

**Privacy and Research involving Genetic Databases and Biobanks:
Attitudes across the southern region (Cyprus, Greece, Israel, Italy,
Malta, Portugal and Spain)
Preliminary Report**

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INTRODUCTION

Comparing attitudes related to research with genetic data in such group of countries too different could be a very hard work. But it became very simple because in most of them there is not any systematic survey about the understanding of people towards genetic data. But, we cannot say the same when we are analysing the different legislation — every country have some kind of legislation about the right to privacy, or about data protection, and sometimes also about genetic data and biobanks.

1. *ATTITUDES TOWARDS GENETIC INFORMATION*

There is not any formal study about people attitudes towards genetic issues or genetic data. But in general Cypriots have always been positive in participation in genetic research projects and sharing private information with the researchers¹. They feel they can share information especially when they have personal or family interests in dealing with familial cases and inherited conditions that may involve either themselves or their children. The attitude is different when people are asked to participate in genetic research projects — much people get suspicious and less enthusiastic in taking part, even though all measures are taken for protection. Something equivalent is going on Malta where the first attitude is “fear” of genetics, especially when the subject is related to reproductive technology, possibilities of embryo selection and prenatal genetic diagnosis and stem cell research. But if we speak about these issues this “fear” appears also in a large percentage of population in Portugal; something like Spain where have been made a lot of studies that show that most people are reserved to share their genetic information with others, especially with regard to the wider public domain – for example, industry and insurers and employers. These studies also show that people are more willing to share their genetic information with scientific researchers than with

¹ The provision of a signed informed consent form is nowadays a *sine qua non* condition for any research Project in the health sciences.

their relatives. To sum up, these studies suggest that although many people anticipate negative consequences of genetic developments, the great majority have high expectations about the increasing use of genetics in prevention, diagnosis and treatment of diseases. In Portugal, as in Greece, there is not any sociological study about this. We only can say this when we try to analyse the newspapers. But we always can say that they are “professionals of the fear”. However, some relevant work on these issues was already made by *Conselho Nacional de Ética para as Ciências da Vida - CNECV* (National Council of Ethics for the Life Sciences)². For example, the *CNECV*, on Opinion 43/CNECV/01³ on the project of law about personal genetic information and information regarding health (“Projecto de Lei n.º 28/IX) defined a concept of individual privacy from the ethical point of view: “Individual privacy: from the ethical point of view, it matters the protection of individual freedom, defining a zone of personal life virtually not accessible to any external intrusion. The term “privacy” may include four different dimensions: a) *Physical Privacy*, this meaning the limitation of physical accessibility, of any kind, without self-consent; b) *Mental Privacy*, this meaning the restriction of any illegitimate interference on person’s mind or will; c) *Decisional Privacy*, which is referred to the freedom on individual choice; and d) *Informational privacy*, reached through the imposition of limits to the non-authorized access to individual information”. And in Italy genetic privacy and bio-banking have not been the subject of widespread discussion⁴.

Very interesting is the opinion on bio-banks from the National Bio-Ethics Committee of Italy: “as well as ensuring respect for individuals’ rights and private life, bio-banks might become instrumental to a new type of solidarity among social groups and generations, based on the voluntary sharing of samples and information – a sort of common resource that should be available in compliance with democratic participation principles.” As well as to protect one’s life and health, the need to reconcile interests is generally acknowledged in respect of the processing of genetic data for socially relevant purposes of medical and scientific research (as based on the provisions contained specifically in legislation). Careful attention is also paid to pharmacogenetics and pharmacogenomics, providing the use of genetic information increases the beneficial effects of treatment and reduces the risk of adverse effects (according to the “doing good” and “avoiding harm” tenets) and there is no risk of falling into the “genetic reductionism” trap .

2. LEGAL APPROACHES TO PRIVACY

The right to privacy is protected in all legislations – and it begins with a Constitutional protection. And there is some Constitutions as Cyprus Constitution where there is also an express Constitutional protection of the secrecy. This is a consequence of the Universal Declaration of Human Rights, and also from the Oviedo Convention that is ratified by Cyprus, Portugal, Italy and Spain. Israel has also a specific law to the

² An independent body created in 1990 by Law no. 14/90 of the 9th of June for the purpose of "analyzing systematically the moral problems which arise out of scientific progress in the fields of biology, medicine or general health care".

³ Available in www.cnecv.gov.pt.

⁴ But there are several documents from National Bio-Ethics Committee or from National Bio-Security and Bio-Technology Commission or from Italian Data Protection Authority which have been addresses a lot of rules about genetic tests, prenatal diagnosis, processing genetic data for medical purposes or for justice purposes. Some kind of rules which are in Portuguese law – Law n.º 12/2004 about health and genetic information.

protection of Privacy (The Protection of Privacy Law of 1981)⁵. Another important document to the harmonization of the right to privacy was the European Directive for data protection – it is the main source to every protection law in each country. In Portugal the protection is extended to the Civil Code which means that every person could be compensated when his privacy has been violated.

Concerning health information the Safeguarding and Protection of Patients Rights Law (2004) is very complete. It states: “(1) There can be no intrusion into a patient’s private and family life, unless with the patient’s consent and if this is deemed necessary for his diagnosis, treatment or care. (2) Health care shall only be provided with appropriate respect for the patient’s private life and shall, as a rule, be given in the presence only of those persons who are necessary for the provision of health care. (3) A patient admitted to a medical institution shall be entitled to facilities or arrangements which ensure the protection of his privacy, particularly when the medical or nursing staff is providing personal care or carrying out medical tests or other treatment.”

In Italy’s legal system, informational privacy is basically shaped similarly to what is the case in other European countries. But the concept of “privacy” – which has been translated into several Italian words, meaning more specifically “confidentiality” or “discretion” – is not clear-cut, nor are there clear-cut guidelines to establish whether a person’s privacy has been violated; indeed, this assessment is often based on the balancing of the interests at stake following a case-by-case analysis.

The concept of privacy developed thanks to case law, in particular with regard to freedom of expression and – more specifically – freedom of the press. The development took place in the context of the broader concept of “personal rights” – which is somewhat blurred as a definition. However, privacy as a personal right had to carve out its place among the principles recognised by case law in Italy. Initially, the view taken by courts was mostly that “no legal provision allows us to believe that there exists a general principle stipulating the absolute respect for one’s private life.” It was only after 1963 that privacy – meaning the “right to free self-determination in man’s development as an individual” - was recognised in connection with some leading cases; however, in 1975 the Italian Supreme Court (Court of Cassation) ruled that it was inappropriate “to set out stringent, detailed features for the right to privacy, because they would hamper the flexibility required for adjusting the specific contents of that right to the different requirements arising out of different circumstances, areas and periods.”

As for definitions, the recognition by law of the “right to privacy” became finally a reality when the Italian data protection Act was passed (Act 675/1996); however, the Act specifically addressed a different subject matter, i.e. the protection of personal data – according to the so-called “informational privacy” approach, which is other than the conventional “disclosural privacy”.

In Portugal there is a very important jurisprudence from Constitutional Court. The Portuguese Constitutional Court has very recently, solemnly and publicly (in Decision number 442/2007, of August 14), acknowledged the existence of “three manifestations into which the content of the right to the reservation of the intimacy of private and family life is divided – the right to isolation, the right to anonymity and the right to informative self-determination”. The Court also declares that “(...) both in Article 26 of number 1 of the Constitution of the Republic and in Article 80 of the Civil Code, a generic right to reservation is consecrated, which includes the extent of private

⁵ But the right to privacy has been elevated also to the level of a statutory basic right. And the right to privacy is also protected in the Patient-s Rights Law (1996) and in Genetic Data Law (2000) where have been imposed limits to the disclosure of DNA (private) information.

life. The formula “reservation of the intimacy of private life”, used in both the norms, may not, thus, be interpreted in the sense of confining the power of protection to a certain part of private life – intimate life, as an essential part of private life”.

It is possible to refer that, in Portuguese legal norms; the specificity of the protection of genetic privacy has been moulded in Law number 12/2005, of January 26 (law about personal genetic information and information regarding health).

This law, which not only deals with the protection of personal genetic information, as it was mentioned above, intends to regulate: the concept of information regarding health and of genetic information, the circulation of information and the intervention on a human genome in the health care system, but also with the rules for the sampling of and the conservation of biological products for genetic testing or research.

In the terms of number 1 of Article 6, “genetic information is the information regarding health which deals with the hereditary characteristics of a single person or various people, related amongst themselves or with common characteristics of this kind. From this definition is excluded the information taken from tests of consanguinity, studies of zygosity in twins, studies of genetic identification for criminal purposes, as well as the study of physical genetic mutations in cancer”.

It is difficult to say that the legislator, with the emanation of specific rules about the protection of personal genetic information, had the intention to produce an alteration in the general concept of privacy or of the reservation of the intimacy of private and family life, if one wishes to be more rigorous.

It is certain, however, that he has attended to the specificity that this kind of information contains, which has led him to affirm, in number 6 of Article 6 of the referred Law number 12/2005 “genetic information should be subject to legislative and administrative measures of reinforced protection in term of access, safety and confidentiality”.

It is also determined that:

a) “the clinical records of consultations or services related to medical genetics may not be accessed, authorised or consulted by doctors, other health care workers or other employees from other services in the same institution or other institutions of the health care system in case they contain genetic information about healthy individuals” (Article 6, number 5);

b) “the use of genetic information is an act between its holder and the doctor, who is subject to medical deontological norms and the remaining health care workers' professional confidentiality” (Article 6, number 7);

c) “the citizens have the right to know if a clinical record, file or medical record or research record contains genetic information about him/herself and his/her family and to know about the purpose and the use of this information, the manner in which it is stored and the duration of its conservation” (Article 6, number 8);

d) in relation to gene therapy, “medical intervention, whose objective is to intentionally modify the human genome may only be accomplished if the conditions established by law are verified, for preventive or therapeutic reasons” (Article 8, number 1) and that “any medical intervention whose objective is the genetic manipulation of characteristics considered as normal, as well as the alteration of the germinative line of an individual is forbidden” (Article 8, number 2);

e) “the communication of the results of genetic tests should be accomplished exclusively to the patient him/herself, or, in case of diagnostic tests, to the one who legally represents him/her or who is indicated by him/her, and within an appropriate medical consultation” (Article 9, number 3);

f) “in the case of state of heterozygousness, presymptomatic and predictive tests, the results should be communicated to the patient and may never be disclosed to third parties without his/her permission expressed in writing, including doctors and other health care workers of other services or institutions or of the same consultation or service although not involved in the testing procedure of this patient or of his/her family” (Article 9, number 4);

g) “in the case of prenatal or preimplantatory tests, the results should be communicated solely to the progenitor, the progenitors or respective legal representatives” (Article 9, number 5);

h) “nobody may be prejudiced, in any way, in case of having a genetic disease or due to his/her genetic heritage” (Article 11, number 1);

i) the insurance companies may not use genetic information to condition the conditions present in the insurance contract” (Article 12);

j) the patronal entities may not take advantage of genetic information regarding its workers (Article 13) and it may only be used in the “benefit of the worker and never to prejudice him/her, as long as the protection of the individual's health, his/her and the remaining workers' safety is safeguarded, that the genetic test be carried out after informed consent and after appropriate genetic counselling, that the results be handed exclusively to the patient and also as long as his/her working condition is never put at stake” (Article 13, number 3);

k) “genetic tests may not be requested, nor already existent genetic information be used for adoption purposes” (Article 14, number 1);

Law number 12/2005, of January 26, also defines the concept of “genetic database”, considering it to be part of the category of “any record, computerised or not, which contains genetic information about a group of people or families” (Article 7, number 1), that “the genetic databases which contain family information and the genetic records which allow the identification of relatives should be maintained and supervised by a doctor specialised in genetics or, if this is not possible, by another doctor” (Article 7, number 3), and that “any individual may request and have access to the information regarding him/herself contained in the files with personal data, in accordance with the law”.

In the same legal document, the concept of bio banking, or “bank of biological products” is also defined, determining in number 1 of Article 19, that “for the purposes of this law, the “bank of biological products” is understood to be any repository of biological samples or of its by-products, with or without a set duration for its storage, whether it uses prospective sampling or previously sampled material, whether it was obtained as a component of the routine rendering of health care, whether in screening programs, whether for research and that it includes samples which may be identified, identifiable, anonymised or anonymous”. It is also established that “the banks of biological products should only be constituted with the purpose of rendering health care, including the diagnosis and the prevention of diseases, or basic research or applied to health” (Article 19, number 3) and which “should always guarantee privacy and confidentiality, avoiding the storage of identified matter, controlling the access to the sampling of biological matter, limiting the number of people authorised to do so and guaranteeing its security regarding loss, alteration or destruction (Article 19, number 8).

Regarding the conditions for the anonymisation of the samples, the following is established:

1) “only anonymous or irreversibly anonymised samples may be used, the identified or identifiable samples should be limited to studies which may not be accomplished in any other way (Article 19, number 9);

2) “the storage of non-anonymised human biological matter by the entities for commercial purposes is not permitted;

3) “in case of an absolute necessity to use the identified or identifiable samples, these should be given a code which should be stored separately, but always in public institutions (Article 19, number 11);

4) “if the bank involves identified or identifiable samples and the possibility of the disclosure of the results of the accomplished studies is foreseen, a doctor specialised in genetics should be involved in the process” (Article 19, number 12);

5) “the researchers responsible for studies of samples stored in bio banks should always verify that the rights and the interests of the individual to whom the biological matter belongs are duly safeguarded, including his/her privacy and confidentiality, but also in relation to the conservation of the samples, which may later be necessary for the diagnosis of a family disease, in the context of genetic testing on these individuals and their families” (Article 19, number 14).

In Portugal, the regime for the creation and maintenance of a DNA profile database is being elaborated for the purpose of criminal identification and investigation.

Although there is no relevant provision in the Greek Law, genetic data fall under the category of medical data, they are therefore considered as sensitive personal data. Furthermore there is a specific regulation about medical assistance to human reproduction. According to Article 1460 of Greek Civil Law: “The identity of a third person who has provided the gametes or the impregnated ova may not be disclosed to the persons interested in having a baby. Medical information concerning the third person (donor) is kept in an anonymous record. The child may have access to the record, only for health-related issues. In Spain the constitutional protections of privacy are explicitly focused on the intrusion of third persons into the personal information, therefore into medical and genetic data.

3. *PRIVACY: INDIVIDUALS VS GROUP*

In general all legislations have a concept of privacy with a very individualistic view. Privacy is understood as a right to respect of private and family life. Really this is the main idea also in the Universal Declaration of Human Rights or in the European Convention for Human Rights. But according to article 2 of the Oviedo Convention “the interests and the welfare of the human being shall prevail over the sole interest of society or science”. And according with it, we can see in Portuguese legislation a permission to know genetic information by relatives when this information is important for a health treatment or for preventing disease (article 18, number 6, Law n.º 12/2005); however “information regarding health, including registered clinical data, blood test results and other additional tests, interventions and diagnoses are the individual’s property” (article 3, number 1, Law n.º 12/2005). This recognition of different interests from the subject’s of privacy information is also extending when there are some contagious diseases which impose a national registration of the patients; and when there are any judicial interests⁶. Similarly occurs in Israel where the law does recognise some of the interests of the public to legitimately override the individual interest in privacy, for the sake of public interests, e.g. reportable infectious diseases to the health authorities or infringement of privacy in cases of alleged criminal acts, but in such a

⁶ According to article 135, number 3, of Criminal Procedure Code the Court “may decide for the bearing of testimony with the breach of professional confidentiality whenever it deems justifiable, according to the principle of prevalence of the predominant interest, namely taking into consideration the indispensability of the testimony to uncover the truth, the seriousness of the crime and the need for the protection of juridical assets. The intervention is processed by the judge, officiously or on request”.

case a specific permissions by authorities, like courts or the attorney general, is needed. Also in Italy, both legislation and case law – especially vis-à-vis freedom of expression – have been striving consistently to balance conflicting interests rather than prioritize a given set of interests. Reconciling the interests at issue is committed first and foremost to lawmakers; however, courts are also bound to tackle this issue, and the difficulty in doing so is sometimes compounded by the fact that the legal standards to be relied upon in striking the balance are worded in general terms.

In general terms we can say that every legislations recognises that individual's privacy could be legitimately overridden in order to protect public health, or relative's health.

3. COMPARISON OF SIMILARITIES AND DIFFERENCES OF CONCEPTIONS OF PRIVACY

There are very different attitudes towards the use of genetic information. Countries such Portugal or Cyprus have not surveys aimed at assessing attitudes towards genetic issues or genetic data. And if in Malta there is a “fear” of genetics, Cypriots in general want to participate in genetic research and they have not any problem in sharing genetic information; similar in Spain where people are reserved to share their genetic information, especially when this implies to give information to relatives or when they give information to the wider public domain, but they does not have problems when they share information with scientific researchers – because they have high expectations in their work. Genetic data in Portugal could be could be collected to health purposes; so people does not have to give an express consent to permit the collection; but when this collection is for research purposes a written consent is necessary. However even here we have not any report about population attitudes. But analysing the authorizations from National Commission for Data Protection we can say that we are very carefully in respect with disclosure privacy information, whether it is genetic information or not. Nevertheless National Commission for Data Protection has given authorization to do genetic databases for scientific purposes. And there is also recent legislation establishing rules to the creation of biobanks (for health purposes, for scientific investigation, for identity purposes and criminal investigation).

Every country has a constitutional right to privacy, and it is protected by different legislation, much of them inspired in the Universal Declaration of Human Rights, European Convention on Human Rights and Oviedo Convention. The use of genetic data in research is also possible but it is always necessary a free, and written consent.

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