lines, isolated DNA, or human tissue. At the same time information relating to the samples is being stored alongside the very samples. The pieces of information being kept also show great variability depending upon the objectives of the biobank on the one hand and the corresponding legal framework on the other. Despite such conceptual mayhem, biobanks have appeared all over the world in one form or another. Therefore, we would like to argue that the lack of conceptual clarity in the dawn of biobanks has led later to further confusion in the legal concept of biobanks.

THE BIOBANK AS A COMMERCIAL ENTITY?

Another argument that supports our claim that biobanks should be considered a fiction is based on the European legal consensus on non-commercialisation and non-commodification. The Oviedo Convention[5] imposes a categorical ban on the commercialisation of any part of the human body. Its Article 21 specifically stipulates that '[t]he human body and its parts shall not, as such, give rise to financial gain'. The convention enjoys widespread support in Europe, as 27 countries have already ratified it. If someone argued that it is meant as a mere rhetorical statement, the explanatory note of the Oviedo Convention[6] leaves no room for such an interpretation, as in the memorandum it is clarified that '[u]nder this provision organs and tissues proper, including blood, should not be bought or sold or give rise to financial gain for the person from whom they have been removed or for a third party, whether an individual or a corporate entity such as, for example, a hospital'.[7] Only technical types of activity that are performed on the collected organs and tissues (such as their sampling, testing, pasteurisation, fractionation, purification, storage, culture, transport) may legitimately give rise to reasonable remuneration. For instance, Article 21 does not explicitly prohibit the sale of a medical device incorporating some human tissue that has been subjected to a manufacturing process as long as the tissue as such is not sold. Furthermore, this article does not prevent a person from whom an organ or tissue has been taken or extracted from receiving some compensation for the expenses incurred or loss of income. All these elements of remuneration or compensation would not assume any types of banking activity for profit.

The first challenges to the possibilities of commercialisation and the characteristics of the 'bank' in biological sample collections has already appeared in the first internationally known population-based biobank project of Iceland. As the majority of Iceland's population has lived in isolation from the rest of the world for more than 1000 years, researchers anticipated great results from collecting the samples on this island. However, there have been ethical and legal concerns in connection with this scientific and business project from the start.[8] While secrecy and data protection is an essential element of banks, opting out and even broad consent to transactions would be considered as unacceptable in the bank sphere. All these problems already indicated in the very early phase of the development of biobanks that sample donors have a more complex relationship with the collection of the samples than mere one-sided donations and the authorisation for any future use of their samples. The identification of the future scientific utility with the present general public interest simply did not work, and the bank metaphor did not help to see future public utility either.

DO TISSUE DONORS OWN THEIR SAMPLES THE SAME WAY AS BANK ACCOUNT OWNERS OWN THEIR MONEY?

With regard to the ethical and legal issues of biobanks, a number of new legal questions have emerged in addition to almost all the classic problems of medical law. To what extent do the activities of biobanks affect the legal status of human tissues? Is there a danger that future developments will inevitably lead to the situation in which human tissues will be treated as commodities or/and commercialisable goods?

Ever since the announcement of the Human Genome Project, in public debates as well as in legal regulations, the community and the commercial aspects of biobanks were simultaneously present in the case of both biobanks and genetic databanks. Numerous legal attempts have also been made to confer a special status on the human genome, analogous to the idea of considering natural or cultural treasures the common heritage of mankind. The most prominent example in this regard is the Universal Declaration on the Human Genome and Human Rights,[9] a document adopted by UNESCO in 1997. In its Article 1, the declaration introduces a specific legal category in relation to the human genome according to which, in a symbolic sense, it should be treated as a heritage of humanity.

We have already mentioned that in the European context, according to the Oviedo Convention, 'the human body and its parts shall not, as such, give rise to financial gain'.[10] All this, of course, is in reference to the prohibition of commercialisation of human tissues, rather than to the other aspects, such as intellectual property. At the same time, however, it is also apparent that when tissue samples are exchanged for research purposes, or when there is a change of governance at the biobank, this usually gives rise to a legal situation that is similar to the legal transfer of ownership. The question of ownership in connection

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with biological samples has already arisen in several legal cases. One of the most well-known debates of this kind was elaborated in the American Catalona case. In St Louis, Missouri, Dr William Catalona set up a biobank at the Washington University and, in the course of 25 years, went on to collect 3500 samples from patients diagnosed with prostate cancer.[11 12] In this case agreements between the researcher and the donors were overridden by the fact that the biobank has been used by the university for public purposes. This legal solution indicated that the court regarded the sample collection differently from a biobank, and considered it as a public entity that belongs to the university not to the scientist. The ruling was upheld by the Supreme Court in 2008.

THE LEGAL STATUS OF THE PARTIES AFFILIATED WITH BIOBANKS

From the above it must be clear that radically different models exist in connection with the property rights of biobanks. Biobanks reserve for their donors some elements of ownership in the form of the right to withdraw samples and the right to decide what should be done with their own samples.[13]

As a rule, before taking and using biological samples, biobanks are required by the law on data protection and health to provide the donors with information and to obtain their consent. The legal and ethical controversy concerns the question of whether a single, general or open consent is acceptable in the case of the samples' use in different researches and, furthermore, to what extent the various researches can be linked. Because of its practicality, the idea of the so-called 'open consent' has numerous supporters worldwide. According to this model, patients would give a general consent regarding the use of their samples in medical research, without receiving previous notification about the details of the research, which would make it possible to use the same sample in different researches. In our view, from this special trust relationship it follows that as an exchange for broader and, to a certain extent unspecified, use of the biological samples in the open consent model, it would be desirable to compensate the donors by offering them greater involvement in the projects. Sue Weldon,[14] for example, goes as far as advocating the idea of 'scientific citizenship'. In that model, granting access to the samples is based on the principle of solidarity, as the results of later researches will benefit everyone.

BIOLOGICAL SAMPLES AND DATA: DO THEY CONSTITUTE BIOBANKS AND DATABANKS?

Genetic samples, along with any information they can give rise to, belong to a different category of data compared with personal and health care data, which as a rule may be accessible only in special cases by breaking the personal code. It appears now, however, that after the initial period of very strict legal separation, genetic samples are going to share the same fate as personal data: they, too, are about to become subject to data protection laws. It is true that the possession and collection of biological samples are subject to several other property and health law regulations, but the information derived from samples may itself challenge privacy protection. In this regard, the European Court of Human Rights in its ruling in the Marper case[15] had far-reaching repercussions: while it primarily dealt with human-rights guarantees in penal procedures in the context of storing DNA samples taken from criminal suspects, it also touched on the legal classification of genetic samples and data ruling that 'the retention at issue constitutes disproportionate interference with the applicants' right to respect for private life and cannot be regarded as necessary in a democratic society'.[16] In the court's view, all the unlawfully retained information—the fingerprints, the DNA profiles and the sample itself—qualify as personal data under the data protection convention, because each one can be directly linked to the persons suspected.[17]

Within a few years of the creation of the first biobanks, a wide range of new possibilities emerged in anonymisation and coding, accompanied by a dazzling variety of new terminology.[18] This terminological proliferation basically has three main reasons. One stems from the fact that anonymity has a different meaning in legal and in medical practice. It follows from the norm of personal data protection that a sample or data marked with a code cannot be regarded as anonymous, if the breaking of the code reveals the identity of a natural person. By contrast, in medical practice coded samples and data are often referred to as anonymous. Conceptual mayhem also lies in the nature of genetic information. It is well known that the comparison of a DNA sample with another sample from the same person can positively identify that person even without the need for any personal data, which leads many people to think that a genetic sample can never be considered anonymous.

While most of the biobanks work with coded or anonymised data, many people have already been led to question the reliability of the biobanks' claims about the secrecy of their data. Ruth Chadwick is among those scholars who think that it is about time we abandon the idea of guaranteeing privacy, because that is simply no longer tenable in a complex world, where the samples are repeatedly moved, both electronically and physically. It would be much better if we adopted the principle of 'veracity'.[19]

There are numerous signs suggesting that the strict privacy regulation of biobanks is problematical. In addition to the above-mentioned concerns, rejection of the right to privacy is often motivated by the misbelief that the right to privacy is without limitations.[20] Both the Data Protection Directive[21] and the European Convention on Human Rights (ECHR) protect the right to a private life, but also permit interference of the right to privacy provided they are necessary for the protection of health and proportionate to the protection of health.

By contrast, the legal field continues with its demand for full compliance with the rules on the processing of personal data as long as the possibility to link them to concrete natural persons remains. Regardless of the existence of a large number of alternative concepts, such as 'collective' consent, 'open' consent or 'broad' consent, these are not recognised by law and can be considered more as the researchers' wishes projected into the realm of ethics. On top of that, the attempts to soften the law are often based on misunderstandings. The legal regulations of data protection do not apply to data that qualify as anonymous under the law. It is possible to formulate the research objective in such a way that permission is asked to participate in several simultaneous projects, naturally, after clarifying the differences between the various research objectives. Beyond this, however, the use of samples originally collected for studying individuals' genetic susceptibility to cancer but subsequently turned over to research into behaviour genetics, for example, is hardly reconcilable with the self-determination principle postulated in data protection legislation, regardless of the inconvenience of having to ask repeatedly for the donors' consent or to carry out anonymisation. Alternative models have been urged and recommended since the completion of the Human Genome Project. 'To facilitate the discovery phase of genomic research

that is problematic using current approaches, individuals may share their data in a creative commons.'[22] Another model was provided by PXE International: a contractual relationship between researchers and patients to ensure that the products of research conducted with donated tissues will offer benefits to patients with this rare genetic disorder. (PXE refers to a rare genetic disorder, to the pseudoxanthroma elasticum).

FUTURE OF BIOBANKS IN ECONOMIC CRISIS?

In the time of economic crisis, any reference to banks has seemed to be even less attractive models than before, both metaphorically and strategically. The widely used term 'biobank' not only blurred the boundaries between the human rights-based norms in the field of biomedical research and the commercial legal norms, but have also contributed to the transformation of biomedical disciplines into new commerce-oriented fields.

It seems that biobanks have not yet fulfilled the great hopes they had initially inspired; their focus and methodology, along with their basic concept, will probably have to be revised from time to time. One of the conceptual problems concerns an overemphasis of the genetic aspect at the expense of a complex approach to the analysis of the individual environmental factors. Although many people think of biotechnology as a key emerging industry, we need to point out that biobanks themselves will not—and in fact under the law cannot—be profitable.

Their relatively limited success so far is partly linked to legal problems. As at the moment it is still uncertain how the—sometimes unduly—strict restrictions of data protection will be reconciled with the broad research use of genetic samples and information stored in biobanks, the existing research cooperations stand on a shaky foundation. Parallel to this, biobank donors are also changing their attitudes towards their biological samples. New biosocial group identities are established, and perhaps this will initiate a more active role of the participants in biobank research. Groups of people sharing the same genetic and medical conditions may form interest groups worldwide, often with wealthy investors interested in biotechnology. As a result, biobanks may be established from the bottom up, in accordance with the interests and needs of the people concerned. This latter model will probably give rise to less legal concerns and more autonomy than the former. Interestingly, these bottom-up initiatives do not use the word 'bank' but refer to more humanised biosocial identities. In other words, they refer to the specific group of donors rather than to the particular structure of the collection. They respond to collective and public interests instead of commercial and private ones. Good alternatives, perhaps, to the 'bank approach'.

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