



EurocanPlatform WP10

# Biobanking: FAQs

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# Frequently Asked Questions: What should I ask my doctor and why?

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## Introduction

The European Cancer Patient Coalition strongly encourages cancer patients and patient organizations to be involved in biobanks' constitution, their studies and their research.

ECPC would like to contribute towards this goal by empowering patients and educating them on their rights regarding tissue donation, the process and risks involved, the access to information on the clinical research performed on their sample and the protection of their personal data. As one of the members and contributors of the European BBMRI Forum, ECPC has contributed to bring the patient perspective into clinical research and biobanking but also to inform and educate its members about the importance of understanding their involvement in biobanking and research.

ECPC board and staff members, notably ECPC Vice-President Kathi Apostolidis, and Kalliopi Christoforidi, Projects & Policy Officer, shared their experience with expert medical researchers, namely WP10 leader: Dr. Peter Riegman, Dr. Maria Grazia Daidone and Jacqueline Hall in the context of the EuroCanPlatform project (<http://eurocanplatform.eu/>), in order to create a document comprising a Glossary together with the most Frequently Asked Questions with regards to Biobanking

The document is written in a patient friendly manner with translations in many EU languages to follow shortly. Our members and readers are invited to communicate to us any other topics they would like to see covered in the Glossary and F.A.Q. or even to write articles to be included. The research group will review such requests and will add new content as the need arises.

## Glossary

**Biobank:** A collection of **biological material** (e.g. animal, plant, human (skin, blood, organs, hair, saliva, etc.) bacteria, yeast, molds etc etc.) with corresponding documentation that can be used for research purposes. Biobank is a very broad term crossing many fields of study e.g. agriculture (storage of seeds) to human samples for medical research.

<http://en.wikipedia.org/wiki/Biobank>

**Human sample:** A portion of human biological material e.g. bodily fluids - such as blood, saliva, urine, cells or pieces of human tissue such as skin or tumour.

[http://en.wikipedia.org/wiki/Tissue\\_\(biology\)](http://en.wikipedia.org/wiki/Tissue_(biology))

[http://en.wikipedia.org/wiki/Bodily\\_fluid](http://en.wikipedia.org/wiki/Bodily_fluid)

**Medical research:** Research conducted to advance and support the knowledge in the field of medicine

[http://en.wikipedia.org/wiki/Medical\\_research](http://en.wikipedia.org/wiki/Medical_research)

**Genomic data:** Data derived from DNA using molecular biology techniques. The format of the data can be kept in many different ways depending on the technique used and can include the entire [DNA sequence](#) of organisms and fine-scale [genetic mapping](#).

<http://en.wikipedia.org/wiki/Genomics>

**Population-genetic data:** The genomic data used in the study of genetic diversity in populations

[http://en.wikipedia.org/wiki/Population\\_genetics](http://en.wikipedia.org/wiki/Population_genetics)

**Molecular data:** Data derived using molecular biology techniques for the study of molecular characteristics of cells and tissues, e.g. DNA sequences, levels of genetic expression, biomarkers and protein structure and function that are key to modern research.

<http://en.wikipedia.org/wiki/Sequencing>

**Diagnostic work-up:** The medical inspection, pathology report and associated molecular tests that are used to define the medical diagnosis of a disease

[http://en.wikipedia.org/wiki/Medical\\_diagnosis](http://en.wikipedia.org/wiki/Medical_diagnosis)

**Clinical response:** The response of the disease to the treatment

**Clinical outcome:** The health status of the individual at a later point in time e.g. disease free after 5 years.

**Policy:** The rules establishing the conduct of the organization

**Consent:** Giving approval or agreement, particularly and especially after thoughtful consideration.

<http://en.wikipedia.org/wiki/Consent>

**Withdrawal of consent:** To withdraw your agreement

**Personalised or precision medicine:** Customization of healthcare and medical decisions, practices, and/or products being tailored to an individual patient and individual patient's specific disease, where use of genetic information and molecular data plays a major role. Based on findings from personal molecular or genomic characteristics to predict response to different treatments or clinical outcome.

[http://en.wikipedia.org/wiki/Personalised\\_medicine](http://en.wikipedia.org/wiki/Personalised_medicine)

**"opt in"** consent system: Explicit consent (agreement) must be requested from each participant before providing samples to biobanks. Donors must be provided information about the project to understand the risks and benefits in order to make a decision.

**"opt out"** consent system: It is presumed that everyone generally agrees to give samples i.e. agreement is presumed unless a person explicitly states their refusal to participate. This system is sometimes used in the area of organ donation for transplantation.

[http://en.wikipedia.org/wiki/Organ\\_donation](http://en.wikipedia.org/wiki/Organ_donation)

**Specific informed consent:** Refers to when a specific medical research project is defined and the details can be outlined to the patient, the patient then decides if they agree to participate or not in that specific project.

[http://en.wikipedia.org/wiki/Informed\\_consent](http://en.wikipedia.org/wiki/Informed_consent)

**Broad consent:** A general area of research may be identified to the patient (e.g. cancer research, genetic research or medical research) but without specific projects in mind. This means the donated sample can be used within the scope provided without having to re-contact the patient to obtain a specific consent for each future project. Any such future project will be conducted in compliance with local rules and ethical approval by an appropriate committee.

**Personal data:** Information that can be used on its own or with other information to identify, contact, or locate a single person, or to identify an individual in context

[http://en.wikipedia.org/wiki/Personally\\_identifiable\\_information](http://en.wikipedia.org/wiki/Personally_identifiable_information)

**“Coded” samples:** Personal details are removed and replaced with numbers to provide multiple layers of password-protection to ensure the donor's rights to privacy.

**Sample custodian:** The person or entity responsible for the sample once it has been removed from the body

**Information sheet and consent documents:** The documents presented to you that outline the project or area of research and where you sign to give (or not give) your agreement to participate.

**Research ethics committee:** An independent body consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and well-being of human subjects

[http://en.wikipedia.org/wiki/Ethics\\_Committee\\_\(European\\_Union\)](http://en.wikipedia.org/wiki/Ethics_Committee_(European_Union))

**Regulatory body:** A [public authority](#) or [government agency](#) responsible for exercising autonomous authority over some areas of human activity in a [regulatory](#) or [supervisory](#) capacity.

[http://en.wikipedia.org/wiki/Regulatory\\_body](http://en.wikipedia.org/wiki/Regulatory_body)

**Cost-recovery:** In biobanking, cost recovery involves the sharing of the costs incurred for sample collection and management. When researchers apply to use the stored samples, they may be asked to provide money to the biobank to help cover the sample collection and management costs.

**Follow-up data:** Data on the patient's experience during or after treatment, clinical response and the treatment outcome.

**Laboratory tests:** Molecular and genetic techniques performed on samples

**Research results:** Data produced from research studies from research laboratories, the findings of which may or may not prove to be medically significant.

**Incidental findings:** Previously undiagnosed medical conditions that are discovered unintentionally

[http://en.wikipedia.org/wiki/Incidental\\_findings](http://en.wikipedia.org/wiki/Incidental_findings)

**Clinical trials:** Tests in [medical research](#) and [drug and diagnostics development](#) that generate safety and [efficacy](#) data for health interventions. This data can be used for submission to regulatory authorities for approval of new therapeutic approaches

[http://en.wikipedia.org/wiki/Clinical\\_trial](http://en.wikipedia.org/wiki/Clinical_trial)

## Answers to Frequently Asked Questions on Biobanking

### 1. What is a biobank?

A **biobank** is a collection of **biological material** with corresponding documentation that can be used for research purposes. Biobank is a very broad term crossing many fields of study e.g. from storage of seeds for agriculture to **human samples** for **medical research**. Here we focus on biobanks for medical research that store human samples such as blood, saliva, urine, cells, skin biopsies or other tissue samples. These may be collected through routine medical procedures or through additional medical procedures, where needed. In cases of the deceased, whole organs can be collected in a biobank. The genetic information from each human sample can be linked to the individual's medical history and may be linked to lifestyle data (e.g. diet, smoking etc.). Medical research biobanks contain human samples from large numbers of people and they are created to look for explanations as to how genes and the environment interact in order to prevent diseases or treat them more effectively. In these biobanks, human samples are normally saved for many years.

As well as providing access to human samples and their associated data, biobanks may offer access to a variety of medical information, including **genomic data**, **population-genetic data** and **molecular data**, which would be too expensive for many individual medical research laboratories to maintain.

### 2. What is a biospecimen?

A biospecimen (or biological material, or biological human samples) is often used to refer to a sample of biomaterial in a biobank. In a biobank for medical research, biospecimens could be represented by blood, saliva, urine, cells, skin biopsies or other tissue samples, and could be stored in freezers at – 80°C as frozen samples or, in the case of a tissue, at room temperature as histologic block, similar to the ones used for diagnostic purposes.

### 3. Why are there biobanks in hospitals?

When a patient is received at a hospital, part of the **diagnostic work-up** or treatment will depend on samples of blood or tissue taken from the patient, e.g. for tumour diagnosis. The facilities storing this type of sample are called diagnostic biobanks or archives. Hospitals also house human biobanks that contain samples used for treatment, like blood transfusions, stem cell treatment, etc. Often, diagnostic biobanks contain excess tissue or blood samples that can be valuable for medical research. In each country there will be a legal framework that regulates the use of surplus or left over tissue or blood for scientific purposes.

Good health care does not stop after giving the patient a diagnosis or treatment. Good health care should include searching for ways to offer better treatment or diagnosis for new patients, especially for life threatening diseases or those severely impacting on life expectancy or quality. To explore

these it is crucial to study the characteristics of human samples of people who have already undergone treatment. With medical research on human samples it is possible to for example to:

- Find characteristics of patients that respond well or less well to a particular treatment, to better understand why this happens, and to establish the characteristics of patients who cannot endure a certain treatment before it is given (i.e. predict toxicity). This can improve diagnosis and the selection of treatment options thereby offering the best treatment from the start.

- Find molecular features (**biomarkers**) such as indicators of **clinical response** or **clinical outcome** that can be detected in human samples obtained to monitor the course of the disease.

- Understand the molecular aspects of disease progression and so identify new drug targets or biomarkers for an early or improved diagnosis.

- Understand how a disease originates and/or how it is inherited, giving us means to avoid or delay the onset of disease.

- Find new proteins or molecules that might be useful to influence drug treatment

#### 4. What do biobanks do with samples?

Medical biobanks collect, store, and process samples and the associated data according to existing regulatory standards that ensure high quality and cost-effectiveness. Human samples in biobanks and their associated information are made available to medical research projects that have been checked for their scientific content and their regulatory compliance. For different types of medical research there are different types of biobanks designed to answer different needs and research questions. For example, a difference in approach can be seen between biobanks integrated in hospitals versus population based biobanks. Although both are interested in improving health care, population based biobanks involve healthy people from the general population who volunteer to give samples (mostly blood samples) and the biobank follows this group by routinely asking for updated data on the individual over decades. This type of biobank can help identify predisposing factors or susceptibilities to a particular disease, whereas, hospital integrated biobanks collect samples from patients who already have (or may be suspected of having) a certain disease. Archives containing biomaterial that are kept for juridical reasons often have room for secondary use of that material. Research groups, that may not have, or can save valuable time, equipment, or funding to collect it on their own can make use of these medical archives as biobanks.



## 5. Where are the samples used?

Biobanks may be used by medical research organizations such as universities, hospitals, not-for-profit organizations, diagnostic laboratories, public and private pharmaceutical companies or equipment and diagnostics companies.

Biobanks may differ in terms of their **policy**, often driven by national legislation of the country in which they operate, as to who can access the samples contained within them. If you are unsure please ask your doctor to explain this in more detail in your particular case.

## 6. What do I gain from donating a sample to a biobank?

There are possible short and long term benefits to participating in bio-banking which can help both society and medical research. In some cases, immediate personal benefit to you could arise e.g. if your sample may be examined to identify why a certain treatment does not provide the expected effect for you or to aid with your diagnosis.

Having a sample taken may also allow you to participate in clinical trials that are testing new treatments. However, medical research is experimental, so what a researcher discovers from your sample and data may be of little value to you or your family directly. It takes years to confirm and develop scientific methods, technologies and drugs which are safe and effective to use on a routine bases in patients. Samples need to be analyzed from a large number of people before any conclusions can be made. This can take many years. However, it can also happen that your children or other family members may have the same genes predisposing for the same disease you unfortunately have acquired and so could benefit in future from your contribution.

In participating in a bio-banking project, you are contributing to a very important resource for supporting high quality medical research that could help future cancer patients. Your sample will go into a large sample pool that may be used in medical research to investigate the cause of diseases, to prevent diseases and to identify better treatment options for the general population.

Bio-banking also stimulates collaboration between many stakeholders (doctors, pathologists, scientists, patients, lawyers, governments etc.) which will bring together diverse expertise and benefit the whole medical research community and society. Encouraging debate can promote harmonization and high quality practices. Bio-banking can also provide a chance for patients to interact with researchers and to be involved in long term decisions in research.

Please note, in most instances in Europe, you will not be paid for giving your sample (it is voluntary), nor will you receive any financial benefits as a result of any medical research conducted.

## 7. What do I agree to when I allow my sample to be included in a biobank?

Before agreeing (**consent**) that your sample can be stored in a biobank you can ask to be kept informed, as to how your sample and the related information will or will not be used, where it will be kept and for how long, how it will be protected and who will be able to see or use it. You may be asked some questions relating to your health, nutrition and lifestyle or if you are willing that information may be obtained from your medical records which track your medical history. [Different forms of consent are explained in 11.](#)

## 8. What if I change my mind regarding use of my sample?

If you have agreed (**consented**) that your samples shall be saved, you can change your decision at any time (this is called '**withdrawal of consent**' or '**opt-out**'). If you decide to withdraw your consent, you must tell your doctor and contact at the biobank as appropriate. Biobanks can differ in how this procedure is handled. You may have the option to decide that your samples and related information shall be removed from the biobank or that they could remain in the biobank in a completely non-identifiable form. It is unlikely that data already obtained from your samples will be withdrawn since it may already have been used.

Be aware, that even if you ask for the sample to be returned to you, it is unlikely to happen. In most cases where samples have already been used for medical research, it will not be possible to retract these results from the biobank. Ask for information on what will happen with the sample in your particular situation.

The decision to allow or not to allow your sample to be stored at the biobank is entirely up to you. Any consequences of your decision, including any that may affect your treatment in any way and which should be clearly explained to you.

## 9. Can biobanks be used for personalized medicine?

'**Personalised medicine**' is a new model of healthcare treatment – it delivers targeted diagnostics, treatment and advice on nutrition n which are tailored to an individual. **Personalised or precision medicine** will be effective for the majority of people once genetic and molecular information derived from their samples has been systematically understood.

To achieve this, we need to study of genetic and molecular information to predict the risk of disease, identify new targets for treatments and identification of markers predicting positive or negative reaction to treatment options. Therefore biobanks are needed as they contain a large pool of resources in the form of coded genetic materials that could be used by medical researchers to understand the links between genes, medical data and environmental factors.

## 10. Is the biobanking process governed by any national or international laws?

The area of bio-banking is generally highly regulated in Europe. There are also laws regarding privacy of data which are relevant to the data collected and produced in bio-banking. Many organizations have released best practise guidelines (e.g. OECD <http://www.oecd.org/about/>, IARC <http://www.iarc.fr/>, WHO <http://www.who.int/en/>), ISBER <http://www.isber.org/?page=BPR> and the Committee of Ministers has released a recommendation to member states on medical research on biological materials of human origin. Best practise guidelines and recommendations are not laws, however, but rather recommendations.

Currently in the European Union there is no single specific law on bio-banking but it falls under other existing regulatory frameworks. Specific laws on bio-banking exist as a patchwork of national and local laws. Since the laws between countries can differ substantially, it can make exchange of human samples between European countries more complex and can sometimes slow down international medical research collaborations. The subjects in frequently asked questions [11](#) Consent format, [12](#) Children and incapable, [13](#) Data protection, [14](#) Governance, [15](#) Commercial gain and [16](#) Access are regulated by local law or regulation.

More specific information on individual EU countries legislation can be found at the hSERN website: [www.hsern.eu](http://www.hsern.eu).

## 11. What does specific vs. broad consent mean and what is an ‘opt-in’ or ‘opt-out’ system?

There are many different ways to give or acquire consent. The main objective is to inform the patient about using their **biomaterials** or that the **biomaterials** might be used for medical research purposes. The term **informed consent** stands for the fact that information is given or available. **Signed informed consent** means that the information has been given and that the patient agrees to the information with a signature as proof. The information is usually put in **Information sheets and consent documents**. They might need additional explanation again depending on the local regulations and the risk involved for the patient. At low risks the information sheet and a form to consent or opt out can be sufficient. An “**opt in**” system means that explicit consent (agreement) must be requested of participants to provide materials to biobanks. An “**opt out**” system presumes that everyone generally agrees to give samples (presumed agreement) unless they explicitly state their refusal to participate. This system is only used in some countries for left over materials or secondary use of archived materials. As soon as it concerns an extra sample that is taken from the body for research purposes, opt in will be obligatory. It is also used in some countries for organ donation for transplantation. Different countries may use different models, although most countries in Europe favour the opt-in model. Even in those countries where an “opt-out” system exists, this system will never be applied in

situations that involve significant risks that could affect a patient's quality of life. If significant risks are present, each patient will still be informed of the risks, and asked if they wish to participate or not.

Other terms such as “**specific**” informed consent and “**broad**” consent may also be used. **Specific** informed **consent** means that a specific medical research project is already identified and can be outlined in detail to the patient. The patient can then either consent or decline to participate in that specific project. **Broad consent** means the general area of research may be outlined to the patient (e.g. cancer research, genetic research or medical research) but with no specific project defined. This means the sample can be used within the scope of the permission provided without having to re-contact the patient to obtain a specific consent for each project in the future. Any future project would still be performed in compliance with local rules and ethics approval by an appropriate committee.

## 12. Who gives consent for those under age or those incapable of managing their own affairs?

The principles of human dignity and the right to the integrity of the person are recognized throughout the European Union. In particular, it is required that any intervention in the field of biology and medicine cannot be performed without free and informed consent of the person concerned. The rules concerning who is the legal representative of persons unable to manage their own affairs and children diverge in different EU countries. Any previously expressed objection by the patient/person must be respected, and **informed consent** from the subject or the legal representative should be sought wherever possible. In this case, in many countries the consent is given by either close relative or custodian who is responsible for the person in question. In the case of teenager patients, it is preferable to ask this question also to them, to obtain a shared opinion by the adolescents and their parents.

## 13. How will my personal data be protected?

All **personal data** related to your sample, such as your name and address, is highly regulated and regarded as strictly confidential throughout Europe. Only a very limited number of medical staff will have access to your personal data.

Each sample will be “**coded**”, meaning that personal identifiers are removed and replaced with numbers under multiple layers of password-protection to ensure that your personal details are screened from unauthorised viewing. The coding is needed to enable the re-identification in case an incidental finding is done that needs to be communicated to the treating physician and for the addition of follow-up data.

Laws vary between nations and it is common for some public authorities to apply for access to this data in certain situations e.g. for public health research, criminal investigations, etc. If you have questions about data security, please make direct enquiry to the biobank concerned.

The patient information and consent documents presented to you by the biobank are likely to confirm that no insurance companies or employees will see any of the questions that you may answer or know that your sample was used in any medical research. If you are not sure, please ask at the biobank for more information.

#### 14. Who will be responsible for the sample I give to the biobank?

Different countries and biobanks may have different rules about who is governing the sample once it has been removed. Information regarding who will be responsible (also known as the '**sample custodian**') should be written in the **information sheet and consent documents** presented to you. Samples will be released for use in research only after projects have been reviewed and approved by appropriate national authorities (such as **research ethics committee**, data protection and/or other legally delegated **regulatory body**, as applicable by country).

In most cases, you will be informed of the area of medical research within which the sample would be used (e.g. cancer research, medical research, biomedical research etc.). If you do not agree with the scope of medical research that is proposed, you should express your concerns. Please ask your doctor for more information if you are unsure.

You may ask for your sample to be destroyed, however it is very unlikely that the sample would be ever be returned to you. Any medical institution that would store the sample will be allowed to use it only for medical research purposes and could do so only after receiving approval from the competent public authorities. If you do ask to withdraw participation, any data already generated from your sample (research results, tests results etc.) will not be destroyed since it may already be used in research or stored in databases.

#### 15. Does the biobank gain any commercial advantage from use of my sample?

Academic biobanks (i.e. not the commercial entities) are not supposed to become for-profit business. Biobank samples may not be sold at a profit, as dealing in human samples is prohibited in Europe. It does cost money to collect and store samples, therefore sometimes medical researchers who use the samples may be asked by the biobank to pay the costs that were made to collect, preserve, store, safeguard the quality, retrieve and send the sample (called '**cost-recovery**'). This does not mean that the sample itself has been sold by the biobank, but is rather a sharing the costs incurred for sample

collection and management. Contact the relevant biobank for detailed information related to its internal procedures on sharing the samples with third parties.

### 16. Who will have access to my sample, how will it be securely stored?

The physical storage of samples must comply with existing regulations that ensure highest safety both of the quality of the sample and any personal data that is associated with the sample. Only authorized staff should have access to the samples and data stored in biobanks. When the sample is used medical scientists can access the sample and the coded data after they have received permission of an Internal Review Board (IRB) and or Medical Ethical Committee (MEC). When the research is performed within a large multicenter research project the sample might be shipped to another institute for research which might be abroad. Depending on the local regulations it may not be kept there but must be shipped back to the biobank after the research is performed or upon agreement any left overs must be destroyed.

The storage of samples involves the coding of information related to the sample when giving out the sample for research. If this sample is not to be used for your treatment or future diagnosis, all information relating to the sample will be provided on anonymous basis, without allowing any medical researcher or public authority to link the sample with your personal data.

Biobanks should also take steps to avoid incidents or disasters (e.g. fire or flooding) that could damage the samples.

### 17. What are the risks involved when participating?

The main risks for participants in bio-banking relate to the following:

**Privacy.** As well as samples, clinical data is needed to perform the medical research, although this does not mean that the identity of the patient must be known. However, the ability to trace the patient and the treating doctor may be required, so the link between personal and clinical data may not be completely broken. In addition, way to collect **follow-up data** (i.e. patient experience during or after treatment, clinical response and the treatment outcome) is required for medical research when needed. Normally, one layer of coding is used and this is considered adequate to ensure the protection of personal data and still allow unrestricted clinical examination. Therefore, the risks surrounding privacy can be protected with proper measures are being put in place.

**Risks of stigmatization and discrimination.** An individual's sample contains genetic material that can reveal private information, such as racial origin and disease predisposition that could cause personal

distress if released into the public domain. Genetic data can also be used to identify the individual but only with highly advanced technical knowledge. The security precautions described in sections 10 & 12 are designed to prevent this hazard.

**Physical risks.** In the case of intervention for collecting a sample e.g. surgery, biopsy or taking blood sample etc. a higher degree of risk may be involved. Sample collection that is done routinely in the clinic poses a low inconvenience or risk of physical harm to participants since these are routine procedures that would be performed on the patient in any case e.g. a blood draw or collecting tissue as part of surgery.

If participants have to make additional visits to the clinic for additional sample collections to be made, this may be inconvenient to patients. For some types of biobanking, additional biopsies or surgery may sometimes be requested, depending on the type of surgery and the health of the individual, the risks will likely be similar to that of undergoing a regular surgical procedure.

**Feedback of research results.** In a hospital, the **laboratory tests** are performed in a routine setting where established procedures are in place and are validated (checked), this avoids mix-ups and contamination problems. However, medical research is experimental and does not always follow these same strict procedures. Also it takes years, and several studies, to confirm **research results** and to prove they are medically relevant. This means there are variable risks, since research results may not be correct or medically confirmed and this kind of information is not always suitable to give back to the donor. So what a researcher discovers from your sample and data may be of little value to you or your family directly. Bio-banking practices do vary regarding feedback of experimental results that may be relevant to you, so you may wish to know the policy of the biobank to which you are considering contributing. If in doubt, please ask for more information.

**Incidental findings.** These are unexpected results, disputing or changing the original diagnosis and therefore, possibly also the chosen treatment options. Practices vary on if and how this information is transmitted to the patient and the treating doctor. If these incidental findings are reported, this must be done through the treating doctor, who can decide on the impact of the findings and re-assess the original diagnosis. It is also important to consider, if there is an alternative treatment available, as well as the severity of the disease. The performed test should also be judged on its reliability and in doubt should be repeated on new material.

### 18. Are there risks involved donating a sample?

Note, that the risks involved for a patient when taking part in bio-banking in medical research is highly dependent on the type of medical research being conducted and the way the samples are taken. The following examples show an increasing risk for the patients involved.

**Example 1.** If a tissue sample obtained after an operation (i.e. residual tissue that would otherwise have been destroyed) is used in research there is no extra inconvenience or physical risk for the

patient when the sample is collected. With regards to the patient's privacy, as long as normal security measures are in place the risk should be minimal.

**Example 2.** An additional blood sample is taken for research purposes as described above. This poses additional inconvenience for the patient. Having a blood sample taken can be uncomfortable and there can be a very small chance on bleeding or wound infection, however, if performed at time of withdrawal for other medical purposes, it would not add any measurable extra risk. The privacy concern is still present in this example.

**Example 3.** When extra tissue samples (e.g. from skin and nails, to lung or liver) are taken, depending on the procedure and frequency, the inconvenience can become high as well as the medical risk through complications. The privacy concerns still apply.

**Example 4.** The situation that poses the highest risk is encountered when testing new drugs or surgical procedures. These are done within **clinical trials** testing new ways of treating patients. Therefore, clinical trials have very strict regulations to protect the patients for the risks involved. Tissue samples from surgery may be required during these clinical trials or in order to assess patient eligibility for these trials.

Given the differing degree of risks in the different examples, it is clear that the rules and regulations can vary in the different examples in order to best serve the patient's interests. For example the rules of clinical trial would be too strict for the first example where low-risk observational research on residual samples is performed.

### **19. Will I receive any information or feedback about my sample or what it has been used for?**

This is entirely depending on the risk involved for the participant, if a biobank can decide to feedback results through the treating physician. In case the research tests are not performed in a routine setting, where established procedures are in place, which are validated (checked), aimed at avoiding mix-ups and contamination problems, it is not advisable to even ask for feedback. However there are research programs that make use of tests performed in a routine laboratory, where the right procedures are in place, then it could be possible to allow feedback of results through the treating physician. Asking might help to get some idea to the risk involved. See

### **20. How do I know if I am eligible to give a sample?**

The clinical staff that is taking care of you, before surgical or medical intervention, should ask your willingness to donate for research purposes the leftover biologic material after completion of the diagnostic procedures. In some countries this question for left over materials can be asked after the surgical or medical intervention. Consent is mostly asked when procuring samples looks promising for inclusion in a study. However, for secondary use or left over materials, where sample are stored in



archives serving diagnostic or legal purposes, there might be an opt-out system, when it is unknown if samples might be used for research. The research idea requiring these samples might even come decades later.

### **21. How are samples collected?**

Samples are in general collected by the clinical staff that is taking care of you, and your participation will require little extra effort on your part. How samples are collected is largely depending on what sample is collected. Samples such as blood, saliva, urine, cells, skin biopsies or other tissue samples should be collected according to the normal routine hospital procedures used for diagnostic purposes. The collection of samples follows the same safety rules. When samples are taken after surgery, it will not be noticed at all.

### **22. How long does the sample donation process take?**

Just as long as the normal diagnostic procedure. For convenience, if samples are taken in the hospital they are collected at the same time the samples are collected for the normal diagnostic procedure.

### **23. What personal information will I have to disclose if I decide to give a sample??**

This is entirely depending on the research performed later. For clinical outcome or disease progression the clinical data can be used in the hospital and no further data is needed. In case the planned research involves revealing correlations to behaviour, social status, family disease history, habits in food intake drinking, smoking etc., you are asked to answer questionnaire asking the specific area of interest. The answers are stored in a database for later use.

### **24. Can I choose what my sample is used for?**

Usually not, because such choices could interfere with the outcome or complicate the research plan too much. Participation is mostly considered as not useful. However, sometimes biobanks offer in the consent to make such choices.

### **25. How long will my sample be kept for?**

Biospecimens, if not immediately used, can be kept in biobank also for several years, and can represent resources of immeasurable value for the possibility to assess the clinical usefulness of the molecular markers discovered using novel technologies.

## Conclusions

To summarize, bio-banking (particularly where no additional intervention or physical risk is present) is generally considered to be a low risk activity although depending on the type of bio-banking and clinical research, these can differ.

If in any doubt or you would like more information before making your decision, please discuss this with your doctor and the biobank. A useful method is to write down your questions, and those of your family, and take them with you to your appointment.