

Guidelines for health professionals about DNA / Biobanking in Europe

BIOBANKING SUMMARY

- ***A "biobank" is a: "service unit, non-profit organization for the collection and preservation of biological material used for diagnosis, for studies on biodiversity, and for research".***
- ***The [Declaration of Helsinki](#) on Biobanking states that all biobanks must take donors through a process of informed consent before accepting samples.***
- ***Information relevant for potential donors to biobanks should be expressed simply and unambiguously, outlining what is involved and the nature of any risks, should there be any.***
- ***Biological samples are stored and used for research in all areas of medicine, not only genetics. Different biobanks store different kinds of human tissue, depending on the aims of the research.***

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What is a Human Biological Bank?

Biological samples are collected systematically, from patients and other members of the public. They are then stored specifically for the purposes of medical research. These stores are called 'Biobanks', and some of them are used specifically for research into genetics diseases and disorders

Biobanks are defined as: "service units, non-profit organizations for the collection and preservation of biological material used for diagnosis, for studies on biodiversity, and for research ".

The Council of Europe recommends the health authority to consider the biobank as: " a non-profit organization to be officially recognized by the health authorities of the Member States and must ensure proper handling, storage and distribution of material."

Biobanks vary significantly in size. Some are held within medical institutions and hold only a relatively modest number of samples, some are held in research laboratories, and some countries have large-scale, national biobanks

The P3G project is a worldwide initiative to provide comprehensive information about different biobanks, with the aim of harmonising the flow and protection of biological data in a way that both enhances research and protects the interests of the donors and participants. Detailed information can be found at the [P3G website](#)

Why do biobank exist?

Dedicated biobanks are set up specifically in order to examine DNA and try to establish how mutations cause diseases, and thus develop treatments to counter them

Biobanks may also be set up for storing biological samples such as bone marrow from an individual, so that in the event that they develop a serious disease - Leukaemia for example - the healthy stored cells can be used for transplant in order to help them overcome the disease

However, there are many de facto biobanks in the form of stores of biological material from patients, taken and kept in hospitals or laboratories. The samples may not have been taken specifically for the purposes of genetic research in these cases and may have grown in an ad hoc way

What are the different types of biobanks?

From a very general point of view biobanks can be grouped into two broad categories in relation to the type of samples stored; namely we have biobanks of organs and tissues for therapy and transplantation and genetic biobanks

Biobank of organs and tissues for therapy and transplantation

The collection and storage of organs, tissues, cells and products (DNA, proteins, etc.) for therapy, diagnosis and research, is not a new practice since it has been carried out for many years in laboratories and hospitals. As a matter of fact a significant amount of useful biological samples of human beings came from ordinary health assistance acts and it's stored in biobanks of organs and tissues for therapy and transplantation

Genetic Biobanks

Genetic biobanks are a specific type of Human Biological Banks in which are collected and stored tissue samples and cell lines used to perform researches on genetic diseases or to define the genetic component of common diseases

Population Biobank

Particular genetic Biobanks are those who collect and preserve biological material of population groups; this type of biobank is defined population biobank

Population Biobanks are essential resources for the advancement of scientific knowledge because they are because they are an indispensable tool for studies on genetics

Several countries have set up national biobanks, holding the biological data of tens or hundreds of thousands of people. These biobanks try to encourage members of the public

to donate samples, instead of just taking their samples from patients who are being treated

Epidemiological Studies

Genetic epidemiology studies population groups also through population biobanks

Epidemiology deals with disease patterns and factors associated with causation of diseases with the ultimate aim of preventing the disease

The most widely accepted definition of genetic epidemiology is: "a science which deals with the etiology, distribution, and control of disease in groups of relatives and with inherited causes of disease in populations".

Some biobanks can be found university hospitals, or are set up by pharmaceutical companies for the purposes of their own research and drug development. If you are dealing with individuals considering donating samples to a biobank in order to participate in research, you should inform them of the purpose and aims of the biobank is

Some common aims of biobanks:

Treatments for the most common genetic disorders

Some genetic diseases are quite common and affect large numbers of people. For example, some forms of cancer are more heritable than others, meaning that some people will be more genetically susceptible to its development than average

Research is carried out into how to treat these relatively common types of diseases more effectively, or cure them completely

Personalised medicine

This is treatment that is tailored to the particular genetic make-up of the individual receiving it, and is known as 'pharmacogenetics'

Pharmacogenetics offers the possibility of increasing the efficacy of drugs for serious diseases (such as cancer, for example). Drug regimes are often an approximation of what is needed by a patient. Trial and error, using a combination of drugs - which are all individually toxic in their own right - is currently used to find the right balance for treating each individual

Pharmacogenetic research offers a potential solution to this, reducing the risks of the treat

Development of new drugs

Together with pharmacogenetics, the other major branch of pharmacological research is pharmacogenomics.

Pharmacogenomics is a new science that has developed from classical pharmacogenetics and from the [Human Genome Project](#)

Pharmacogenomics can be defined as the science that is interested in how new knowledge about human genome and its products (RNA and proteins) can be used in the discovery and development of new drugs.

Stem cell research

Stem cells possess significant potential for the development of treatments and cures for a wide range of genetic conditions.

A stem cell is one which can be manipulated to become any type of body cell, which means that stem cells can in principle be used to treat disease or repair damage in any part of the body

Some people may wish for their stem cells to be stored in case they need to use them in the future for treatment, should they develop a genetic disorder which can be treated using them

Health surveys

We need to understand better how genetic diseases affect people as their illness progresses over time and throughout a person's life, in order to develop more appropriate and effective treatment plans as people's needs change

To be able to develop treatment depends on carrying out research with comprehensive collections of DNA samples, collected from those affected by specific disorders

Environmental factors

Many diseases have an 'environmental' factor (such as asthma or diabetes, or again, some forms of cancer) that can influence how a disease will affect an individual

It is important to examine how things like background air pollution, or use of alcohol, affect the development of diseases in different individuals, and how these factors interact with a person's genetic make-up

Age demographic databases

Many countries have an 'ageing population', where a greater proportion of society is elderly

Healthy ageing is an important area of research to improve the lives of elderly people, and because they are economically inactive, but heavy users of healthcare

Genetic Biobanks: specific purposes

Genetic Biobanks attract the attention of the scientific world because they are a valuable resource in relation to the development of knowledge of the human genome.

The major purposes of genetic biobanks can be summarized as follows:

- Encourage research to identify the mutations that cause genetic diseases.
- Encourage the collection of individuals with genomic characteristics useful to understand the genetic basis of complex diseases and genetic disease predisposition.

- Make samples available to pharmacogenetics research useful to understand genomic variations that are associated with different responses to medications.
- Centralize the collection of samples of specific genetic disorders and make available cell lines essential for in vitro testing of innovative therapies.
- Offer researchers a service for the development of their studies and promote communication and exchanges between different groups of scientists

Is it safe to join a biobank?

As a health professional, you will probably have taken samples from patients before, and therefore you will be aware that these procedures are relatively painless and low risk. The same is true of joining a biobank

The procedure carries the same risk as, for example, any minor cut which punctures the skin and carries a very small chance of an infection being introduced into the body

Potential DNA donors may be less concerned about any physical discomfort in donating a sample than about their safety in respect of the security of their data

Sample traceability and anonymity

The protection of individual rights and especially the privacy of every individual is one of the most sensitive aspects in the management of a biobank. For this reason the central point of the question concerns the nature of the data; generally the identification of a sample can vary from irreversible anonymisation to complete identification:

- **Anonymous:** these are samples collected and immediately identified only by a code. The patient data are not recorded; therefore it's not possible to trace the source
- **Anonymized:** biographical data of the patient are removed after the award of the code and after no connection is possible
- **Identifiable (pseudonymized form):** these samples are identified by a code known only to the charge of the biobank and her / him collaborators. The possibility to trace the origin of the sample takes place, if the results of scientific benefit to the donor, on the basis of decisions expressed in the written informed consent. It is correct to specify that if these samples are used for scientific purposes, the possibility of tracing

the donor is almost never exercised, since it is neither useful nor necessary for the presentation of results

- Full identification: the sample is identified by name and address. This option is possible only at the express request and / or consent of the person concerned or persons entitled and in each case exclusively for personal and family interests (eg diagnosis)

As a consequence of modern methods of molecular genetic analysis and electronic data processing, the information content of biobanks and the possibilities of disseminating such information are currently rising rapidly

This new trend raises the question of the need for regulation in this field in particular as regards the protection of the donor

What permission do biobanks need in order to do research?

The "[International Declaration on human genetic data](#)" elaborated by the UNESCO, and adopted the 16 October 2003, is the first international legal instrument that settles a number of rules about biological samples and on the personal data which may be collected from those samples

The [Recommendation of the Council of Europe](#) to member States on the use of biological material of human origin for purposes of biomedical research clearly sets out the limits within which should be included all the activities in health research that involve the removal of biological material of human origin which must be kept for research use

A requirement which have to be met to use biological samples preserved when genetic data is to collect a previous, free, informed and express consent from the concerned person

Individuals need to give explicit consent to the use of their samples for a particular purpose. They cannot be taken or used without the permission of the donor

Internationally, especially in Europe, the essential elements of information for the donor/patient – that must be registered with analytical procedures in the documentation of the future agreement or disagreement - are:

- voluntary nature of participation

- the purposes, the nature, the extent and the duration of the proposed use, including proposals for genetic testing
- the extent and the conditions of a possible transfer of samples and data, particularly when exported;
- the possibility or otherwise of the communication of research results to the donor
- advice on the possible consequences of disclosure of results of genetic testing for the donor and his family, including any obligation to disclose (eg insurance companies)
- the form of storage and data link
- the possibility to anonymize samples or to identify them with a code
- security measures adopted for the protection of personal data
- any state's right of access to data and samples;
- the right of the donor to withdraw his consent at any time without penalty; the destination of samples and data in case of withdrawal or if the biobank is closed
- any commercial prospects of research (including the filing of any patent)
- the issues of payment of expenses of the donor
- the question of participation of the donor to any diagnostic / therapeutic benefits of the research

At International level, as at European level, the regulation on biobanks is focused on the distinction between biobanks for therapy and transplantations and biobanks for research. The distinction is significant from a legal perspective, because they are clarifying the different "purposes" for the collection and for the use of the material in the two cases.

De facto, this distinction implies the need to use different informed consents

Detailed information on recommended consent routines for research on biobank samples where no consent was obtained, or the consent is unclear can be found

Can biobanks use samples from old collections without consent?

Numerous collections of bodily substances established for the purposes of medical diagnosis or therapy in the past, often very long ago, have now assumed great value for research owing to the development of new techniques of molecular genetic analysis

These collections would be lost to research if they were to be judged retrospectively by present-day criteria and if effective informed consent were demanded for their use

It is advisable that these historic collections of samples are not managed according to current standards

Can individuals say no to the use of their samples in particular types of research?

You should discuss this with the people who are deciding whether or not to consent to donating their sample to the biobank, by explaining exactly what research will be carried out

However, it is important to explain that many studies can be too complex for most biobanks to offer individuals the choice of opting out of some types of research. Instead individuals may prefer to choose not to volunteer; for more detailed information see the section on [informed consent](#)

Will participants be told about the results?

You should discuss this with the potential participants when they are deciding whether or not to give consent. Generally, participants are not told results of biobank research

If the study you are involved with is one where the identity of the DNA donors is coded or anonymised, then there may be no way for results to be transmitted back to the DNA donors, even if they would like to know the results

Whether or not the results of research using your DNA samples are fed back to the participants depends mainly on the particular study being carried out. If feedback is offered, it is also up to the participants to decide whether or not they wish to receive such feedback

If in the course of research it is discovered that a participant has, or is likely to develop a genetic disorder, this may give the individual the opportunity to start taking preventative measures and begin treatment at an early stage. However, some people may prefer not to know about such results especially if no preventative measure or treatment exists for the condition in question

Who will be able to see information held in a biobank?

Participants donating tissue to a biobank are entitled to know who will have access to their information

It is usual that just the organization that takes the samples will know personal details such as individual names and addresses

An important point is whether, and subject to what conditions, third parties, from the fields of both academic and industrial research, should be given access to biobanks

In principle, to optimize the research results and also in the public interest biobanks with their data and samples should be as much as possible available for medical research

Adequate quality assurance measures are the only way to ensure that biobanks remain usable for a variety of research projects over very long periods of time

Will the police be able to get access?

Most biobanks are anonymised so there is no way to ever link an identifiable individual to a particular set of data

The information held in biobanks is confidential medical information and so is inaccessible by the authorities, except in the most extreme cases where there is a specific public safety concern

Will insurance companies be able to get access?

People considering taking part in research may have questions about whether or not insurance companies will be able to access personal genetic information about them

Whether or not insurance companies are legally entitled to find out personal genetic information, and whether or not research participants or those who have taken genetic tests are obliged to disclose any such information varies depending on the way in which a diagnosis is made

The positions for different types of tests in the UK are shown below, or for a breakdown of the situation you can also consult material produced by the London Ideas Centre, [here](#)

Diagnostic testing

If a person discovers that they are a carrier of a disease because they were exhibiting symptoms of illness and were tested for a diagnosis, then they are obliged under UK law to provide this information to insurers

Predictive testing

If a person found out this information because a member of their family had a condition and they had a test to find out whether or not they will as well, then they are similarly obliged to tell their insurer

Genetic research

The situation is different for information discovered in the course of genetic research. A research participant may be a member of the public who was not undergoing medical treatment but decided independently to take part in a research study

The person may have discovered coincidentally through the study that they are a carrier of a disease. In cases like this, they are not obliged to tell their insurers of their condition

The importance of insurance issues has been recognized by many European governments and legislative bodies. The World Health Organization has recognized that participants in research, who may suffer from a disorder, are in a vulnerable position in relation to insurers. It therefore discourages these participants from granting insurers access to their genetic information

This is only an issue however in cases where DNA samples have not been anonymised and the donor is still identifiable. Where the samples have been anonymised and there is no danger of identification, there would be no personal information for an insurance company to use

Can research participants leave a biobank after they have joined one?

This depends on the biobank and on what is agreed on joining

Individuals considering donating samples are entitled to know about their right to withdraw consent and the implications of doing so when they are making their decision

Whilst an individual has the right to [withdraw consent](#), it may be impossible for biobanks that anonymise samples to be able to identify a particular sample in order to destroy it

Withdrawal is only possible if the [anonymization process](#) has not taken place. Also, if analyses have already been performed on an individual's sample, it is likely to be impossible to erase results from databases or reports that may have already been issued

Intellectual property and ownership of samples

Once samples have been given to the biobank, both the biobank and the donor can legitimately claim the samples as their property; as a matter of fact, legally, the problem of the properties of the sample is complex and still debated

In the present situation, generally it's agreed that the samples belong to the donor, which makes them available - granting use to the extent of the consent given - in a spirit of solidarity towards future benefits arising from research

The researcher is recognized as the custodian of the sample and is responsible for the proper management of the sample while he's the owner of the scientific discoveries derived from the research

However, the [European Union Database Protection Directive](#) was devised in 1995 to act as a guideline for how personal data should be used

The usual practice in Europe is that DNA data belongs to the researcher or team that creates it. The individual who donated the DNA and who was the subject of that research has no legal entitlement to the research or the data it produces

Where a drug or therapy is invented as a result of research carried out using donated DNA samples, the organisation that developed the treatment may claim ownership of the product they have created

In order to gain ownership of the product they will often apply for a patent (also known as intellectual property rights) of the treatment so that they have the rights to its production

In order that the DNA donors who enable the research to go ahead are reimbursed for their donation and can benefit from their investment in the research as well, the research organisation may offer benefits in a range of ways. These are explained fully in the section entitled Access and benefit sharing

For more detailed and thorough information you can refer to [P3Gwebsite](#) where, in the section "P3G Observatory", you can find a very up-to-date Comparison Chart of Guidelines on Biobanks.

SUMMARY OF THE BENEFITS OF PARTICIPATING IN RESEARCH

- Genetic research offers the possibility of developing cures for many serious, and sometimes fatal, diseases
- Research into treatments for diseases is done using biological samples donated by people affected by them
- Those who participate in genetic research will help people in the future who are or will be affected by disease

- It may be acceptable to offer benefits and incentives to research participants, in recognition of their investment and contribution
- Genetic research cannot be done without the participation of sample donors. Without this participation it will not be possible to develop new drugs, therapies and treatments

What is 'benefit sharing'?

Benefit sharing is the result of collaboration between those carrying out the research, and the members of the public - including patients - who enable the research to go ahead by donating biological samples

Genetic research is carried out in order to develop treatments and cures for diseases

Where research is successful and advances in treatments are made, 'benefit sharing' is the means by which the lives of affected communities are helped by these advances

Those who participate in research by donating their samples for research therefore receive a 'return on their investment', and these returns can be offered in a number of different ways

Why is it important?

Genetic research has the potential to transform lives by developing new treatments that can cure or ameliorate the symptoms of inherited disorders, or prevent them from occurring at all

Those who participate in research by donating biological samples are entitled to know about the developments and advances that may result from the research. They are also entitled to know how these developments will reach the people who need them

It might not always be clear to potential research participants how laboratory research is turned into real improvements to health. Drug development takes time, and so there is a delay between research beginning and drugs being produced. You should inform potential research participants of this when making a decision about whether or not to donate samples

'Benefit sharing' helps to build good relations between researchers and those who, by donating samples, enable the research to go ahead. Benefit sharing helps to ensure that research can continue to develop new treatments, and to ensure that the pace of improvements to health is maintained

What are the benefits derived from research with biobank?

Medical research has high expectations on the discoveries that may arise from the knowledge of our genome and its implications with modern medicine

The role of Biobanks, as institutional collections organized and structured in accordance with common and shared rules, becomes central because they constitute an important tool for research whose positive results bring benefits not only to the donor and his family but to the whole human community

Benefit sharing and patient groups

Close links between patient groups and researchers are essential in ensuring that research into curing genetic disease can continue

If a patient is considering participating in research has a genetic disorder, you may be able to direct them towards a national or international support group for the condition being researched

Patient groups play a crucial role in facilitating communication and the transmission of benefits to those who need them and who have participated in research

Patient groups can provide the link between the researchers, the research participants and patients affected by the disease, and ensure that the benefits returned to the research participants are fair and appropriate

In some cases it is can be difficult to find a patient group for a specific disorder (for example in the case of rarer conditions). However, there are European organizations that you can contact in order to find out more about the disease, and what help might be available

The [European Society of Human Genetics](#) has contact details for all the national genetics networks across Europe.



Equal distribution of benefits

The purpose of benefit sharing is to make sure that advances made by the pharmaceutical industry in drug development are shared out between those who can benefit from them, and who may have participated in the research itself.

Benefit sharing schemes should attempt to direct resources, health benefits, knowledge or financial support to affected communities

Benefit sharing schemes can take a number of forms and are facilitated by a number of different agencies and bodies

What forms can it take?

Commercial benefit sharing

The issue of commercialization of biological material is still a subject of wide debates and reflections and it is closely related to some basic concepts:

"TISSUE PROPERTY"

"PATENTABILITY OF LIVING MATTER"

"FREEDOM OF SCIENTIFIC RESEARCH"

The focus concerns the definition of the legal status of the human body and the property of the tissue; the general trend is to protect the human body and its genome from all forms of economic exploitation while acknowledging the possibility of profits attached to intellectual property arising from the personal scientific discoveries or applications.

Technology Transfer

'Technology Transfer' describes how raw scientific research, and the use of medical technology, is turned into real benefits to health

Research into new drugs for genetic disorders is carried out using DNA samples donated by individuals participating in research

Drugs developed as a result of this research are the outcomes of the 'technology transfer'

Drug manufacturers carrying out the initial research may offer a subsidy on the drug to those who donated their samples, or links with patient groups and health providers facilitate opening the pathways by which the drugs can get to the people who need them

Health promotion and training

Benefits like these are important due to the local, national, and international inconsistencies in the provision of information across Europe about genetic diseases and treatments for them

Investment into training and education about genetics and health could help large areas of the continent and significant numbers of people

Investment into training and education can directly benefit patients and their communities, and can provide a base for the continuation and expansion of genetic research in the future

Improvements to infrastructure

Pharmaceutical companies can donate money towards specific practical improvements to health infrastructure. For example, enhancing information and IT systems, or investing in new medical equipment.

Alternatively, a financial contribution can be offered to local healthcare providers, or community services for those affected by genetic disorders. Donations of this kind may be able to pay for disabled access to buildings, or provision for those who are hard of sight or hearing, for example

Honesty and integrity



It is important that benefits offered to research participants and patient communities are both deliverable and delivered. You may wish to find out the limits of any research and the possible speed of delivery of the benefits to be realized from a particular study

Laboratory research cannot be turned immediately into new treatments, and not all research into treatments for a genetic disease will bring about a cure straight away. You should make this clear to individuals who are considering participating in research

However, potential research participants may be willing to take part if the research body offers some commitment to ensuring that they or the affected patient community will benefit

Legality

The legal status of incentives, donations and returns to research participants may differ between countries

You should consider this in particular when research is being done collaboratively across national borders by several teams in different countries

Potential research participants are entitled to know how and where their data will be used, as well as the nature and extent of any benefits that may be returned to them in recognition of their involvement

If you wish to find out more about genetic research that is taking place in your country, [please contact your national genetics network](#)

Access rights to outcomes of research

In order to enable genetic research to continue and develop new improvements to health, the scientific community needs some degree of open access to the results of previous research programs

This means that some sharing of personal genetic data donated by individuals is necessary. You should explain that this is the case to potential research participants, before they agree to provide genetic data

Whether or not patients are happy for their DNA samples to be seen and used by other research teams is a personal matter for them. They may or may not agree to participate, but in either case, what is important from an ethical point of view is that they have been informed

Biobanks and genetic research are supervised and externally audited, to make sure that researchers are using data appropriately. The ability of researchers to be able to continue with research in future depends on them adhering to high standards of data privacy

NB: Disclosure of patients identity can be prevented in some cases by anonymising or encrypting data samples (see section [Sample traceability and anonymity](#))

This is not carried out in all studies however as it is not appropriate for the aims of the research in every case

Pharmaceutical companies

Drug manufacturers invest in research and development of new drugs to treat an increasing number of disorder

Drug companies recruit their own volunteers to take part in clinical trials, though they may also wish to use data collected by public or other private research organizations. Once again, this will vary from study to study

Potential DNA donors are of course entitled to make a decision on whether or not to submit samples, on the basis of the information provided to them by individuals such as you, i.e. researchers or health professionals

Whilst individuals may be concerned about large pharmaceutical organizations having access to their DNA data, they are obliged to follow strict international standards of privacy and confidentiality

Can healthcare companies pay to see public sector biobanks?

Some biobanks make their samples and/or data available to interested researchers, from both the public and private sectors

Private sector biobank will often charge researchers a fee for having access to their samples and/or data

The precise arrangement will vary, and there is no single European protocol which can be applied in every case

Why do biobanks need the samples, and samples from so many people?

This is done in order to ensure the accuracy of results

Researchers use genetic biobanks to investigate the causes of inherited diseases. They do this by looking at mutations in a person's DNA

The more a mutation occurs in these people when compared against people without the condition, the greater certainty there can be about what causes the disease. Therefore the more DNA data there is to begin with, the greater the chance of finding these root causes

This in itself is important as the more knowledge researchers have about what causes a disease, the more can be known about what kinds of therapies will be needed in order to treat or prevent it

What is a "cohort study"?

A Cohort Study is a study in which patients who have a certain condition and/or receive a particular treatment are followed over time and compared with another group who are not affected by the condition under investigation.

For research purposes, a cohort is any group of individuals who are linked in some way or who have experienced the same significant life event within a defined period.

Therefore the cohort study is a methodology that has been used to evaluate clinical treatments but that is also the basic methodology to set up [epidemiologic studies on genetic factors](#) associated with diseases.

Why do some biobanks look to recruit families, some twins and some just take individuals who volunteer?

Genetic information has provided the key to unlocking the mysteries of many diseases

The study of one single family can reveal important information on genetic differences. Since the genetic differences within one family are relatively small, this increases the chance of identifying important differences that lead to some people having the condition

Traditional designs for distinguishing non-genetic shared family effects from genetic effects have been studies of twins. Twin studies provide somewhat more specific information than recurrence risk ratios.

Twin studies have been traditionally used to estimate the genetic contribution to a trait through the comparison of monozygotic pairs (who share all their genes) with dizygotic twins (who share half of their genes in common). The greater similarity of monozygotic twins than dizygotic twins is considered evidence of genetic factors.

How long are biobanks set up to run for?

Most biobanks are established with the intention of lasting for a long period of time, usually for many years

The biobank is likely to have a policy of disposing of material after storage for a period of, for instance, 10, 20 or 30 years. In some countries legislation exists on the period of time that samples and data can be stored

Many biobanks – in particular, the planned large-scale population-related projects – are designed in such a way, in terms of their objectives, that bodily substances and data, as well as information from and about persons, are stored for long periods of time.

This raises the question of the degree of specificity required for donor consent to the handling and use of their samples, data and information prior to collection and/or recording, in order to meet the criteria of ethical and legal acceptability.

This question arises in particular if the research for which the samples and data are to be used cannot be concretely identified at the time when consent is to be obtained because the details are not yet known.

The issue on the preservation period of the data is related to the viability of anonymisation process. In general, identifiable features can be eliminated from research data bases after some years, so the data is rendered anonymous again and it cannot be related to an identifiable person anymore

What happens when they close down?

If a biobank was created for a specific purpose that no longer has relevance, or if the establishment hosting the biobank closes, then the samples stored in the biobank should all be destroyed

In some cases, samples would be transferred to another host organisation. In such cases the accepting organisation must continue to protect the privacy of the sample donor, and ensure that they comply with the terms of consent given by participants that originally donated their tissues

Biobanking procedures across Europe

The following European countries currently have no specific regulations in place regarding DNA banking and genetic research procedures:

Norway, Portugal, Ireland, Greece and Hungary

If you wish to find out information regarding data privacy in the country in which you practice, click the following link to individual nations [European Information Commissioners offices](#)

It is a personal decision for each individual whether they wish to be involved with research studies that operate internationally across different countries

However, individuals may need your help in order to make this decision as they will rely on information about the study that comes from you as a health professional