

## BIOBANKS UNDER ITALIAN LAW:

### PRINCIPLES AND GUIDELINES FOR COLLECTION OF HUMAN TISSUES FOR SCIENTIFIC AND MEDICAL PURPOSES

## Biobanks under Italian Law: Mind the Gap!

In Italy, there is no law specifically addressing the issues raised by biobanks. In fact, there are no legal provisions governing the collection of human tissues for scientific and medical purposes, except for the collection of blood and organs for transplantation. Nevertheless, some important private biobanks do exist in our country, and some scientific entities are carrying out genetic research projects involving small isolated communities, such as the populations of Cilento and Vallo di Diano, near Naples, and in Sardinia, aimed at discovering the existence of genetic factors that may cause certain serious illnesses. These activities are currently subject to rules and guidelines mainly deriving "soft law", such as non-binding recommendations issued by international organisations or opinions published by international and national ethics committees or guidelines issued by medical and scientific associations. Therefore, there is no definition of "biobank" in the Italian legal system. We therefore must refer to a definition elaborated in 2006 by the Italian National Committee for Biosecurity and Biotechnology, according to which "genetic biobanks" are collections of human samples, that can be linked to the anagraphic, genealogic and medical data of the persons from which they have been extracted. The possibility of correlating genetic and other personal data makes this information "personal" in nature, so that the data protection legislation would apply to the processing of medical and genetic data in the context of the functioning of a biobank. Nevertheless, Italian law has not yet established a specific legal framework governing genetic data.

In particular, in 1999<sup>1</sup>, law no. 135 had granted the Data Protection Authority the power to issue, within the following twelve months, a specific regulation authorizing certain categories of persons to use genetic information<sup>2</sup>, but no provision was enacted until 2003, when the new Privacy Code came into force (legislative decree 196/2003) and renewed the mandate to the Italian Data Protection Authority. Finally, the general authorization was enacted on 22nd February 2007.

An initial observation concerns the choice of administrative instrument, such as an authorization by an independent authority, to govern this subject matter, considering that the law has not given any specific indication about the contents of the authorization. This circumstance raises some concerns as to the compliance with the rule of law, especially on such a sensitive matter, which involves individuals and their fundamental rights.

<sup>1</sup> Art. 17, par. 5, of legislative decree n. 135 of 11 May 1999 (which contains "provisions concerning the treatment of personal sensitive data by public entities") specifically regards genetic data: "The treatment of genetic data, regardless of who processes it, is permitted only when specifically authorized by the Guarantor, after hearing the opinion of the Ministry of Health, who requested the opinion of the Higher Health Council for this purpose. Treatment authorized by the Guarantor may be continued until the issue of the authorization provided for in this article, which must be issued within twelve months".

<sup>2</sup> Authority set up under law n. 675 of 31 December 1996: Protection of persons and other parties for the processing of personal data.



The second remark regards the definition of “genetic data” chosen by the authorization; in fact, it refers to the definition provided for by the Recommendation of European Council 1997 (5), which is particularly broad as it includes under the category of “genetic data” all information, of any nature whatsoever, concerning the hereditary characteristics of an individual or concerning the pattern of inheritance of such characteristics within a related group of individuals. This choice means that information about family medical history must also be included in the definition, with all the problems which this would imply with respect to the utilization of such data by insurers and employers.

The general authorization established the only situations where genetic data, as previously defined, may be processed: in particular, they may be processed exclusively

- 1) for medical and scientific purposes;
- 2) in order to enforce a right in court;
- 3) in order to fulfil legal obligations related to social security and safety in the workplace.

In any case, the processing of genetic data must be indispensable, or in other words the same purposes may not be attainable through the use of anonymous genetic data or other kinds of personal information. Therefore, a scientific project that uses genetic data, when this is the only way to allow the research to be conducted, would fall under the scope of the authorization.

With specific reference to biobanks, the privacy issue has to be analysed with respect to two different activities: the collection of genetic data and the storage of such data. In fact, with reference to the collection of genetic data, what the authorization mainly requires is compliance with the principle of informed consent: this means that the person must issue a written consent after having been provided complete information on the purposes and the methods of the processing, the duration of the storage of the genetic data and samples, the possibility that the data and samples may be used for other purposes, and any other relevant information. In addition, the person undergoing a genetic test must be granted the right not to know the results, in order to avoid potentially serious psychological consequences, in case of unexpected results.

In fact, even if the right not to know has not yet been expressly faced under specific provisions of Italian law, it is addressed in the medical Code of ethics, that requires the physician to honour documented will of the patient not to

be informed (art. 30)<sup>3</sup>; in addition, art. 90 of the Privacy Code makes reference to this principle providing that “The authorisation ... shall also specify the additional items of information that should be included in the disclosure ... with particular regard to the purposes sought and the results to be achieved also with regard to unexpected information...”. Therefore, from the implementation of the principle in this context, one can infer that the right not to know must be taken into account, because it represents an enhancement of personal autonomy. However, it is not an absolute right, in the sense that it may be restricted when disclosure is necessary in order to avoid risk of serious harm to the patient himself or to third persons, and the related assessment of each case is up to the physician<sup>4</sup>.

With reference to the second phase involving the storage of genetic data, even if the authorization establishes a complex security system to ensure that the information remains confidential, including a coding process, the availability of a large amount of genetic data may give rise to possible conflicts between the right to privacy of the data in question and opposing third party interest in gaining knowledge of such information; in fact, while it is not possible in any way to test a person without his consent since, under Italian law, art. 13 and 32 of the Constitution protect people against any kind of restriction of personal liberty, when it is not authorized by law or a court of law, in a biobank lots of genetic identifiable data is recorded for long periods of time, and therefore they could become known without the need to test person in question again.

The main scenarios in which conflicts could potentially arise would occur within medical and legal contexts. The first one is well exemplified by one of the first statements in Europe made in 1999 by the Italian Data Protection Authority, which authorised a woman to have access to her father’s genetic information without his consent in order to make a mindful reproductive choice: in that case the woman asked the hospital for her father’s genetic information and the hospital rejected her request; so she decided to demand the Data Protection Authority to let her access the information. The reason underlying the Authority’s permission was the fact that the need to protect the psycho - physical well-being of the woman was found to prevail over her father’s

<sup>3</sup> Art. 30: “La documentata volontà della persona assistita di non essere informata o di delegare ad altro soggetto l’informazione deve essere rispettata”.

<sup>4</sup> Cfr. R. Andorno, The right not to know: an autonomy based approach, in *Journal of Medical Ethics* 2004, 30, 435-439.



right to privacy. This case shows that the right to genetic privacy can not be conceived as an absolute right since, on the one hand, the right of an individual to keep his own genetic information secret is superseded by opposing fundamental rights such as health, and, on the other hand, the interest of a person to know his own genetic features, when this requires the knowledge of one of his relatives' genetic inheritance, must be filtered through other fundamental rights, in order to be granted. As a consequence of this decision, the authorization provides that genetic data may also be processed without the consent of the person in question (whose data is being used), in order to protect another person's health or to allow another person to make a mindful reproductive choice.

Another scenario involving conflicts could arise in the legal context, or in other words between defending the confidentiality of medical and genetic data and requests to use such data in legal proceedings (not only criminal proceedings, as in the case of the identification of perpetrators of criminal offences but also civil proceedings such as paternity suits). This circumstance is especially critical in Italy, which is one of the very few countries in Europe that has not yet created a genetic databank for forensic purposes, and therefore the public authorities may often need to access the stored samples in order to extract genetic profiles.

In these situations, the general authorization allows lawyers to access the information in order to investigate in accordance with law 239/2000, even without the consent of the person in question, provided that the following conditions are met: 1) the right which must be defended in court is deemed to rank, in terms of importance, substantially at the same level as right to privacy<sup>5</sup>, 2) the data will be processed only for that purpose and 3) only for the time necessary to achieve that purpose. With regard to the construction of the term "equal ranking" of the right sought to be defended, the following is worth noting: the Data Protection Authority in 2003 issued a circular letter clarifying that a public or private body that receives a request for access by a third party must examine, on a case by case basis, the actual substantive rights involved, and only after a review on such basis decide which right should prevail each case in question. The only indication provided for under Italian law regards the prevalence of rights of personality over all other interests.

<sup>5</sup> This provision was already contained in law 675/1996 and law 135/1999 (art. 16), and now art. 60 (and 26 for private entities) of the Privacy Code with reference to sensitive personal data. This principle was also applied by Consiglio di Stato n. 5873/2004 and Tar Campania n. 650/2007.

These provisions imply that the public or private body that keeps a biobank must balance opposing interests and issue a decision on the access to the requested information on a case-by-case basis. Therefore, in the absence of more specific guidelines, and with the increasing availability of stored genetic data, it is likely that the Data Protection Authority and the courts will often be requested to intervene in such cases of conflict.

So far, we have focused upon the circumstance that the privacy issue is the only one to be addressed by Italian law on the matter of biobanks for scientific purposes: this implies that the collection and storage of human samples is not regulated "per se", but the human tissues are considered by law only as "carriers of genetic information". This explains why the authorization often uses the terms "data" and "tissue" interchangeably, starting from the definition of a biological sample as a "container of genotyping information which characterizes an individual". Thus, although on the one hand, all of the guarantees on data security set out under the Privacy Code and under the general authorization have been extended to cover also biological samples, on the other hand, there are no legal provisions addressing the matter of scientific research performed using human samples.

In reality, the Italian legal system requires the consent of the person in question prior to undergoing any medical treatment, in accordance with the principle of informed consent in medical practice, which derives directly from art. 32 of Italian Constitution<sup>6</sup>. However, this provision is not enough, because it does not prohibit the collection of human samples that are already available (and therefore do not need to be taken from an individual) without the person's consent authorizing their use in a scientific research project. We also note that although Italy ratified the Oviedo Treaty<sup>7</sup>, which expressly requires the individual's consent prior to his participation in any scientific research (art. 16) and prohibits the use of any part of a human body removed over the course of an intervention unless the appropriate disclosure and consent procedures are followed (art. 22), it did not establish the means of ratification. Therefore, the process has not been completed and the Italian government has yet to issue the decrees necessary to implement the treaty in our legal system.

<sup>6</sup> Together with art. 2 and art. 13 Cost., according to which personal liberty is inviolable. See Constitutional Court dec. 438/2008.

<sup>7</sup> By law 145/2000.



It is possible that the Italian legislature attempted to fill this gap regarding the principle of informed consent in this context, on the occasion of the implementation of the directive 98/44/EC, concerning the patentability of biotech inventions, effected through law 78/2006<sup>8</sup>. In fact, art. 5, sec. 3, of this law provides that where an invention is based on biological material of human origin, the patent application must include a document certifying that the person from whose body the material had been taken had expressed his/her independent and informed consent to his/her participation in the research<sup>9</sup>.

Of course, this is an unusual way to establish such a principle, proving that the Italian legislature still must take important steps in order to fill all the relevant gaps in the regulation of biobanks.

In conclusion, various issues related to biobanks are not still covered by Italian law and this gap may give rise to risks of violation of fundamental rights such as the right to personal autonomy, as well as uncertainties that may discourage scientific research. Therefore, what is really necessary is an organic regulation which guarantees security and quality standards in the storage of human samples through the establishment of ethical and operational standards, agreed upon at the international level.

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<sup>8</sup> This law is quite restrictive, since it introduces new limitations with respect to the directive, probably because our legislature seized this law as an the opportunity to attempt to regulate some issues still not covered under Italian legislation, such as informed consent and genetic discrimination.

<sup>9</sup> Besides that, art. 4 of the law 78/2006 adds new limitations to the patentability of biotech inventions: while the directive established that inventions shall be considered non-patentable only where their commercial exploitation would be contrary to public order or morality, under Italian law, inventions shall be considered non-patentable also where their commercial exploitation would be contrary to human dignity (and the protection of human and animal health, biodiversity, etc.).