EGAN
European Genetic Alliances' Network

FAQ on Biobanks

Often specialists from several fields will work together to analyse sample results fully

Staff will be experienced at gathering samples with as little discomfort to you as possible. But that doesn't mean you have to look if you don't want to!

Introduction

Developments in genomics and in bio-informatics have made it possible to analyse quantities of data and samples that, even a few short years ago, would have been unimaginable. This has created the possibility of examining the complex interplay that operates between genes, and between genetic, environmental and lifestyle factors in the search to understand common complex diseases (heart disease, diabetes, cancer and mental health disorders, to name but a few) and to develop targeted therapies to treat and possibly even cure them.

Generating the data necessary to undertake this research has led to the establishment of "biobanks" in the public and the private sector around the world. The largest of these may contain tissue samples and data from half a million or more people. Patients, families and members of the general public are increasingly likely to be asked to volunteer to contribute to a biobank to help medical research.

In this fast changing field it is important that those asked to contribute their tissue and to volunteer potentially sensitive personal information have the opportunity to be clear about what is being asked of them. To help promote understanding and to secure informed involvement with the activities of biobanks and the research they make possible we have assembled a list of questions that have been frequently asked of us by those contemplating volunteering to be part of this large scale research activity. The answers and the current booklet are a result of a collaboration between the European Genetic Alliances Network (EGAN) and Roche. We hope the information given contributes to clarify the aims and purposes of biobanks, so as to help promote informed engagement by patient and from healthy citizens.

The answers given to these questions are inevitably general. They may not all apply in every detail to any particular biobank, so if you are asked to volunteer and you have specific issues you wish to resolve, you should discuss them with the sample collector or other responsible persons before proceeding.

We look forward to any comments and suggestions for improvements to this leaflet. Please send them to alastair@gig.org.uk and we will endeavour to incorporate them in any future revision of this leaflet.

Don't be afraid to ask staff to hold your hand if you're nervous!

FAQ – Biobanks

1. What is a biobank?

In a biobank, also known as a biorepository, biological materials and the data associated with those materials are collected, stored, processed and distributed. The purpose can be scientific research or medical treatment. Typically, those "biological materials" are human samples – such as tissue (including organs) or blood and other body fluids - and the "data" is any information, including medical information pertaining to the donor of that biospecimen. A biobank can also include tissues from animals or plants, cell and bacterial cultures, or environmental samples (soil, water).

Biobanks exist within a variety of institutions, including academic medical institutions, and pharmaceutical and biotechnology companies. They can also be stand-alone organizations, including independent companies (both for-profit and non-profit) that can provide biobanking services and access to samples as a service to the research community or patients.

Modern biobanks that support research are highly complex in their operation. They are often health related large, specialized organizations comprised of individuals with expertise spanning biology and pathology); informatics and information technology infrastructure, laboratory operations, ethics and applicable laws, rules and regulatory requirements. Biobanks are committed to respecting the rights of tissue donors, while simultaneously serving the legitimate needs of biomedical researchers.

Among the biobank's activities are:

- **Recruiting donors** and supporting them through the **informed consent** process. This means they must coordinate with ethics review boards to design protocols that provide the proper degree of donor protection.
- Interfacing with clinicians and other qualified medical personnel to **collect tissues** and to transmit those materials to the biobank. The biobank also provides systems and support to collect the donor's **clinical and other information** from their medical records, from the patient or doctor interviews and other sources. That information is then formatted for secure storage (either as hard copy or, generally, in electronic form).
- Operating a biobank with full **logistical support**, including appropriate systems for the collection transportation, and storage of samples, pathology review, molecular biology analysis, and procedures to receive, manage, and distribute biospecimens for use in authorized research projects.
- **Supporting processing laboratories** that can extract molecular components from tissues (such as DNA and RNA) and add these derivatives to the biobank's inventory.
- **Providing scientists with secure, non-patient identifying** access to the inventory of specimens and data so that they can request materials that support their research protocols.

The research made possible through the use of BioBank published in medical journals and used in training future generations of researchers and doctors

2. Which categories of biobanks exist and what are their goals?:

A biobank is the general term for a repository of biological tissue. But there is currently no universal classification system for biobanks. However, several categories are commonly distinguished, including tissue type, purpose, ownership, volunteer group, and size (see **Table I**). For example:

There are biobanks created from newborn screening blood spots by state newborn screening laboratories. These biobanks may be used for population-based determinations.

Tumor banks are another class of biobanks, in which tumors from cancer patients are studied for biomarkers associated with disease.

Biobanks of umbilical cord blood contains donated cells from a recent pregnancy for use in transplantation and stem cell research.

Population-based biobanks are defined as large repositories of donated human DNA and/or its information, collected from volunteers with and without disease, used to identify genes that contribute to human disease, and to investigate possible therapies

Table I

Human Biobank Classifications

Tissue Type	Tumor tissue, cells, blood, DNA, or DNA array results
Purpose / intended use	Research, forensics, transplantation, source for therapeutics (e.g. umbilical blood, stem cell biobanks for individual or community use), or diagnostics
Ownership	Academic & research institutions, hospitals, biotechnology & pharmaceutical companies, and stand-alone biobank companies and foundations may hold biobanks. Ownership may be private, public or in partnership across sector boundaries
	Public, managed in partnership with government
Volunteer group / group of participants	*Population-based*, such as all newborns, adults, or pregnant women
	Disease-based, including only those with a specific disease
Size	Disease group, regional, statewide, or national

3. Is a biobank the same thing as a patient registry?

No, a biobank is not the same thing as a patient registry, but they can be complementary as they contain information that can be mutually helpful in carrying out research. A biobank will contain human tissue samples, and/or a variety of body fluids. A patient registry will have information and data on patients, patient populations, patient groups and sub-groups as well as general health care information, mortality and hereditary data, but no body material. Information between a patient registry and a biobank can usually only be shared following patient consent and when subject to the limitations imposed by appropriate ethical review.

4. Where do population-based biobanks exist?

National population-based biobanks exist, or are being developed in many countries, including Estonia, Canada, Iceland, Japan, Latvia, Singapore, Sweden and the United Kingdom. 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, from a few thousand to as many as a million volunteers. Most of them are public population-based biobanks, managed in partnership with the national government. A few also receive partial funding from research foundations.

Many lessons have been learned about the development of research using public sector biobanks in ways that will sustain patient and public trust and confidence in these resources. For instance, a planned biobank in the Kingdom of Tonga was unsuccessful because it awarded exclusive licensing to a private company without public consultation. In contrast, the population-based biobank in Estonia has been very successful, partly because its policies have been transparent and responsive to the public. The biobank infrastructure in the United Kingdom, perhaps in response to these contrasting events, has developed policies that provide for active public involvement.

5. How big must biobanks be?

The number of samples necessary depends on the research question that scientists seek to answer. All medical research results depend on appropriate statistical analysis. To arrive at conclusions that are reliable and not likely to be a coincidence or due to chance, it is always necessary to examine a number of key samples in each group. This will allow the identification of shared or common characteristics, such as a biomarker that is typical for a disease. Generally, the more complex a question asked is, the larger the group of research participants will need to be. Commonly, study sizes range from less than 100 to many thousand participants. A biobank that contains samples that will allow a number of such studies to proceed may therefore reach considerable size.

Specialists will take a thorough history from you, and this is a good opportunity to ask questions

Samples are closely examined by specialists

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

Genetic information has been able to provide the keys to unlock the mysteries of many diseases.

The study of a single family can reveal important information on the genetic differences in samples taken from individuals that have a particular condition, compared with those that do not..The majority of genetic differences within one family will be relatively small, thus increasing the chances of identifying the difference that may result in the condition under investigation.

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

The study of tissues taken from families and twins involves methods that intensively investigate a known, identifiable, specific condition. A different approach is to study a broad cross section of the population to identify particular biological markers that correlate with a particular disease. Such investigations are best performed with as many subjects as possible. Thus, a wide range of genetic backgrounds are generally included.

7. Are there limits to the research that may be done?

Whenever individuals provide tissue for a biobank, they will have to explicitly consent to the use of their tissue for particular purposes. The consent may be limited ("narrow") to the sample being used to investigate a single specific disease area, or a specific biological test. It could also be more encompassing ("broad") permitting the use of the tissue for a number of purposes, investigating any biological marker, for any disease, at any time in the future. Most commonly, compromise between very narrow and very broad consents is used, providing both optimal use of the sample for research and consideration of the donor's autonomy whilst also taking into account possible future uses that cannot be specified at least until the sample is taken. The nature of the consent provided defines the research that may be performed.

8. Who will be able to access the information about a specific individual in a biobank?

Participants donating tissue to a biobank should always be told who may have access to the information held about them, under what circumstances, and for what purposes, and to which degree their identity will be protected. It is usual that the person taking the samples will know personal details such as the participants name and address, but this information will be separated when the sample goes into storage and for future uses.

All researchers that use the tissues in a biobank would like to make new discoveries based on their work, and they would normally want such discoveries to be published in scientific journals, or perhaps result in reports that are submitted to regulatory authorities that review new medical treatments. However, the information in these reports or publications will not identify donors, nor permit anyone to link information to an identifiable person.

9. Could a person's participation at a biobank affect his / her insurance?

Since information resulting from research based on samples from a biobank is kept strictly confidential and since it is usually anonymized or coded (or double-coded), it cannot be disclosed accidently. Moreover, biobanks fall within the definition of medical confidential information. In Europe and in the US, data privacy regulations and other legislation would prohibit a transfer of this kind of information. Personal medical information can only be disclosed to a third party by a doctor with express consent of the person to whom that information relates.

10. Will the police be able to get access?

For the reasons pointed out under Q 9, this is not possible unless a court order is issued.

Sometimes it's a good idea to take someone with you for an invasive procedure, such as a spinal tap

Take the time to read and consider the information you are given at your appointment in relaxed surroundings and discuss it with your family

11. Can the donor withdraw from a biobank after having joined one?

The right to withdraw, the implications of such withdrawal and any limitations (for example with regard to uses of samples or data prior to withdrawal) should be fully explained when the donor consents to provide a sample for a biobank. If samples have been anonymized a withdrawal is no longer possible. Withdrawal would only be possible as long as the anonymization process has not taken place.

In all other circumstances (coded, double-coded samples) a withdrawal of both specimen and data for future use is possible at any time upon the participant's request. All future analyses will then be carried out without using this sample. Analyses already completed will not be modified (i.e. continue to contain the participant's information as part of the overall result).

12. How long are biobanks set up to run for?

The life of the biobank depends on its intended use, and is generally specified in both the research proposal that is approved by ethical review and in the Informed Consent. Some samples that are collected for a very specific purpose may only be kept until this purpose has been achieved; others are collected for longer-term storage, for a period of say 10, 15, 30 years, or longer. Once the decision is made to remove samples from the biobank, they are destroyed, whereas data may continue to be retained. In some countries legislation exists to control the period of time that samples and data can be stored.

13. What happens when they close down?

If a biobank was created for a specific purpose that is no longer relevant, or if the establishment hosting the biobank closes, then the samples stored in the biobank should normally be destroyed. It is conceivable that the samples would be transferred to another host organisation. In that case, the accepting organisation must continue to protect the integrity of the samples and to ensure that they comply with the terms of the consent given by the original sample donors.

14. Can a donor say no to particular types of research?

Specific questions like this need to be discussed before consenting to donate a sample to a biobank, but it is likely that respecting such individual requests will be too complex for the biobank. It will therefore usually mean that participating donors wanting to restrict the use of their samples are not considered at all.

15. Will participants be told about their results?

Individual biobanks may make their own arrangement regarding communicating results to participants. However, for reasons of data protection and confidentiality, samples are coded or double-coded, precluding direct communication of individual results back to the patient. In addition, since most of the research conducted is early stage research, the medical significance of any results is still unclear, and it would be difficult or impossible to advise the participant of the meaning of the result. The scientific value of a biobank is the ability of the researcher to place the result into context through comparing information from many, many other samples.

16. What happens if research results show that the donor has a problem? Will he / she be told? What if the donor does not want to know?

This should be discussed when consenting to donate a sample to the biobank, because, for most biobanks, the results are not conveyed back to the participants.

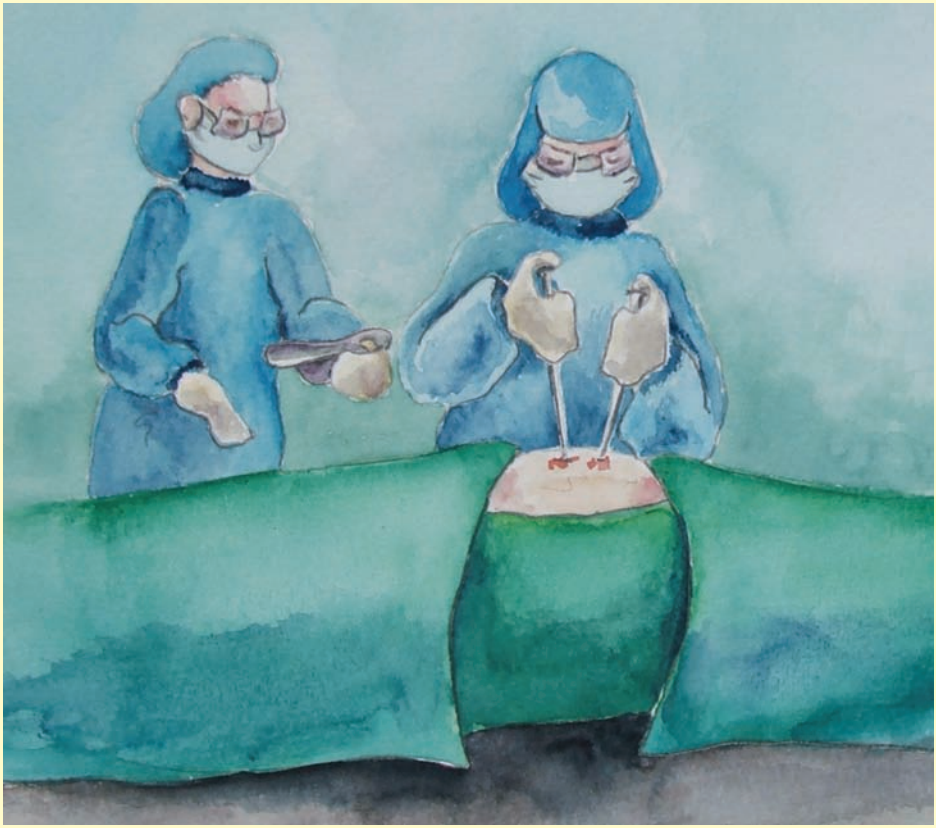
Biobanks do not provide information back directly to donors, but may do so to their doctor or other healthcare provider that obtained the sample. So it may be possible to ask the healthcare provider to pass on any information that they receive if it is in a form that is clinically useful. Certain research results are communicated via publications which are then used to develop new treatments or to inform clinical practice.

17. Is it safe to join a biobank?

The potential health risks from participation in a biobank might result from a mishap associated with the procedure of tissue collection. The donation of a blood sample carries the remote risk of injury, resulting in local tissue damage, and any skin puncture carries the remote chance of an infection being introduced into the body.

18. How is the provision of further information organized?

Once a person has donated his / her sample, he / she may hear nothing more. Some biobanks provide newsletters and other general updates to sample donors to keep them informed of progress. It may also be possible that their samples have helped contribute to a new medical finding or treatment that is reported in the media.



Sometimes samples can be gathered as part of your operation

19. What if patients want to join a clinical trial but not give a sample to a biobank for further research uses separate from the trial?

When giving his / her informed consent for a clinical trial, a person may also be given the opportunity to agree separately to participate in a biobank or to decline such participation. In the vast majority of cases, if the person does not wish to participate in the biobank, it will have no impact upon his / her participation in the clinical trial.

20. When is it worth to join a biobank?

Since the answer to this question is a very personal one, each person has to make his / her own decision. No one can make the choice for them. Because it should be a well-informed decision, potential participants can and should ask any and all questions that could influence their choice *before* they agree to donate a sample. A consultation with their personal physician might be particularly helpful in resolving any anxieties they may have about participating

21. Do healthcare companies have biobanks?

Biobanks exist inside a variety of settings, such as academic medical institutions, pharmaceutical, diagnostics and biotechnology companies. Most healthcare companies, believe that access to these specimens has the potential for operating insights that would make new drugs and diagnostic tools more effective and safer, and thus feel a scientific and moral obligation to use this opportunity subject to the constraints of consent and ethical review.

22. Can healthcare companies obtain samples from public sector biobanks?

Some biobanks do make available their samples and/or data to any interested and approved researchers, be they from the public or commercial sector. Such access will depend on the approval of a research protocol and has to confirm that the proposed use is in line with the objectives of the biobank from whom the samples have been requested.

Staff will be keen to include your family in discussions about your case – but only with your consent

23. Will being in a biobank give a participant any direct benefit such as better medicinal care or a financial reward?

Donation of a sample to a biobank is almost always voluntary and undertaken for altruistic rather than for monetary motives, namely to help move research along and ultimately make progress in creating better medicines. Generally, donors will be reimbursed for expenses incurred, such as travel costs and/or time off work, but there will not be any further direct benefit for participants in terms of treatments. The hope is that new knowledge can be generated through research to reveal samples on disease causes and future treatment options.

24. How can someone find out if he / she is eligible to join a biobank?

There is an increasing number of biobanks now being established.

Generally, a person will be asked directly to participate in this research by his / her health care provider, often in the context of participating in a drug trial or other clinical research which he / she is contributing to. If someone wishes to proactively volunteer, then the best source of information on biobanks operating in his / her local area is the internet. Examples of weblinks to some biobanks are given below. However, consultation with a physician is advisable in any case.

25. Resources for Federal and International Guidelines, Regulations and Policy Issues

Non-profits and universities

Australasian Biospecimen Network (ABN)
The purpose of the Australasian Biospecimen Network (ABN) is to provide a forum to address technical, legal / ethical, and managerial issues relevant to human *biospecimen* repositories within Australia and New Zealand.

Collaborating with Commercial Tissue Repositories: An Ethics Guide for IRBs, Researchers, and Policymakers
This guide serves as a summary and analysis of the ethical issues involved in medical center collaborations with commercial tissue repositories.

Genetic Alliance BioBank
The Genetic Alliance BioBank is an advocacy owned repository for biological samples and clinical data. It provides centralized, standardized collection and archiving; highest biorepository and participant protection standards; open access for all organization approved researchers; advocacy organization control.

HumGen International
The HumGen website deals with the social, ethical and legal aspects of human *genetics*. Many different issues are explored, such as confidentiality of genetic data, consent to genetic testing, and stem cell research.

International Society for Biological and Environmental Repositories
ISBER, the International Society for Biological and Environmental Repositories, is a division of the American Society for Investigative Pathology. Based out of Rockville, Maryland, and founded in 2000, ISBER's main goal is to provide information and guidance on the safe and effective management of biological and environmental specimen collections (*read more*).

onCore UK
An operational goal for onCore UK is to achieve a confederation with other biobanks. This will benefit all involved by allowing the sharing of expertise and information, the establishment of harmonized standards for the operation of cancer biobanks and provide a means access to a larger pool of biosamples from the confederated banks.

P3G Consortium
The Public Population Project in Genomics (P3G) is a non-for-profit international consortium to promote collaboration between researchers in the field of population genomics.

BBMRI
A pan-European and broadly accessible network of existing and de novo biobanks and biomolecular resources. The infrastructure will include samples from patients and healthy persons (with links to epidemiological and health care information), molecular genomic resources and biocomputational tools to optimally exploit this resource for global biomedical research.

Government

Human Genome Project
This site contains information on the Human Genome Project, which ended in 2003.

National Cancer Institute Office of Biorepositories and Biospecimen Research
The OBBR serves as the coordinating and management center for overarching biospecimen-related policies, practices and other related issues across the NCI's biorepositories.

http://www.ethikrat.org/_english/publications/Opinion_Biobanks-for-research.pdf: This is an opinion of the German National Ethics Council on biobanks for research (2004)

International

http://www.coe.int/T/E/Legal_Affairs/Legal_co-operation/Bioethics/Texts_and_documents/Rec_2006_4.pdf: This is the Recommendation Rec(2006)4 of the Council of Europe on research on biological materials of human origins

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