

Tissue for Research Manual

BeCytes Biotechnologies



BECYTES BIOTECHNOLOGIES

Support to life science researchers to develop preclinical studies aimed to improve human health, by providing access to primary hepatic cells, tissue for research and related services.

Tissue for Research

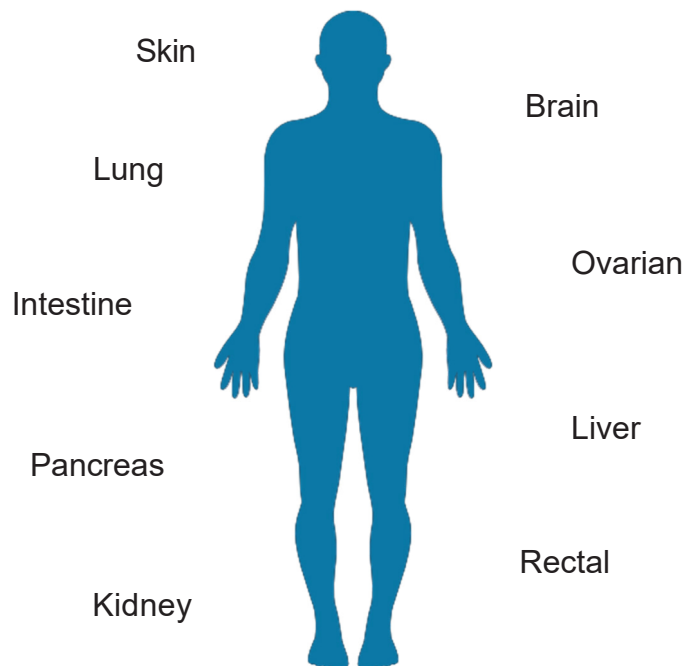
Access to high-quality tissue samples is critical to conduct investigations and make meaningful discoveries. However, obtaining human biospecimens can be a challenging and time-consuming process.

The acquisition of human cells, tissues, or organs are from human donors who have provided their consent. These samples are then processed and preserved for use in various research studies. Human biospecimens can be obtained from a variety of sources, such as organ donors tissues discarded for transplantation or wated tissue.

The use of biospecimens in research is critical for advancing our understanding of human health and disease, and for developing new treatments and therapies. BeCytes Biotechnologies has created a platform capable of cordinating the donation of human tissues and cells for biomedical research purposes, which encompasses strong collaborations with national and international procurement centers, biobanks and hospitals that allow us to provide the researchers with a wide range of tissue samples.

BeCytes Biotechnologies understands the importance of accurate and reliable data in research, which is why we are committed to providing our clients with high-quality tissue samples.

Our projects follow the local and international ethical and legal regulations for the adquisition, processing and storage of biospecimens for research pruposes established in Law 14/2007 on biomedical research, European guidelines (2004/23/EC, 2006/17/EC, 2006/86/EC), and RD 1716/2011. The approval of Institution Review Boards (IRB)of the banking intituiton will be necessary for the biospecimen transfer.



BeCytes healthy and tumoral tissues for research

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Take your Investigation to the Next Level

Take your research to new heights with BeCyttes Biotechnologies - our cutting-edge procedures, unparalleled expertise, and dedication to scientific advancement give you the competitive edge you need to obtain suitable results for your research.



Extensive network

Thanks to our key partners (Biobanks, hospitals, OPOS, etc.) , we have access to a great diversity of healthy and pathological tissue in multiple formats and conditions.



Extensive donor information

Researchers can have access to first-hand information about the donor post medical record where the most relevant data is reflected.



Possibility to customize tissue procedures

The researchers can tailor the procurement and processing of biospecimens according to the conditions needed for research.



Ability to deliver fresh tissue to Europe and the USA next day after delivery

Our logistic experience has allowed us to deliver tissue samples next day after delivery to Europe and USA, with a direct contact with the researcher and an immediate response.

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On-demand Projects

Having access to customized tissue samples can make a significant difference in research, enabling scientists to more accurately and efficiently study specific biological processes and diseases.

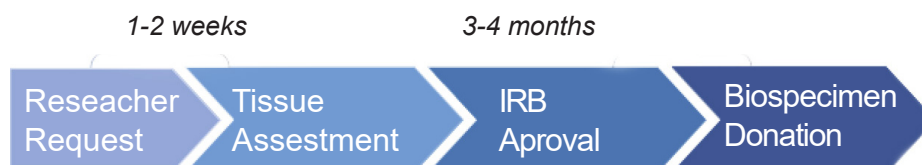
We understand the importance of customized biospecimens procurement for research projects, for that reason, we work closely with researchers to identify their specific donor inclusion criteria requirements and source high-quality tissue that meet researchers needs. We have access to a vast network of global tissue collections and can provide a range of tissue types, including healthy, diseased, and cancerous tissues, as well as different tissue formats, such as fresh, frozen or formalin-fixed paraffin-embedded (FFPE) samples.



How does the acquisition of human tissue samples work?

Once we receive the [request form document](#), our team will evaluate the feasibility of the project within one to two weeks. If project conditions are accepted, we will proceed with the project submission process. This process typically takes between three and four months to complete.

Upon IRB approval, we will work diligently to ensure that biospecimens donations receive the highest quality tissue samples as quickly as possible.



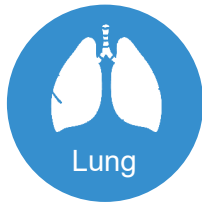
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On-going Projects

One of the major advantages of working with on-going projects is that we have the resources and specific knowledge needed to respond to your research needs quickly and efficiently.

Our team has expertise collecting different human **fresh** tissue typologies such as **skin, liver, lung, pancreas, fetal, rectal, ovarian, stomach, breast, and Dorsal root ganglia tissue**. This has allowed us to be able to validate a wide range of protocols for the collection, processing, and storage of human tissues.



Biospecimens Inventory

BeCyttes Biotechnologies is aimed to be a leading provider of human biospecimens to researchers worldwide. The extensive sample collections that we provide offer researchers the opportunity to conduct cutting-edge research into a wide range of diseases and disorders, ultimately leading to the development of new treatments and therapies that can improve patient outcomes.

The main areas of biobanking samples that BeCyttes can provide are the following:

- **The tumoral and NAT (normal-adjacent tissue) tissues** includes solid biopsies from different cancers types, such as liver, lung, kidney, breast, melanoma among others.
- **Neurological tissue** bank includes post-mortem tissue from patients with neurodegenerative diseases.
- **Biological fluids** bank includes collections of liquid biopsy samples from patients with various diseases and disorders, such as inflammatory bowel disease, liver vascular disease, neurodegenerative diseases, gastrointestinal and pancreatic oncology.

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Human biospecimens and all associated processes are performed in accordance with international legal requirements.

- **Spanish Legislation:** Law on Biomedical Research 14/2007, Law on Data Protection and Guarantee of Digital Rights 13/2018, Royal Decree 1716/2011.
- **European Legislation:** 2004/23/EC, 2006/17/EC, 2006/8/EC.
- **European Directive on the protection of persons when using textile samples for research** (2004/23/CE)
- **USA Legislation:** The Common Rule - Federal legislation, Health Insurance Portability and Accountability Act (HIPAA) - Human Tissue Act - Law.
- Our **donors** are providing informed **consent** to ensure they voluntarily confirm and are willing to participate in our particular research project. Donors are also informed and understand our objectives, the potential risks and benefits, and the general purpose of collecting biological samples for research purposes.

Ethics

BeCyttes Biotechnologies complies with all ethical standards and regulations applicable to the acquisition, handling, and supply of human and animal biological products for basic research carried out in respecting fundamental rights for the human body.



International regulations of ethics in biomedical research

Nüremberg Code (1946), Helsinki Declaration (2013), Belmont Report (1978) and Oviedo Convention (1997), Committe of ministers resolution (1978), standarts of good practice



The recommendations of the World Health Organization

WHO works to promote ethical standards and appropriate systems of review for any course of research involving human subjects.



General Data Protection Regulation (GDPR)

The main goal of GDPR is to protect individuals' fundamental rights and freedoms, particularly their right to protection of their personal data.

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In this section you will find some of the most frequently asked questions from our customers about tissue distribution. If you can't find the question you're looking for, don't hesitate to contact us and we'll be more than happy to help.

- **What Is the minimum number of biospecimens needed to submit a project?**

EU legislation establishes that for a research project the number of cases must be sufficient to establish research results. We advise that the number of samples should be at least between 10–12 cases.

- **Can researchers distribute BeCytes biospecimens for 3rd parties?**

European legislation does not allow the commercialization of human beings but it is allowed to distribute to 3rd parties as long as and when it has been specified in the framework project.

Tissue samples distribution could be associated with costs derived from marketing activities, including fees for obtaining and holding patents and licenses for distribution, as well as the application of manufacturing standards.

- **Who is in charge of logistics?**

It is the client's decision. BeCytes can take care of all the logistics, the preparation/packaging of the samples, the organization of the shipment with different world-renowned couriers, the documentation, the follow-up and the delivery to the destination. The client can take care of the logistics if they prefer. In this case, BeCytes will be at their disposal for anything they need. Our goal is to deliver the samples as quickly and as safely as possible.

- **What are the requirements for transporting samples?**

The transport of biological samples must comply with international transport regulations.

All our shipments comply with these regulations, following the indications of the competent entities. Our biological samples are packed following the "IATA packing instruction 650".

- **What are the requirements for importing/exporting vsamples from/to the Europe?**

BeCytes complies with all requirements for the export of non-infectious biological samples for research outside and inside the EU. Each country has its own regulations for the export and import of biological samples. In the case of Spain, the following legislation applies:

National

- Royal Decree 65/2006, of January 30, 2006.
- Order SAS/3166/2009, of November 16, 2009.

International

- United Nations Committee of Experts on the Transport of Dangerous Goods (UNCETDG) - Air Transport
- Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO)
- Dangerous Goods Regulations (IATA).

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