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PROCEEDINGS

Biobanks as basis for personalised nutrition? Mapping the ethical issues

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Definition—biobanks that are the focus of our attention

Biobanks are defined as "collections of samples of human bodily substances (e.g., cells, tissue, blood, or DNA as the physical medium of genetic information) that are or can be associated with personal data and information on their donors. Biobanks have a twofold character, as collections of both samples and data [1]".

In this context, the terms "data" and "information" mean the (genetic) information *o*f individuals obtained from these samples as well as health-related and life style-related information *about* these individuals. This *linkage* of material samples with personal data and information, the *two-fold function* of biobanks, is what makes these collections of samples so important.

The subject of this article is biobanks that have been set up or that are used for *research* purposes. Biobanks that are operated for the purpose of transplantation medicine are not my subject here. Being a member of the German National Ethics Council that has written an opinion on biobanks for research, I will draw upon my work for and within the Council as well as on our opinion *Biobanks for research*.

Procuring, storing, handling and utilizing human biological material and the associated personal data that were gathered with the samples constitute a long-standing practice. This practice, however, is currently undergoing considerable technological change due to the increasingly improved means available to *molecular genetics*. There is hope that it will be possible to establish correlations between genetic make-up and physical condition through the large-scale collection and comparison of human biological material and the personal data and information associated with it—correlations that could lead in the long term to valuable *diagnostic* and *therapeutic knowledge* and that could be also useful for *pharmacogenomics* and for *nutrigenomics*.

It could also lead to insights into characteristics that are particular to *specific groups, communities or populations*. Thus, establishing (large) biobanks could be of decisive importance to the development of the life sciences, medicine and health care. Biobanks should serve both the *well-being of individuals* and the *public interest*.

In addition to the developments seen in the molecular genetics field, another important aspect here is the continually improving means available for the *computer-aided processing* and *electronic transmission* of personal data and information. As a result of this technology, personal data and information have the status of existing independently in time and space, so to speak. Although this type of data is acquired from actual biological material, it can be disseminated and utilized rapidly and globally with the help of electronic media. In view of the *information content* of biobanks, we could also speak of *biolibraries* ("biothèques"), a term that is sometimes used in France, for instance by the French National Ethics Committee CCNE [2].

Biobanks are not just a source of hope for the future; they also trigger fear and distrust in people. The question arises, whether, to what extent and in what ways can biobanks affect fundamental *rights of individuals* or of *communities* and *populations*. I am defending the claim

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that biobanks *require special regulation*. What are the particular reasons for this need and what specific ethical and legal problems exist in this connection?

Reasons why biobanks require special regulation

One of the central points of the discussions has been the issue of *donor protection*, the *applicability* of the principle of *respect for free and informed consent* and the issue of whether donors' right to determine the disclosure and the use of his personal information ("informational self-determination") can be protected in connection with biobanks. The principle of respecting the *individual's autonomy* or *self-determination* is an inalienable and internationally recognized ethical and legal principle. This right can also be endangered by modern electronic techniques. Data linkage can yield information of a quantity and quality beyond those envisaged when the donors gave their consent.

Certain biobanks have special features that give rise to questions concerning the applicability of the principle of free and informed consent and about ensuring informational self-determination. Biobanks are supposed to store human biological material and data and information from and about individuals on a *long-term basis*. During this time a number of new research objectives could arise that go beyond the primary research objectives for which patients and donors gave their consent prior to providing samples. These new objectives were not foreseeable at the time that the original consent was given and therefore the donor could not have issued any specific consent for them.

These questions can involve collections of human biological material which were established *in the past*, possibly many years ago, as part of specific diagnostic and therapeutic measures and have since acquired incalculable value to research due to the development of new means of genetic engineering. In other words, the purpose of such *collections as a whole* can *change* and be *transformed* from being biobanks for diagnostic and therapeutic purposes into biobanks for research. Many donors may have even *died* in the interim. How should we deal with biobanks of this type, looking at them from the standpoint of free and informed consent and the protection of informational self-determination? Data and information can be pooled from *a variety of data sources*. The Icelandic project offers a typical example of this. This data linkage "may yield information of a quantity and quality beyond those envisaged when the donors gave their consent [3]".

Genetic data in particular contain information not only about the donor of the biological material but also about the donor's *genetic relatives*. Do these persons also have to be asked for their consent before an individual donates biological material?

Biobanks are "activity complexes" with various areas of activity or figuratively speaking—with *different* "*departments*", namely, the *procurement, storage, handling and utilization* of human biological material and the data and information associated with them. These four areas are not linked with one another *per se*; rather they often are divided for reasons of organization. In the case of large biobanks in particular, each of these areas can have *specific actors* who are not identical with the actors in the other areas. "The question arises of how to provide for a consistent 'chain of responsibility' to ensure observance of the rules—in particular, those of donor protection—at all levels of the organization [4]."

How can diffusion of responsibility be avoided?

Who should be given access to biobanks and under what conditions samples and data may be transferred and exported?

What is to be done with the stored tissue samples and data when a biobank is closed down?

Free and informed consent, the right to informational self-determination

As a prerequisite for applying the principle of free and informed consent, a *concrete stated objective* for the procurement, storage, handling and utilization of human biological material and personal data and information must be cited *before* they are collected. However, there can be circumstances under which the principle of free and informed consent either cannot be applied at all in this way or only with difficulty. This can also be the case with biobanks due to their respective special features. This gives rise to the question of the ethically justifiable and legally permissible *material scope of consent*. In the course of our discussions within the German National Ethics Council and our cooperation with our French colleagues, we have talked about the *conflicted relationship* between the principle of free and informed consent and researchers' interest in being able to conduct projects as quickly as possible and with as little hindrance as possible—the latter being something that not only accommodates scientific and economic interests but should also be in the public's interest.

Interests have to be weighed against one another here. A decision has to be made whether *research* should make certain concessions to this principle or whether concessions should be made to research when *consent* is granted. Allowing the donor to grant blanket consent for all future research projects whose stated objectives are not foreseeable at the time the donation is made would constitute an enormous concession to research. Advocates argue in favour of this solution, trusting in the integrity of the researchers. This group has its eye focused on smoothly

running projects. Critics on the other hand point out that the degree of concessions is dependent upon whether and to what extent the spirit of the principle of free and informed consent—namely, protecting the donor and safeguarding his rights of personality—can be guaranteed in ways other than through the granting of express consent for each individual and concrete research objective. In this connection, calls are being made for *confidentiality of research*—in analogy to patient confidentiality—which scientists would have to obligate themselves to observe. The type of consent would also have to be made dependent on the level of identification of the samples, data and information, since this determines the degree of risk that rights of personality might be violated. Stripping data of all identifiers (deidentification or anonymization) would be counterproductive in many cases because research findings might make it necessary to return to the donors with new questions in order to advance our knowledge.

In addition, it is conceivable that there are areas in which the free and informed consent of *individual donors* for the procurement, storage, handling and utilization of samples and personal data is not adequate because a *new quality of information* results from the *linking* of data from many individuals. This new quality of information also includes a new dimension of potential for abuse and for the discrimination and stigmatization of groups, communities or populations. The relationship between the *rights of the individual* and the *public interest* requires clarification here.

A public debate on all these issues must be initiated in our countries, a debate in which special attention must be paid to the protection of *persons who are unable to give their consent*.

An unbroken "chain of responsibility": the role of a custodian as an institutional safeguard

The principle of self-determination of the individual is so fundamental that it must be regarded as a point of view that structures the previously mentioned fields of activity (procurement, storage, handling and utilization of human biological material and of data and information). This principle, however, can only become operative when there is an unbroken "chain of responsibility" (une "chaîne des responsabilités" [5]) and when the various fields of activity are regulated on a *coherent* basis. The capability to assign responsibility also entails the capability to *hold accountable* for abuse. Given the complex organizational structure of biobanks, thought should be given to creating the position of a *custodian* or "trustee". This person would coordinate the various activities involved in biobanks and be responsible for ensuring that high standards are maintained.

This trustee could hold a *central, linking function* within the system. His task could consist of ensuring that *ethical principles* and *legal regulations* that are aimed at protecting donors and their data relevant to the particular area are observed in each of the said areas in accordance with the consent issued by the donors. The custodian could also oversee *access* to biobanks and ensure that human biological material and information are handed out solely for the purpose of scientific research—in other words, not to employers, insurance companies, the police or similar offices. In the case that biological material and related information are to be issued for research purposes, he would have to ensure that this is done only in a way that is consistent with the consent issued by the particular donor. This trustee would also have to regulate access to biobanks under due consideration of various aspects of *fairness*. For example, this would mean preventing monopolies from using biobanks. And lastly, in the event that a biobank ends its operation, a custodian could also have the job of preventing the improper use of the human biological material and information stored there. Being advised by an ethics commission could be useful in individual areas of his work.

Each rule and regulation should take the different sizes and structures of the individual biobanks into account. This also applies to establishing the position of a trustee and his authorization. In the case of smaller biobanks a trustee in addition to the data protection officer might not be necessary.

In addition the involvement of *ethics committees* should be expanded beyond current practice. "The involvement of an ethics committee and the requirement of its approval are intended to ensure that a narrowly worded consent is not exceeded that a consent in broad terms is not inappropriately given an even wider interpretation, and that exceptional circumstances in which consent may be waived are not illegitimately invoked [6]".

Limits on the commercialization of the human body—benefit sharing—new solidarity issues

Collecting large amounts of samples, data and information for research purposes opens up a new set of problems, which involve issues of *solidarity*, *altruism* and *social justice*. Human biological material and related data and information can be particularly valuable to research when they are available in large quantities. Individuals, groups, populations and countries donate them for biomedical research that is conducted in the public interest. The findings produced by this research and the therapies that are developed from them—such as medical drugs—offer *commercial benefits* to *research* and *industry*. On the other hand, the principle that the human body cannot be commercialized applies in many countries. International

guidelines also build upon this principle. As a consequence, it is possible that all parties involved (such as researchers and industry) reap economic benefits from research that is based on the donation of samples—that is, everyone except for the altruistic donors themselves, be they individuals, groups or entire populations. For this reason, one has to raise the question, what limits does the principle of the non-commercialization of the living body as well as the high value of unpaid donations of samples and data in the name of solidarity place on benefit sharing. Ways to regulate benefit sharing are currently being discussed at the international level, and there is an awareness of the risks involved in benefit sharing: the notion that human biological material and data made available to a biobank bear the character of a donation for research could be undermined were donors to have an individual claim to the products resulting from the research or were they to receive a financial consideration in return for their donation. However, one might consider whether *other forms of benefit sharing* might be conceivable. The guiding idea behind the suggestion of benefit sharing is that although payment of direct financial consideration to the donor should be out of the question—in other words, donors should not have a share in the economic profits derived from the industrial exploitation of findings developed on the basis of their samples—nonetheless the question should be asked whether the benefits arising from this research should not also benefit—in the broadest sense of the word—those who donated samples. This could take the form of contributions to public welfare funds, which could be located and organized at different levels. Those who gain economic benefits (industry, researchers, etc.) could support project-related funds, disease-related funds, group related funds, national and international funds. They could also provide an easier access to drugs and to health care.[1]

Summary

A new framework must be developed for biobanks to bring the development and use of research into line with the protection of the individual and of groups. When developing this framework, care must be taken to gear it to the fundamental principle of respect for human dignity, the principles of medical ethics [autonomy, the patient's welfare, *primum non nocere* (the physician's precept of "first, do no harm"), fairness] and other standards and regulations that are of relevance in this context. This is a task that must be tackled at the international level as well.

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[1] Cf. for example, the Statement on Benefit Sharing issued by the HUGO Ethics Committee on 9 April 2000. This statement recommends "that profit-making entities dedicate a percentage (e.g., 1–3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts".