Privacy and Research involving Genetic Databases and Biobanks

Stage Two Regional Report (Element One)
Group B (Coimbra Group)

“The description of the regulation within and between the regional member states”

Countries: Cyprus, Greece, France, Israel, Italy, Malta, Portugal and Spain

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Based on reports from members of the consortium.

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A. Regulating Biobanks and Genetic Databases (BBGD) research using personal information

1. Bio-bank and genetic database research using personal information and privacy protection by the law

1.1. The scope of the law

The goal in this topic is to establish the circumstances in which the law regulates the activities of researchers using personal information for the purposes of Biobanks and Genetic Databases
Therefore, we must look at the legislations that implement the data protection directive (data protection act) and the rules that determine its scope.

**List of relevant legislation across members involved:**


**France:**
- Data Protection Act: Law 2004-801 of 6 August 2004, implementing Directive 95/46/EC and modifying law 78-17 of 6 January 1978 (Protection of Data Subjects regarding the Processing of Personal Data);

**Israel:** not being a member state of the European Union, Israel does not apply the EU directives as such. However, the Israeli authorities do take into consideration the EU conventions and directives and implement them in the Israeli legislation. The main laws dealing with genetic data protection in Israel are:
- The Protection of Privacy Law;
- The Patient Rights Law;
- The Genetic Information Law.

**Italy:**
- Ministerial decree no. 78 dated 25 January 2001 – ‘Features and Arrangements Applying to the Donation of Blood and Blood Derivatives’;

**Malta:** Data Protection Act: Maltese Data Protection Act of 2001, implementing Directive 95/46/EC (although at the moment of its introduction Malta was not a member state).

**Portugal:**
- Data Protection Act: Law no. 67/98, October 26 implementing Directive 95/46/EC;
- Law no. 12/2005, January 26 (Act on personal genetic information and information regarding health): regulates biobanks and genetic databases;
- Law no. 5/2008, February 12 regulates the implementation of a database of DNA profiles, for civil and criminal identification purposes, and it has rules on the safety, storage and management of genetic data, in those situations;
- Law no. 12/2009, Mars 26, which implements Directives 2004/23/CE, 2006/17/CE and
2006/86/CE on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

Spain:
- Royal Decree 1720/2007, of 21 December, which develops the Data Protection Act;
- Law 41/2002, which regulates health data protection;
- Law 14/2007, of 3 July, on Biomedical Research (Law on Biomedical Research).

1.1.1. The scope of protection: the use of the term ‘personal data’

Considering that the data protection directive defines ‘personal data’ as “any information relating to an identified or identifiable natural person (‘data subject’)” and further states that “an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity”, it is important to see how the legislation of the countries involved is consistent in this topic.

For instance, how consistent are countries regarding:
- The interpretation and/or application of the terms ‘anonymised’ and ‘identifiable’?
- Group (family) members being considered data subjects with respect to data gathered from/about others?
- The considerations of data from deceased people?

Cyprus:
The Data Protection Act (Law 138(I)/2001) does not contain a clear statement that “anonymised” and “reference” collections fall outside its scope but this is clearly enacted from the definition of “personal data”.
The term “identifiable” and “anonymised” are not specifically defined in the data Data Protection Act.
The distinction can become clear from the definitions of “data subject” and “personal data”. According to the Data Protection Act “personal data” or “data” means any information relating to a living data subject; consolidated data of a statistical nature, from which the data subject cannot be identified, are not deemed to be personal data. According to the same Act, “data subject” means the natural person to whom the data relate and whose identity is known or may be ascertained, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural, political or social identity.

The “biological sample” is not explicitly referred in the definition of “personal data” in Law 138(I)/2001. However, the Cyprus National Bioethics Committee (CNBC) in reviewing research protocols and applying the “Operational Guidelines for the Establishment of Ethics Committees in reviewing biomedical research involving human subjects in Cyprus” (ΚΑΠ 475/2005) issued by Ministerial Order considers information extracted via scientific analysis of biological samples, to be medical data.

The definition of “personal data” been implemented in Law 138(I)/2001 does not include information or sample relating to deceased persons.
Also, there is no indication that «group data» would be considered as «personal data» in the context of the same law.

**France:**

The article 2 of the Law 79-17 of 6 January 1978 (modified by Law 2004-801 of 6 august 2004) gives almost the same definition that one can find in the Directive: *personal data* is any information related to a physical person who can be identified directly or indirectly through an identification number or other peculiar elements. To determine if the person is identifiable every possible means allowing identification in the hand of the responsible of the treatment or any other persons must be taken into account.

The term identifiable had been defined in the Law 79-17 of 6 January 1978. Nevertheless the term “anonymised” is not defined.

The definition of personal data does not include biological samples. Nevertheless, the Article 56 of the Law 79-17 of 6 January 1978 related to personal data and computer files mentions biological samples: if the research requires the processing of identifiable biological sample, enlightened and express consent is required.

There is no definition of anonymisation. However, the Law 79-17 of 6 January 1978 (modified by Law 2004-801 of 6 august 2004) in its article 55 envisaged a coding procedure to guarantee confidentiality of the processing of data for health research.

The definitions of “physical person” is only concerning living persons, so the definition of ‘personal data’ does not include information or sample relating to deceased persons Nevertheless, Article 56 mentions that information related to deceased can be processed unless if participant has expressed his opposition in written when he was alive.

In case of re-identification, information or samples that are ‘anonymised’ or in a ‘reference’ collection can be considered to be personal data.

Law 79-17 of 6 January 1978 (modified by Law 2004-801 of 6 august 2004) does not either explicitly or implicitly recognizes family members ever to be data subject with respect to data obtained from a relative. However it is important to say that family is always considered as third party.

**Israel:**
In Israel, both "anonymised" and "reference" collections fall outside the confidentiality protected by data protection law, as long as no use is done with them in order to stigmatise groups, communities, ethnic origin, or culture.
Both terms "identifiable" or "anonymised", as used within the directive, are defined within the Israel Genetic Information Law.
The definition of ‘personal data’ has been implemented in Israeli legislation to include a biological sample.

Regarding the shared nature of genetic data, a treating practitioner and a provider of genetic counselling may provide genetic information to another treating practitioner or to another provider of genetic counselling for the purpose of imminent treatment of the person, unless the person has given notice of his objection thereto. Notwithstanding the objection of the person, the information may be given to another treating practitioner of the Ethics Committee set according to the Patient Rights Law, after having heard the person involved, is convinced of all the following: (1) Communication of the genetic information regarding that person is required of the maintenance of the health of a relative or to improve such person's health, and for the prevention of death, disease or serious disability of such relative, including an unborn relative; (2) Communication of the genetic information in the only way of achieving the object referred to above; (3) The benefit to the relative as a result of communication of the genetic information to the treating practitioner is greater than then harm that might be caused to the person, or the reasons given by the person for not communications the information are not reasonable in the circumstances of the case.

**Italy:**

Italy’s Data Protection Code (Legislative decree no. 196/2003) contains the following definition of “personal data”: “‘personal data’ shall mean any information relating to natural or legal persons, bodies or associations that are or can be identified, even indirectly, by reference to any other information including a personal identification number.

Depending on the specific circumstances, anonymised data may also fall within the scope of the concept of “personal data”.

The Data Protection Code provides that “‘identification data’ shall mean personal data allowing a data subject to be directly identified”, and it defines “anonymous data” as follows: “‘anonymous data’ shall mean any data that either in origin or on account of its having been processed cannot be associated with any identified or identifiable data subject”.

The Data Protection Code does not specifically address the issue of whether ‘biological samples’ might constitute ‘data’ for the purposes of the Code. Following the approach adopted by the Article 29 Working Party, the Italian Data Protection Authority considered that biological samples could not per se constitute “personal data”, although they do contain personal data. The general authorisation on the processing of genetic data defines biological samples as follows: “any sample of biological material containing information on an individual's genotypic characteristics”.

The information relating to deceased persons is personal data and may be accessed by certain entities. More specifically, the Data Protection Code provides that “The rights as per Section 7 [Right to Access Personal Data and Other Rights], where related to the personal data concerning deceased persons, may be exercised by any entity that has a vested interest therein or else acts to protect the data subject or pursues family-related purposes deserving protection”.

Regarding the shared nature of genetic data, under the Italian Law, if a given piece of information relates to a group of identifiable individuals, then that piece of information is a personal data related to each of those individuals.

**Portugal:**
In Portugal, the definition of ‘personal data’ that we may find in article 3. a) of Law no 67/98 (Data Protection Act) is quite similar to the one we may find in article 2. a) of Directive 95/46/EC. On Article 3. a), Law no 67/98 states that “‘personal data’ shall mean any information of any type, irrespective of the type of medium involved, including sound and image, relating to an identified or identifiable natural person (‘data subject’)

Also, the Data Protection Act states that “an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an indication number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.”.

In Portugal, all generally identifiable, identifiable coded and linked anonymised collections fall into the definition of ‘personal data’, and, consequently, into the scope of Law no 67/98. According to this law, if it becomes possible to identify the data subject, the information relating to him or her will be considered as personal data.

As it will be referred again below, the Data Protection Act does not cover biological material. However, information collected from biological material is considered to be personal data. In Portugal, there is specific legislation on the collection of biological samples for health purposes (Law no. 12/2005, January 26 - Act on personal genetic information and information regarding health) and for the purposes of criminal investigation (Law no. 5/2008, February 12 - regulates the creation of a database of DNA profiles, for civil and criminal identification purposes).

Recently was enacted Law no. 12/2009, Mars 26, which implements Directives 2004/23/CE, 2006/17/CE and 2006/86/CE on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

The definition of personal data under Portuguese law makes no distinction between living and deceased data subjects; therefore, the Data Protection Act applies to both, as the Data Protection Authority considered on Decisions no. 51/2001 and no. 72/2006. Law no 67/98 itself does not recognise, explicitly or implicitly, family members as ‘data subjects’ with respect to data obtained from a relative. However, Law no. 12/2005 may be interpreted as recognizing ‘genetic data’ as collective information. We may say that Law no. 12/2005 enlarges the concept of personal data to cover ‘group data’ when genetic data is involved. However, this is not a strict rule. We may admit this idea as a ‘principle’, but there is no general access by relatives. Nevertheless, on article 6, no. 9, Law 12/2005 states that “citizens have the right to know if a medical record, file or clinical or research folder contains genetic information about themselves and their family, and the right to know the purposes and possible uses of that information, the way of storage and periods of conservation.”

As it will be referred below, only regarding biological samples Law 12/2005 states clearly that Some family members (direct relatives and siblings) “may have access to a stored sample, if necessary to a better knowledge of own genetic condition”, although is restricted the knowledge of the genetic condition of the subject from whom the sample was collected or any other relatives (Article 18, no. 7).

Spain:

In Spain, Data Protection Act is applicable if there is the possibility to link any information with an identified or identifiable person. To determine whether a person is identifiable, should be taken in consideration all the means likely reasonably to be used either by the controller or by any other person to identify the said person. Data Protection Act defines ‘identifiable person’ as ‘every person whose identity can be determined, directly or indirectly, with any information related to his physical, physiological, mental, economic, cultural or social identity’. A physical
person is not considered identifiable if that identification requires disproportionate periods of
time or activities.
Therefore, if the possibility mentioned above does not exist, and those ‘anonymised’ and
‘reference’ collections are not possible to associate with personal information, we can consider
that neither anonymised collections nor reference collections fall inside the scope of data
protection law.

The definition of ‘personal data’ has been implemented in Spanish legislation to include
information or sample relating to deceased persons. The ‘source subject’ is defined in Law on
Biomedical Research in the following terms: ‘living being, no matter his or her state of health, or
deceased from whom the biological sample is obtained’.
Nevertheless, the Royal Decree 1720/2007, of 21 December, is not applicable to the data relating
to deceased persons. However, the relatives can request the cancelation of those data according
with specific circumstances.

In Spain, according to Law on Biomedical Research, ‘family members’ are not ‘data subjects’.
‘Ley 14/2007’ establishes that the subject source shall be informed on the genetic data of a
personal nature that are obtained in the genetic analysis according to the terms in which he
manifested his volition, notwithstanding the right to access that is established in the legislation on
the protection of data of a personal nature, which could entail the revocation of the previously
granted manifestation of free volition. On the other hand, when the subject source has exercised
his right not to know the results of a genetic analysis, then only that information that is necessary
for the follow up of a prescribed treatment by the doctor and that has been accepted by the patient
shall be provided. When this information is necessary to avoid a serious damage for the health of
his biological family, then the affected or their legally authorised representative may be informed.
In every case, the communication shall be exclusively limited to the data necessary for these
ends. In fact, it is established, among the points about the source subject should be informed
before proceeding with the genetic analysis, this one: “Warning about the implication that the
information that could be obtained can have for his family members and the convenience for that
person, where appropriate, to communicate that information to them”.
If the subject source refuses to let the members of his family access to his genetic data when it is
necessary for them to avoid a serious damage, it would be possible to go to other alternatives.
The physician would not observe the duty of confidentiality when he decides it based on a higher
legal interest derived, in this case, from a stage of need.
‘Ley 14/2007’ also stipulates that: “In case of genetic analysis to several members of a family,
the results shall be filed and communicated to each of them in an individual manner. In case of
disabled or minors, the information shall be provided to their tutors or legal representatives.

1.1.2. Extending the scope of protection

Is the processing of personal information in the context of research using BBGDs regulated
through other legislation?

Cyprus: no other legislation reported.
France:
- Law 2004-800 of 6 augst 2004, related to definition of collection of biological samples, conditions of declaration and authorisation, scientific utilisations and conditions of gathering.
- Decree 16 of August of 2007. establishing files modalities for declaration and authorisation for collecting biological samples for scientific utilisations.
- Law 2004-806 of 9 august 2004, on biomedical research; establish particular dispositions as regards to consent and information.
- Law 2002-303 of March 2002. related to the rights of patients and to the quality of the health system.

Greece: no other legislation reported.

Israel: no other legislation reported.

Italy: no other legislation reported.

Malta: no other legislation reported.

Portugal:
In Portugal, the protection of genetic privacy has been moulded in Law no. 12/2005, of January 26.
Law no. 12/2005 not only extend the scope of the protection provided by the data protection legislation but also give new, specific and substantial regulations for BBGDs.
This law, which not only deals with the protection of personal genetic information, intends to regulate: the concept of information regarding health and genetic information, the circulation of information and the intervention on human genome in the health care system, the sampling and storage of biological products for genetic testing or research.
In the terms of no. 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 zygotousness in twins, studies of genetic identification for criminal purposes, as well as the study of physical genetic mutations in cancer”.
In no. 6 of Article 6 Law 12/2005 states that “genetic information should be object to legislative and administrative measures of reinforced protection in terms of access, safety and confidentiality”.
Law no. 12/2005, 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, no. 1). It is also stated 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, no. 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”.

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Spain:
Title V of ‘Ley 14/2007’ regulates emerging matters related with the current expansive tendency of biomedical research, such as, the undertaking of genetic analysis, the access and use of its results, as well as the obtaining and use of human biological samples. This Law, at the same time that it prescribes a set of guarantees in relation with genetic analysis and biological samples within the ambit of the protection of data of a personal nature, it creates a set of norms in order to provide trust and safety to researches, and the public and private institutions in their acts within the sector, eliminating the current legal uncertainties.

1.2. The Nature of the protection

1.2.1. Consent

According to the Directive 95/46/EC, in the case of the processing of personal data consent must be ‘unambiguous’ (Art.7(a)).
In the case of special categories of data (including data concerning health or sex life’) consent must (also) be ‘explicit’.
To what extent are nations clear or consistent about what is required for ‘unambiguous’ or ‘explicit consent’?
Is there any suggestion that particular processing either does, or does not, require particular kinds of consent?
Explicit rules on the age at which consent for use of personal information for research purposes can be given/ parental access to such information can be prevented?
There are any rules on re-contacting data subjects?

Cyprus:
Article 2 of Law 138(I) /2001 defines «consent» as follows: «Consent» means consent of the data subject, any freely given, express and specific indication of his wishes, clearly expressed and informed, by which the data subject, having been previously informed, consents to the processing of personal data concerning him.
Article 5 (1) clearly states that ‘personal data’ may be processed only if the data subject has unambiguously given his consent. Cypriot courts have not interpreted the term “unambiguously given consent” referred in the aforesaid article 5 of the Law 138(I)/2001.

According to Article 15 of Law 138 (I)/2001, personal data cannot be processed by anyone for the purposes of direct marketing or provision of services, unless the data subject notifies his consent to the Commissioner in writing.

There is no mention within the Data Protection Law 138 (I) /2001 of age. In theory, however, it applies to all ages. It is expected that at least until children are capable of understanding the implications of data processing it is in their best interests for a responsible adult to receive information and to take decisions on their behalf.

France:
Law 79-17 of 6 January 1978 (modified by Law 2004-801 of 6 August 2004) envisages in its article 7 that the processing of personal data is submitted to the consent of the individual concerned.

In the case of the processing of personal data for health research and when research requires the processing of identifiable biological samples the article 56 envisaged that an enlightened and express consent is required. The term “express” according to the French “Conseil d’État” jurisprudence (legal precedents) means a written and explicit agreement. In the other cases (processing of data for health research) the controller must provide information to the participants and there is a right of opposition to the treatment.

Bioethical Law (Law 2004-800 of 6 August 2004), regulating the collections of biological samples, requires the consent to be given in written if the removal is for research or for genetic research. If the collections are built up within a biomedical research project specific disposition applies. The article 89 of the Law 2004-806 of 9 of August 2004 requires free and enlightened informed consent from participant in biomedical research. Consent is given in written and specific information must be given to the research project prior his consent.

There is no suggestion in law that consents obtained should be “as specific as possible with regard to any foreseen research uses.

Nevertheless, the National Consultative Ethics Committee (CCNE), in its opinion nr. 77 ("Ethical issues raised by collections of biological material and associated information data: "biobanks", biolibraries" 2003) mentions the need for specific consent. “about the fact that there will be storage and where it will be stored, and identify the persons or the structures that will be responsible for keeping elements and information”.

Provided the person concerned agrees, CCNE sayd that “it would be conceivably acceptable that should personal data be scrupulously anonymised, it could be used for subsequent research without renewing consent procedures. However to prevent any abuse, all banks would have to set up some kind of consultative body that persons directly concerned with the initial banking procedures could address enquiries to. These persons would have been duly advised of this possibility, so that they could enquire at any time about the purpose for which the collection and the related information data were to be used.”

Also, a particular consent is asked if research requires the treatment of genetic data as the Article 56 of the Law 79-17 of 6 January 1978 (modified by Law 2004-801 of 6 August 2004) recommends it with the removal of identifying biological samples.

Moreover, the legislator establishes limits to the treatment of specific personal data. Indeed, article 1 of Law 2007-131, 31 January of 2007, modifying the law of 4 March 2004, forbids the use of genetic test results data for insurers even if they are transmitted by the subject. So, in this case, particular processing must not receive specific consent but answer to an interdiction regime.

Considering the age for giving consent, article 59 of Law 79-17 of 6 January 1978 (modified by Law 2004-801 of 6 August 2004) in its chapter related to the processing of personal data for health research considers that when a minor is involved the information and the non opposition procedure belongs to the holder of the parental authority, or to the legal representative when the person is unable to consent.

Italy:
Generally speaking, where the processing of health-related data requires the data subject’s consent, such consent must be given in writing under Italy’s Data Protection Code. A disclosure order by judicial authorities may entail communicating the data to those authorities without any need for the data subject’s consent.

Under article 6 of the Data Protection Authority general authorisation, which deals with consent by data subjects, “The child's opinion shall be taken into consideration, insofar as this is permitted by the child's age and maturity. In any other case where the data subject is legally incapable, or physically or mentally incapacitated, the processing shall only be allowed if the underlying purposes are directly beneficial to the data subject; the data subject's opinion shall be taken into consideration to the extent this is possible”.

The Data Protection Authority general authorisation provides many rules regarding the information to be provided to data subjects and genetic counselling issues.

Once the data subject becomes of age, the information notice shall be also provided to him/her in view of obtaining his/her consent anew whenever this is necessary (section 82(4) of the Code).

Portugal:

Law no. 67/98, on article 3, (h), states that “the data subject’s consent” shall mean any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed”.

In article 6, referring the ‘criteria for making data processing legitimate’ it stipulates that “personal data may be processed only if the data subject has unambiguously in Portuguese language: “de forma inequivoca” given his consent”.

In article 7, while regulating ‘the processing of sensitive data’ (where genetic data is included), it states (in no. 2) that the processing of such data “shall be permitted by a legal provision or by the authorisation of the CNPD when, on important public interest grounds, such processing is essential for exercising the legal or statutory rights of the controller or when the data subject has given his explicit consent in Portuguese language: “consentimento expresso” for such processing (...)”.

The no. 4 of article 7 allows the processing of such data without the need for an explicit consent by the subjects of genetic data. However, it establishes restrictions on the level of the purposes of treatment, which is permitted only when it is necessary for the purposes of preventive medicine, medical diagnosis, to provide medical treatment or for management of health services. The processing of data can only be done by a professional bound to secrecy, the Data Protection Authority has be notified and will have to be taken appropriate measures to protect data involved. The data controller may only use the data collected for the purposes stipulated at the outset to the data subject. If the data controller wishes to use the data for different purposes, then authorization is required from the Data Protection Authority (Article 28 of the Data Protection Act), and this will not be granted if the new purposes are incompatible with the original ones. However, the notion of ‘compatible/incompatible purposes’ has not been properly defined.

Article 12 of the Data Protection Act has implemented Article 14 of the Directive on the right to object by giving the data subject a general right to object to the processing of personal data, on the basis of ‘legitimate grounds’.

There is no suggestion in Law no. 67/98 that consent can only be given by a person above a certain age, although consent general rules are applicable. Besides that, Law no. 12/2005 states that, in case of minors, genetic tests may only be requested with the informed consent of their parents or tutor, always considering minors will.
There are no rules on re-contacting data subjects.

**Spain:**
The Data Protection Act (Organic Law 15/1999, of 13 December) states that the consent of the data subject is “is any indication of his/her will, freely given, unambiguous in Spanish language: “inequívoca”, specific and informed by which the data subject allows the processing of his/her personal data” (article 3, h)).
Regarding health data, article 7 no. 3 of the Data Protection Act stipulates that “personal data referring to racial origin, health and sex life may only be collected, processed and transferred when, for reasons of general interest, that is provided by law or the data subject explicitly in Spanish language: “expresamente” consents”.

### 1.2.2. Provision of information

**Article 10 and Article 11 of the data protection directive require the provision of information to the data subject.** They note that the controller or his representative must provide a data subject with, *inter alia*, the recipients or categories of recipients of the data and *any such further information necessary*, having regard to the specific circumstances in which the data are collected, *to guarantee fair processing in respect of the data subject*.

**What is required when it comes to providing information prior to and/or post consent?**

**Cyprus:**
Article 11.4 of the Law 138 (I) 2001 states that “The obligation to inform may, on the application of the controller, be waived wholly or partly, by decision of the Commissioner where the collection of personal data is performed for the purposes of defense, national needs or national security of the Republic or for the prevention, detection, investigation and prosecution of criminal offences”.

**France:**
As regards to the information provided in a biomedical research, the French “Code de la santé publique”, considers that participants must receive from the instigator a prior written information allowing a free and enlighten consent.
Bioethical Law (Law 2004-800 of 6 august 2004), regulating the collections of biological samples, submits the constitution of collections for research to a declaration procedure. As regards to the information provided before the processing in order to obtain consent, there are still some questions and uncertainty, and there are no specific dispositions to guarantee fair processing in the context of BBGD research.

In the data protection law, the article 57 envisages that when the data where not originally obtained for the treatment and when there are difficulties to re-contact the donor, special dispensation apply and it is mentioned in the authorization files transmitted to the CNIL.

**Portugal:**
The right to information established in articles 10 and 11 of the Directive has been implemented
by the Data Protection Act in Article 10. 
As in the Directive, Portuguese data protection law does not explicitly cover situations where data have been collected from the data subject, and are now to be processed for a purpose other than that originally stipulated. Nevertheless, when the data controller wishes to use the data for purposes not originally anticipated, the information requirement still stands. In such situations, data controllers must submit their request for the use of the data to the Data Protection Authority, as determined by Article 28.

Spain:
Law on Biomedical Research stipulates that: “The information shall include the purpose, detailed plan, burdens and possible risks and benefits of the research. This information shall specify the following matters: “Measures to fight against adverse events that bear upon the subjects who participate in the research” (art. 15. 2.c) It is also established in the same Law, for instance, in relation to genetic screening, that: “The information prior to this consent shall be written and shall make reference to: “The discomforts, risks and adverse events that could be derived from the diagnostic process, including those associated to the taking of samples and to the therapeutic or preventive measures that are offered by the program” (art. 54.6.g).

1.3. The research exemption

The directive states that Member States shall provide that personal data must be collected for “specified, explicit and legitimate purposes” and “not further processed in a way incompatible with those purposes” (Art.6(b)). However, it also provides that ‘further processing’ of data for ‘historical, statistical or scientific purposes’ shall not be considered as incompatible provided that Member States provide appropriate safeguards.

To what extent have different countries recognised a research exemption from the requirement to notify data subjects that their personal data is to be processed for historical, statistical or scientific?

Cyprus:
Article 11 (3b) of Law 138(I)/2001 states that in cases where the processing of personal data is performed for statistical and historical purposes or for purposes of scientific research if it is impossible to inform the data subject or where disproportionate effort is necessary in order to inform him, or if the communication of data is provided by another law, provided that, in each case, a license is issued by the Commissioner, an exemption applies.

France:
There is no research exemption in the chapter related to the processing of personal data for health research. However the article 6 of Law 79-17 of 6 January 1978 (modified by Law 2004-801 of 6 august 2004) considers that a further treatment for historical, statistical or scientific purposes can be compatible with initial finalities if they are achieved in compliance with principles and procedures envisaged by this law.

Italy:
Section 78(5) of the Data Protection Code, concerning “Information Provided by General Practitioners and Paediatricians” provides that: “The information provided pursuant to this Section shall highlight, in detail, processing operations concerning personal data that may entail specific risks for the data subject’s rights and fundamental freedoms and dignity, in particular if the processing is carried out:

- for scientific purposes, including scientific research and controlled clinical drug testing, in compliance with laws and regulations, by especially pointing out that the consent, if necessary, is given freely,
- within the framework of tele-aid or tele-medicine services,
- to supply other goods or services to the data subject via electronic communication networks.”

As for the data collected from third parties, it should be added that section 13(5)c. of the Data Protection Code exempts the data controller from informing data subjects “if the provision of information to the data subject involves an effort that is declared by the Garante to be manifestly disproportionate compared with the right to be protected, in which case the Garante shall lay down suitable measures, if any, or if it proves impossible in the opinion of the Garante.”

There are no decisions by the Italian Data Protection Authority as regards the processing of personal data from this standpoint.

**Portugal:**

There is an exemption to the provision of information. In Article 10, no. 5, the Data Protection Act establishes that the obligation to provide information may be waived “by a legal disposition or decision of the Data Protection Authority (…) namely in case of scientific research when the provision of information is impossible or demands disproportionate efforts (…)”.

**Spain:**

The Data Protection Act (‘Ley Orgánica 15/1999), establishes a special set of rules when the data have not been collected directly from the data subject (art. 5). There are some exceptions from the requirement to notify data subjects that their personal data is to be processed for historical, statistical or scientific purposes (art. 5.5).

Law on Biomedical Research stipulates that: “Genetic data of personal nature can only be used for epidemiological, public health, research or education purposes when the interested subject has expressly provided his consent or when this data has been previously anonimised” (art. 50.1).

In exceptional cases and of general health interest, the corresponding authority, after a favourable report by the authority on data protection, may authorise the use of codified genetic data, always when assuring that third parties may not be able to associate the source subject (art. 50.2).

2. Genetic data and bio-bank research using Biological Material and privacy protection by the law

**Does the law, as it applies to BBGD research using biological material offer the same protection as it offers to personal information?**

**How specific is, in law, the use of biological material?**

2.1. *The scope of The law*
France:
The legislation identified does not simply extend the scope of the protection provided by the data protection law. Indeed, French legislation draws a clear separation between biological material protection and data protection. Legislation related to biological material aims to protect human person’s rights, and all its attributes, like dignity, human body immunity or patient’s rights. This legislation regulates the organisation of the biological resources centres (whether for establishment using samples for research or establishment aiming to transfer the samples), and on the other hand the protection of persons via the regulation of the removal (written consent for research or for genetic aiming), non opposition, gratuitousness, anonymity, health security and non publicity. Plus specific rules for biomedical research and research protocols.

Law on Biomedical Research, Law 2004-806 of 2004, 08 of September, mentions that biomedical research on human being can be conducted if the risks for the persons participating to the research is not disproportionate to the potential benefit of the research activities.

Greece:
There is no specific legislation on biobanks and/or genetic databases so general legislation on data protection is applicable (Data Protection Act: Law 2472/1997). Biological information falls always within the scope of data protection legislation when the identity of the person concerned is (or may be) known. Therefore, biological samples that have been collected anonymously or non-identifiable genetic or medical data are excluded from this scope. Potential implications for privacy protection may emerge in cases of codified or anonymized data. In principle, such data should be treated as sensitive personal data, since there are researchers (or administrative personnel) having access to the relevant code, i.e. to the identity of persons concerned.

Israel:
Law offers biological material the same protection as it offers to personal information. Biological information falls within the scope of privacy protection laws.

Italy:
Failing general provisions on bio-banks more concrete guidance on this point was developed by the “National Bio-Security and Bio-Technologies Commission” and the “Istituto Superiore di Sanita’”; initially they drafted “Guidelines for Genetic Testing” (Working Group Report dated 19 May 1998) and subsequently addressed bio-banks which were defined as “non-profit service units pursuing the collection and preservation of human biological materials to be used for diagnostic purposes, bio-diversity studies, and research purposes.”

As regards specifically the processing of genetic data, article 6 of the Italian Data Protection Authority general authorisation must be considered, as said below.

Under Article 7 of the DPA’s general authorisation (“Processing Operations in Specific Sectors”), “No genetic data or biological samples that are processed or collected, respectively, with a view to individual variability tests for the performance of investigations by defence counsel or in order to establish a judicial claim in a criminal proceeding may be used for other purposes. Genetic data or biological samples that are processed or collected, respectively, with a view to the performance of genetic tests for purposes of prevention, diagnosis and/or treatment in respect of the data subject, or else for scientific or statistical research purposes, may be used for the performance of investigations by defence counsel or else to establish a judicial claim in a criminal proceeding on condition the relevant legislation is complied with.”

Portugal:
As said above, the Data Protection Act does not cover biological material. However, information collected from biological material is considered to be personal data. Also, in Portugal, there is specific legislation on the collection of biological samples for health purposes (Law no. 12/2005, January 26 - Act on personal genetic information and information regarding health) and for the purposes of criminal investigation (Law no. 5/2008, February 12 - regulates the creation of a database of DNA profiles, for civil and criminal identification purposes). Recently was enacted Law no. 12/2009, Mars 26, which implements Directives 2004/23/CE, 2006/17/CE and 2006/86/CE on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

Law no. 12/2005 gives the concept of bio-bankin, or “bank of biological products”, in no. 1 of Article 19, stating that “for the purposes of this law, the “bank of biological products” is understood to be any repository of biological samples or 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 of health care treatments, 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 bank of biological products should only be created for health care treatments, including the diagnosis and the prevention of diseases, basic research or research applied to health” (Article 19, no. 3) and that “should always guarantee privacy and confidentiality, avoiding the storage of identified material, controlling the access to the samples, limiting the number of people authorised to do so and guaranteeing its security regarding loss, alteration or destruction (Article 19, no. 8).

It is also established by Law 12/2005 that:

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

b) “The storage of non-anonymised human biological matter by the entities for commercial purposes is not permitted (Article 19, number 10);

c) “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);
d) “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);
e) “Researchers responsible for studies of samples stored in biobanks should always verify that the rights and the interests of the individual to whom the biological material 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).

Spain:

Law on Biomedical research defines “biological sample” as “any biological material of human origin capable of conservation and that can hold information on the genetic endowment that is characteristic of a person” (art. 3.o).

Regarding the differences of the protection provided by the ‘Ley 14/2007, de 3 de Julio’, we must bear in mind that privacy is protected according to the general principles established by Spanish legal system. The most relevant differences are focused on the following aspects:
- The items covered by the information given previous to the treatment of samples for research purposes of personal genetic data. Those items are more detailed and specific.
- The requirements established by LBR in relation to the principle of consent. The written consent of the subject source, or where appropriate, of his legal representatives must be obtained previous to the treatment of personal genetic data in any case. This is the greatest difference between the treatment of this kind of information and the rest of clinical information. In relation to this latter there are specific exceptions which are not applied in the case of personal genetic data.
- From an organizational perspective, the Law creates different professional entities that are recognised with a specially qualified function based on its impartiality, independence, technical capacity and professional competency that are required to its members. On the one hand, Research Ethics Committees shall guarantee that each research centre that intervenes on human beings or biological samples of human origin does so in accordance with methodological, ethical and legal aspects.
- Quality of the data: the data obtained from the genetic analysis shall neither be handled nor assigned for purposes other than those provided for in this Law.
- Indication of genetic analysis are the next ones: “In the terms provided in article 1.2, genetic analysis shall be undertaken for the identification of an individual’s condition as affected, non-affected or as carrier of a genetic variable that could predispose to the development of a specific disease or to condition his response to a specific treatment” (art. 46)
- On the other hand is specially indicated by our LBR the following quality requirements: “The entire process of genetic counsel and of the practice of genetic analysis for health purposes must be undertaken by qualified personnel and must be carried out in accredited centers that meet the requirements of quality that are established for this purpose by regulation” (art. 56).

Regarding the commercial use of samples, the Law on Biomedical Research stipulates the principle of non profit which means that the donation and use of human biological samples shall be gratuitous, whichever its specific origin, and the compensations that are provided for can in no way entail a lucrative or commercial nature.

2.2. Consent and provision of information
France:
Law on Biomedical Research, Law 2004-806 of 8 of September, mentions the information that must be given to the research participants prior obtaining his enlightened and express consent. This information has to include the objectives, methodologies and durations of the research. It also has to mention the excepted benefits or foreseeable risks or constrained including the end of the research before his term. Eventually it mentions the opinions of the ethics committee. Specific dispositions apply for psychological research and for patient when it is in the interest of that person to not reveal his disease, and for emergency situations. There is nothing on available preventive, diagnostic and therapeutic procedures, because the biomedical research law aims to distinguish from the medical treatment. The biomedical law enounces the general principles such as, consent, gratuitousness, anonymity, health security and non-publicity.

Israel:
Consent to give a DNA sample, or for the conduct of genetic test, can be given only by a person over 18 years, or by a minor who is sixteen years of age with the written approval by the his guardian or the person responsible for the minor. An individual contributing towards either a bio-bank, or a genetic database, ought to be informed prior to consent on:
- The significance of conducting genetic testing to him and to his relatives.
- Any potential adverse consequences associated with participation for either themselves or others;
- The circumstances where access to material held by the BBGD might be permitted without seeking their consent, including police and state authorities;
- That genetic information derived from his DNA sample offers information also regarding the individual's family. It can offer information on likeliness of family members to be affected by genetic disease, it may also provide information of predictability on the assessment of likelihood of ill health, it can reveal secrets about future ill health, even in those who are currently well, including help to determine future risks in future persons, as well as intimate matters like who a person is related to.

The commercial use of samples is forbidden unless the person consented to it in writing.

Greece:
Specific and written informed consent for collecting and processing sensitive data is a general requirement, without exceptions. There is no explicit reference to “potential adverse consequences” in the law. Still the law requires the person concerned to be “fully cognisant”, meaning normally specific information about “potential adverse consequences” as well.

Italy:
Article 6 of the Italian Data Protection Authority general authorisation provides as follows:

- “In compliance with sections 23 and 26 of the Code, genetic data may be processed and biological samples used exclusively for the purposes specified herein, on condition that the person concerned has provided his/her written informed consent thereto”.

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- “In pursuance of section 23 of the Code, consent shall only be valid if the data subject is placed under no constraint and the consent may be withdrawn at any time”.

- “Where a data subject withdraws his/her consent to the processing of data for research purposes, the biological sample will be also destroyed providing it has been collected for such purposes – except where the sample may be related no longer to an identified and/or identifiable individual either from the very beginning or because of the processing”.

- “As regards processing that is carried out by means of genetic tests, including screening, also for purposes of research and/or family reunion, the informed consent of the individuals that undergo the collection of the biological material required for performing such analysis shall have to be obtained. In the said cases, the data subject shall have to state whether he/she wishes to be informed of the findings of the test/research, including unexpected news concerning him/her, where such news are concretely and directly beneficial to the data subject in terms of treatment, prevention, and/or awareness of reproductive choices”.

- “Consent with regard to the information concerning an unborn child shall be provided by the respective mother. Where the processing based on prenatal tests may also disclose genetic data related to the future occurrence of a disease affecting the child's father, the father's prior consent shall have to be also obtained”.

- “If the processing is necessary to safeguard the data subject's life and bodily integrity, and the data subject may not provide his/her consent because of his/her being physically prevented from doing so, legally incapable, or mentally incapacitated, the consent shall be provided by the legal representative or else by a next of kin, a family member, a person cohabiting with the data subject, or – failing these – the manager of the facility where the data subject is domiciled. The provisions set out in section 82 of the Code shall apply”.

- “The child's opinion shall be taken into consideration, insofar as this is permitted by the child's age and maturity. In any other case where the data subject is legally incapable, or physically or mentally incapacitated, the processing shall only be allowed if the underlying purposes are directly beneficial to the data subject; the data subject's opinion shall be taken into consideration to the extent this is possible”.

- “Processing of data in connection with pre-symptomatic genetic tests may only be carried out on non-diseased children that are at risk of genetic diseases if it is concretely likely that treatments and/or preventive measures become available prior to the children's becoming of age. Individual variability tests may not be carried out on children without both parents' consent, where parental responsibility is vested in both parents”.

- “Processing of data in connection with genetic tests for the performance of investigations by defence counsel or else for the establishment of a judicial claim may only be carried out with the informed consent of the person the biological material required for the investigation(s) belongs to – except where expressly provided otherwise by the law.”

The DPA’s authorisation provides as follows in respect of the information to be provided to data subjects and genetic counselling issues:
“5. Information Notices

Except for the processing of genetic data carried out in a non-systematic fashion by general practitioners and/or family paediatricians within the framework of their standard relationships with data subjects as aimed at protecting their health and bodily integrity, the information notices shall include the following items in addition to those referred to in sections 13, 77, and 78 of the Code:

a. a detailed list of all the specific purposes to be achieved;
b. the possible findings, also with regard to unexpected findings that might be disclosed on account of the processing of the genetic data;
c. the data subject's right to object, on legitimate grounds, to the processing of his/her genetic data;
d. whether the data subject is allowed to limit the scope of communication of his/her genetic data and the transfer of biological samples, including their possible use for additional purposes;
e. the retention period of genetic data and biological samples.

Once the data subject becomes of age, the information notice shall be also provided to him/her in view of obtaining his/her consent anew whenever this is necessary (section 82(4) of the Code).

As regards processing operations for scientific and statistical research purposes, the information notice shall also specify the following:

a. that the consent must be given freely and may be withdrawn at any time without this being in any manner detrimental and/or prejudicial to the data subject, except where the data and biological samples do not allow the data subject in question to be identified any longer whether from the start or because of their processing;
b. what arrangements have been made to allow data subjects to be only identifiable for as long as is necessary for the purposes of data collection and/or the subsequent processing (section 11(1), letter e) of the Code);
c. whether the data and/or biological samples may be retained and used for other scientific and statistical research purposes, to the extent this is known, whereby such purposes shall be appropriately specified also with regard to the categories of entity the data may be communicated and/or the samples transferred;
d. how data subjects can access the information contained in the research project, where they request to do so.

As regards processing operations performed via genetic tests and screening for health care purposes, or for research and/or family reunion purposes, specific, clear-cut information shall be provided to data subjects, also in writing, prior to collecting their biological samples or using such samples where they have already been collected – irrespective of whether the processing is carried out by health care professionals and/or public or private health care bodies that have already informed the data subjects in question by availing themselves of the simplified mechanisms mentioned in sections 77-79 of the Code.

Processing operations aimed at the performance of investigations by defence counsel and/or the establishment of a legal claim may only be carried out via genetic tests if the data subject has been informed thereof in the manner specified above.

Portugal:
Regarding the gathering and the storage of biological material, Law 12/2005 establishes some important rules:

- The gathering of biological material (including blood and DNA samples for genetic tests) must have a separate informed consent for the purposes of health care test, in one side, and for the purposes of research, in the other end (Article 18, no. 1);
  - Informed consent should cover the purposes of the gathering, the time of storage of the biological material and its derivatives (Article 18, no. 1);
  - The property right of the biological material after the gathering remains with the person from whom it was taken and, after his/her death or incompetence, the property right belongs to the relatives (Article 18, no. 2);
  - Consent may be withdrawn at any time by the subject, or his/her relatives, after his/her death or incompetence (Article 18, no. 3);
  - If samples were gathered for other purposes than research or health care treatments, they cannot be used for those purposes, unless new consent is given (by the subject, or his/her relatives, after his/her death or incompetence) or samples are irreversibly anonimised (Article 18, no. 4);
  - Some family members (direct relatives and siblings) “may have access to a stored sample, if necessary to a better knowledge of own genetic condition”, although is restricted the knowledge of the genetic condition of the subject from whom the sample was collected or any other relatives (Article 18, no. 7);
  - No commercial use for samples themselves is allowed (Article 18, no. 8).

On consent, Law 12/2005 also establishes that it must have written form, and the information provided and written must cover the purposes of the biobank, kinds of research to be developed, its potentials risks and benefits, conditions and time of storage, measures that are being taken to protect privacy an confidentiality of involving the participants and what researchers intended to do regarding the communications (or lack of it) on results obtained with the biological material collected (Article 19, no. 5).

Legal solutions contained in Article 18, no. 4 and Article 19, no. 15 may implicate re-contacting subjects:
- If samples were gathered for other purposes that research or health care treatments, they cannot be used for those purposes, unless new consent is given (by the subject, or his/her relatives, after his/her death or incompetence) or samples are irreversibly anonimised (Article 18, no. 4);
- Researchers should provide participants (who gave consent) the information on lost, change or destruction of samples, or information on the decision to stop the research or close the biobank (Article 19, no. 15).

Spain:
Law on Biomedical Research stipulates that “The written consent of the subject source, or where appropriate, of his legal representatives must be obtained previous to the treatment of samples for research purposes of personal genetic data” (art. 45.d).

Regarding the obtaining of biological samples, it requires the following aspects:
- The obtaining of biological samples for biomedical research shall be undertaken solely when the previous written consent has been obtained from the subject source and after being informed about the consequences and risks that this can entail for his health.
- The consent shall be revocable (art. 58.1)
Notwithstanding what is provided in the legislation on the protection of personal data, and particularly, in article 45 of Law on Biomedical Research, before providing the consent for the use of a biological sample for biomedical research that is not going to be subject to an anonymisation process, the subject source shall receive written information on many topics related to that research (art 59 LBR):

a) Purpose of the research or the line of research for which he is providing the consent.
b) Expected benefits.
c) Possible inconveniences linked to the donation and obtaining of the sample, including the possibility of being contacted at a later time in order to collect new data or obtain other samples.
d) Identity of the person responsible for the research.
e) Right to revoke the consent and its effects, including the possibility of the destruction or the anonymisation of the sample and that to this end it shall not be applicable to the rest of the research data that has already taken place.
f) Location of the undertaking of the analysis and the destination of the sample at the end of the research: disassociation, destruction or other research, and where appropriate, shall in turn entail the compliance with the requirements provided in this Law. In case that these extremes are not known at that moment, the compromise to inform about it as soon as is known shall be established.
g) Right to know genetic data that is obtained from the analysis of donated samples.
h) Guarantee of confidentiality of the information obtained, indicating the identity of the persons who shall have access to the data of a personal nature of the subject source.
i) Warning on the possibility that information relative to their health may be obtained as derived from the genetic analysis that are undertaken on their biological sample, as well as on their faculty to take a stance in relation to its communication.
j) Warning on the implication of the information that could be obtained for his family members and the convenience that the person, where appropriate, transmit this information to them.
k) Indication on the possibility to get in contact with him-her, for which information on the way to do so may be solicited.

In the event of the use of samples that are going to be anonymised, the subject source shall receive the information contained in sections a), b), c) and d) of this article.

It also is stipulated by Law on Biomedical that “In the health ambit, samples of deceased persons may be obtained and analysed always when it may be of interest for the protection of health, except when the deceased has expressly prohibited it during his life and can be proven. To this effect, the documents of previous instructions and, for lack of, the criteria of the closest family members of the deceased shall be consulted”. (art. 48.2).

The access by the biological family members to information derived from the genetic analysis of the deceased shall be limited to the genetic data relevant for the protection of their health. (art. 48.2, second paragraph).

The obtaining of biological samples from minors or the disabled for biomedical research shall be subject to the following conditions:

a) That the necessary measures are adopted in order to guarantee that the risk of the intervention is minimal for the subject source.
b) That relevant knowledge on a disease or on the situation that is object of research and which are of vital importance to understand, palliate or heal it may be obtained from the research.
c) That this knowledge may not be obtained in another manner.
d) That the authorisation is obtained from the legal representatives of the minor or the disabled person or that, where appropriate, there are guarantees on the correct consent of the subject source (art. 58.5)

2.3. Research exemption

**Greece:** no research exemption.

**Israel:** no research exemption.

**Italy:**
Article 8 of the said authorisation provides, inter alia, that: “Biological samples and genetic data that were collected for health care purposes may be retained and used for scientific or statistical research purposes subject to the need for obtaining the data subjects' informed consent – unless the statistical investigations and/or scientific researches are provided for by law. Biological samples and genetic data that are collected with a view to implementing research projects and performing statistical investigations other than those for which the data subjects' informed consent was originally obtained may be retained and used further insofar as scientific and/or statistical purposes are pursued that are directly related to the initial ones. The foregoing provisions shall apply unless the data subjects' consent is obtained anew, or if the biological samples and genetic data do not allow any longer identifying the said data subjects – whether because of their processing or not –, or if it is impossible to inform the data subjects on account of specific reasons, even after making all reasonable efforts to contact them, and the research programme was authorised specifically by the Garante in pursuance of section 90 of the Code after obtaining a reasoned favourable opinion by the geographically competent ethics committee.”

**Portugal:**
Law 12/2005 establishes an important exemption on the need for consent: “In case of retrospective use of samples or in special situations where consent of the participants could not be obtained due to the amount of data or subjects, their age or any other comparable reason, biological material and data may be processed, but only for purposes of scientific research, collection of epidemiologic data or statistics” (Article 19, no. 5).

**Spain:**
The consent of the subject source shall always be necessary when the aim is to use biological samples for biological research that have already been obtained for a different purpose, irrespective of whether there is an anonimisation. Notwithstanding this, in an exceptional manner, codified or identified samples for biomedical research may be used without the consent of the subject source when the obtaining of this consent is not possible or it entails a non-reasonable effort to the effects provided in article 3.i) of this Law. In these cases, the favourable opinion of the corresponding Research Ethics Committee shall be necessary, which must take into account, at least, the following requisites:

a) That the research is of general interest.

b) That the research is undertaken by the same institution that requested the consent for the obtaining of samples.
c) That the research is less effective or not possible without the identifying data of the subject source.
d) That there is no record of an express objection of the subject source.
e) That personal data is guaranteed confidentiality. (See art. 58.2 LBR).

In relation to those biological samples obtained previous to the entry into effect of Law on Biomedical may be used for biomedical research purposes when the subject source has provided his consent or when the samples have been previously anonymised. Nonetheless, codified samples or those identified for biomedical research purposes may be used without the consent of the subject source when the obtaining of this consent entails an unreasonable effort as provided in section i) of article 3 of this Law or when it is not possible due to the death of the subject source or when they can not be found. These cases shall require the favourable ruling of the appropriate Research Ethics Committee, which must take into account, at least, the following requisites:
a) That it is a research of general interest.
b) That the research is less effective or not possible without the identifying data of the subject source.
c) That there is no express objection by the subject source.
d) That the confidentiality of the data of a personal nature is guaranteed. (Second Transitory Disposition. Previously stored samples).

Other cases of access without the consent of subjects:
- Health professionals of the centre or the establishment that stores the clinical history of the patient shall have access to the data recorded in it in so far as it is relevant for the assistance that is being provided to the patient, notwithstanding the duties of secrecy and confidentiality to which they are subject (art. 50.1 LBR).
- Genetic data of a personal nature can only be used for epidemiological, public health, research or education purposes when the interested subject has expressly provided his consent or when this data has been previously anonymised (art. 50.2 LBR).
- In exceptional cases and of general health interest, the corresponding authority, after a favourable report by the authority on data protection, may authorise the use of codified genetic data, always when assuring that third parties may not be able to associate the source subject (art. 50.3 LBR).

3. ‘Practical guidance’

Cyprus:
“Operational Guidelines for the Establishment of Ethics Committees in reviewing biomedical research involving human subjects in Cyprus” — Cyprus National Bioethics Committee (ΚΔΠ 475/2005); Recommendation (2006)/4 of the Council of Europe concerning research on biological materials of human origin.

France:
The National Consultative Bioethics Committee (CCNE) primary mission is to produce opinions and reports on bioethics. Its freedom and independence lend legitimacy to its recommendations. Those opinions are not binding.
In 2003, the CCNE draw opinion 77, on “Ethical issues raised by collections of biological
material and associated information data: "biobanks", biolibraries".

As regards to consent and previous information the CCNE envisages that, in order to obtain consent, the instigators of a research must provide information at the time of launching the first research program but also when the collection is deposited. It must be specific about the fact that there will be storage, and where it will be stored, and identify the persons or the structures that will be responsible for keeping elements and information. Information must also be given on the expected length of time of storage. Donors must be informed in broad terms of the type of study for which their donations will be used for and of the framework in which studies will be undertaken. In the first instance, it must be fully implemented at the time when the samples and its associated information data are banked.

There is also information about situations in which consent cannot be obtained directly: when the person is minor or incapable of consenting.

**Italy:**
- “Guidelines” by the Italian Human Genetics Society;
- *Linee guida per la citogenetica - Diagnosi prenatale*, 1 Sep 2002;
- *Linee guida per la citogenetica - Diagnosi postnatale*, 2 Sep 2002;

**Portugal:**
No.

**Spain:**
No.