

Information for patients and the public and patient information about  
DNA / Biobanking across Europe

#### BIOBANKING / DNA BANKING SUMMARY:

- A biobank is a store of human biological material, used for the purposes of research. Some of these are specifically for research into genetic diseases and conditions.
- Information about the causes of disease is generated by analysis of the stored samples, and treatments for them are developed using this information.
- The Declaration of Helsinki on Biobanking states that biobanks must take donors through a process of informed consent before accepting samples.
- Donating samples for a biobank is not dangerous or painful

Biobanking / DNA banking

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What is a biobank?

Sometimes a DNA sample may be taken from you in the course of your treatment.

These samples are often stored and may be used to carry out other research as well, if you give your permission for this to be done.

Stores of biological material are called 'DNA Banks' or 'Bio Banks'. There are many biobanks of different kinds around Europe, and as an example,

Follow this link for the website of the UK biobank: <http://www.ukbiobank.ac.uk/>

Follow this link for information on European biobanks: <http://bbmri.eu/bbmri/>

- There are biobanks all over the world, and not just in Europe. The 'P3G' consortium is a group which has compiled information about many different biobanks across the world, and detailed information about them can be found at their website. The project aims to help with the harmonisation of different procedures carried out by the various biobanks, in order to help make research more efficient and protect the interests of potential research participants. You can find out more by visiting the website of the P3G consortium: <http://www.p3gobservatory.org/>
- If you donate a DNA sample to a biobank, it only involves donating a small amount of biological material, and is not a serious or invasive procedure.
- A sample could take the form of a swab of your saliva, it could be a small blood sample, it could be a scraping of skin cells, or it could be a small sample, or 'biopsy' of a tumour or affected part of the body.
- A sample might be taken for a test as part of a regular medical procedure, or you may have been asked if you would like to participate in research by donating a biological sample for research.
- Virtually all medical specialties, not just genetics, store and analyse human biological material in order to advance knowledge and develop new treatments. This

means that 'biobanking' is not really a new development. It has been brought into view particularly in recent years, partly as a result of the high-profile work done in the decoding of the human genome.

- There are also biobanks created specifically for research, instead of from samples from patients who are already receiving treatment. Some countries even have biobanks developed on a national scale for this purpose.

Why do biobanks exist?

- Biobanks are set up so that researchers can examine DNA and try to establish how faults in DNA cause diseases.
- Once research programs can work out the cause of different diseases and conditions, they can use this knowledge to begin to develop treatments or cures that can improve or save the lives of those affected.
- 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.

What are the different types of biobanks, and where are they?

- There are many different types of biobanks, found in different kinds of institutions depending on what kind of research the organization carries out.
- Some biobanks can be found in educational institutions such as university hospitals. Often the collections of material will have grown naturally from samples being taken from patients in the course of treatment.
- Other biobanks are set up by independent research companies or drug companies, who are carrying out research and development into new treatments.

- More recently, several countries have set up national biobanks, holding the biological data of up to several hundred thousand 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.
- If you have been asked if you would like to donate a DNA sample to a biobank, those asking you will be able to tell you what the purpose of their 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.
- 1 in 3 people will develop cancer at some point in their lives, and some of these have genetic causes. More research is needed in order to find out more about how to treat and prevent these effectively.

### Personalised medicine

- 'Personalised Medicine' is treatment that is tailored to the particular genetic make-up of the individual receiving it.
- Humans are all similar, but there is a lot of genetic variation between individuals. Treatment that works well for one person, may not work so well for somebody else.
- Further research is needed in how to develop effective personalised medicine regimes.

## Stem cell research

- Stem cells possess significant potential for the treatment and curing of a wide range of genetic conditions.
- Stem cells are the body's 'building blocks', and can be manipulated to turn into any kind of cell from the body. This means that they may be used to treat a huge range of conditions.
- Some people may wish for their stem cells to be stored in case they need to use them in the future as a treatment, should they develop a genetic disorder. In any case, further research is needed to unlock the full potential of stem cells and develop new and effective therapies.

## Health surveys

- We need to understand better how genetic diseases affect people as their illness progresses.
- If we improve our understanding of the way in which different diseases progress, then more effective and appropriate resources and treatment can be put into place.
- To be able to develop treatment depends on carrying out research with comprehensive collections of DNA samples, collected from those affected by different disorders.

## Environmental factors

- There are many diseases which can be caused or brought on by 'environmental' factors, and these may influence how the disease will affect a person. Asthma and diabetes are two examples of conditions such as this.
- 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 to cause disease.

## Age demographic databases

- Many countries have an 'ageing population'. This is where a growing percentage of the population 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.

## Is it safe to join a biobank?

Joining a biobank by donating a DNA sample is not dangerous. The procedure carries the same risk as, for example, any minor cut which punctures the skin. There is only a very small chance of an infection being introduced into the body.

## What permission do biobanks need from me in order to do research?

If you donate DNA samples to a biobank, the biobank or researchers requesting your participation will need your permission, or 'consent' in order to take the samples and use them for a particular purpose.

- Although samples cannot be taken or used without your permission, if you agree to give 'blanket' consent, you may not be told how they are used in the future for

further research. The kind of consent you give therefore limits the research that may be done using your samples. .

- The P3G website has an example of a generic consent form, of the type that you may be asked to sign when agreeing to donate samples for research:  
[http://www.p3gobservatory.org/download/Modelconsentform\\_Finalnov6.doc](http://www.p3gobservatory.org/download/Modelconsentform_Finalnov6.doc)

Can I say no to the use of my samples in particular types of research?

This should be discussed with you when you are making a decision about whether or not to donate a sample to a biobank.

- In theory, the answer is yes. However, in some cases, because of the potential difficulties in tracing research participants, it may be too complex for most biobanks to offer you the choice of opting out of some types of research. Instead you may prefer to choose not to volunteer.

Will I be told about my results?

This should be discussed with you when you are deciding whether or not to donating your sample to the biobank, but generally participants are not told results of biobank research.

- If the study you are involved with is one where the DNA samples are coded or anonymised, then there may be no way for you to find out your results, even if you would like to find out.
- A health professional such as a doctor, or a researcher carrying out the study must tell you what form the research will take before you agree to donate a sample.
- Whether or not the results of research using your DNA samples are transmitted back to you depends mainly on the particular study being carried out. If the results are offered to you, it is also up to you to decide whether or not you wish to receive them.

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

- If you are going to participate in a biobank, the researchers or health professionals taking the samples should always tell you who will have access to their information.
- Usually just the organization that takes your sample will know personal details such as your name and address.

Will the police be able to get access?

- The collections of samples in most biobanks are anonymised so there is no way to ever link an identifiable individual to a particular set of data.
- Also biobanks contain confidential information and so are 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?

If you are considering taking part in a genetic research study, one question you may have is whether or not insurance companies will be able to access personal genetic information about you.

Whether or not insurance companies are entitled to know personal genetic information, and whether or not you are obliged to tell them varies depending on the way in which you discovered that you have a condition.

### Diagnostic testing

- If you discovered that you are a carrier of a disease because you were exhibiting symptoms of illness and were tested for a diagnosis, then you are obliged under UK law to provide this information to insurers.

### Predictive testing

- If you found this information out because a member of your family had a condition and you got a test to find out whether or not you will as well, then you are similarly obliged to tell your insurer.

#### Genetic research

- The situation is different for information discovered in the course of genetic research. You may be a member of the public who was not undergoing medical treatment but decided independently to participate in a research study. You may have discovered coincidentally through the study that you are a carrier of a disease. In cases like this, you are not obliged to tell your insurers of your condition.
- The issue of insurance is one that has already been noted by governments and legislative bodies. The World Health Organisation has recognised that participants in research, who may suffer from a disorder, are in a vulnerable position in relation to insurers, and 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 I leave a biobank after I have joined one?

This depends on the biobank and on what you agree when you join.

- The right to withdraw consent, and the implications of doing so, should be fully explained when you provide a sample for the biobank.
- Whilst you may have the right to withdraw consent, sometimes it may be impossible for biobanks that anonymise samples to be able to identify your particular sample, in order to destroy it.
- Withdrawal is only possible if anonymization has not happened. Also, if your samples have already been analysed, it is likely to be impossible to erase results from databases or reports that may have already been issued.

## Intellectual property and ownership of DNA samples

This can be a complex issue. Once DNA samples have been given to the biobank, both the biobank and the donor can legitimately claim the samples as their property.

However, the European Union Database Protection Directive was devised in 1995 to act as a guideline for how personal data should be used. You can see the website by visiting this link: [http://ec.europa.eu/justice\\_home/fsj/privacy/law/index\\_en.htm](http://ec.europa.eu/justice_home/fsj/privacy/law/index_en.htm)

- The general practice in Europe is that DNA data belongs to the researcher or team that creates it. The person who donated the DNA has no legal entitlement to the research or the data produced by it.
- Where a drug or therapy is developed from research carried out using donated DNA samples, the organisation that developed the treatment can claim ownership of the product they have created. To do this they will often apply for a patent of the treatment so that they have the rights to its production. Acquiring a patent for something is known as gaining 'intellectual property rights' to it.
- So that the research participants who enabled the research to go ahead are reimbursed for their donation, and can benefit from their investment in the research as well, the research organisation can offer benefits in a range of ways. These are explained fully in the section entitled 'Access and benefit sharing'.

## Pharmaceutical companies

Drug manufacturers invest in research and development of new drugs to treat a huge range of disorders. The decoding of the human genome has created new potential for medicines to target the specific genetic make-up of the person with the disease.

Also known as 'pharmacogenetics', research and development may offer the possibility of genetic treatments tailored for specific individuals.

- Increasingly effective medicines can be developed by minimising side-effects and maximising the efficiency of a treatment program. DNA research is necessary to achieve these goals.

- 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 organisations. Once again, this will vary from study to study.
- You, as a potential DNA donor, are of course entitled to make a decision on whether or not to submit samples, on the basis of the information provided to you by researchers or your doctors.
- While you may be concerned about large pharmaceutical organisations having access to your DNA data, they are obliged to follow strict international standards of privacy and confidentiality.

Where do population-based biobanks exist?

There are several large public population-based biobanks. National population-based biobanks now exist, or are being developed, in Estonia, Canada, Iceland, Japan, Latvia, Singapore, Sweden and the United Kingdom, among others.

Whereas some of these biobanks involve the compilation of genetic, life style and genealogical information, other biobanks are more extensive, with links to individual medical records. These large biobanks range in size, seeking from 60,000 to as many as a million volunteers.

Can healthcare companies pay to see public sector biobanks?

Some biobanks make their samples and/or data available to any interested researchers, whether from the public or commercial sector.

It is also possible that the public sector biobank will charge researchers a fee for having access to their samples and/or data.

Why does a biobank need my sample, and samples from so many people?

This is done in order to ensure the accuracy of results.

- In genetics, most researchers that use the samples stored in biobanks try to investigate the causes of inherited diseases. They do this by looking at defects or 'mutations' in a person's DNA structure. When trying to find out what causes a

disease, it might be that a certain mutation keeps appearing in those with the disease when their DNA is analysed.

- 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 can find out about what causes a disease, the more can be known about what will be needed in therapies to treat or prevent it.

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 many years.

- However, it is possible that some tissues will deteriorate after prolonged periods of storage. This deterioration will mean that the samples are no longer of any value to researchers.
- 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.

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

If you are in the European Union and wish to find out information regarding data privacy in your own country, links to individual nation's Information Commissioners offices can be found via this link:

[http://ec.europa.eu/justice\\_home/fsj/privacy/nationalcomm/index\\_en.htm](http://ec.europa.eu/justice_home/fsj/privacy/nationalcomm/index_en.htm)

- The EuroGenGuide cannot legally make these countries act in a particular way, so it is for you to discuss with your clinicians / researchers whether you wish to be involved with research studies that operate internationally across these countries.
- Some people have concerns about submitting personal data that could be seen by a third party. However, in spite of this many thousands of people have been willing to donate samples to biobanks.

## 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.

For instance, the effect of smoking on health could be studied by following two groups, the first of people who smoke and a second of people who do not. The study would then follow both groups over time to see what health problems, if any, they develop.

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.

- Identical twins have identical genes. So any biological differences between twins must be the result of environmental factors, such as their diet. Twins therefore provide a powerful tool to study the impact of nature versus nurture for many conditions.