

# Biobank "Breast Cancer Tissues and Organoids" Also BCTO BioBank

### REGULATION

### Introduction

Biobanks are fundamental infrastructures for guaranteeing the progress of scientific knowledge, being custodians of biological material which is made available to the scientific community/third party applicants for research purposes.

The "Breast Cancer Tissues and Organoids" Biobank is a new generation biobank, which provides activities for the collection, conservation, centralization, processing and distribution of tissues and their organoid derivatives, from patients with breast cancer, and data connected to them for diagnostic and research purposes. His activity was approved by the Federico II Ethics Committee (#482/21) and by the AOU Federico II health management.

The "Breast Cancer Tissues and Organoids" Biobank also BCTO BioBank is located at the Center for Biological Resources (CRB) of the Institute of Genetics and Biophysics of Naples, belonging to the network of Biobanks and Biological Resource Centers of the BBMRI (http://www.igb.cnr.it/centro-di-risorse-biological), where other biobanks are also located.

### **Biobank Mission**

The Mission of the BC-Tiss&Org BioBank is to support research on breast cancer, through the development of organoids starting from the tumor and healthy tissues of breast cancer patients for the purpose of their molecular and functional characterization, which is fundamental for cancer research and for the development of personalized anti-tumor therapies.

The BCTO BioBank operates on a non-profit basis and guarantees compliance with current regulations regarding the quality and rights of the subjects involved.

The BCTO BioBank is at the basis of improving the quality and health of patients by promoting studies increasingly aimed at personalized medicine and aimed at identifying the causes of the disease and the optimal individual response to therapy.

The "Breast Cancer Tissues and Organoids" Biobank is a service available to researchers to promote the understanding of breast cancer and therefore the identification of innovative and effective therapies.

The "Breast Cancer Tissues and Organoids" Biobank aims to collaborate with other national and international Biobanks and to encourage the development of a network serving the scientific community.



## **Description and characteristics**

The BCTO BioBank represents a new type of oncology biobank, designed to generate organoids from the surgical specimen of patients suffering from breast cancer. The surgical piece will include two portions: one of healthy tissue and one of tumor tissue. Healthy tissue will be used as a control in the molecular characterization studies of the tumors that will be examined.

The sample, as defined above, will then be used for the preparation of organoids. The generated organoids will be classified and expanded to then be partly used for their molecular characterization by immunohistochemistry and partly aliquoted and stored in the biobank.

This new type of biobank has an important added value for the patient because it allows a rapid exchange of information useful for diagnosis, prognosis and research, contributing to a greater understanding of the molecular alterations of diseases, of the individual response to treatment, and to the identification of new therapeutic targets.

Preserved biomaterials include surgically removed tissue samples and derived organoids.

The materials are preserved both in special cryopreservation systems (-80° freezers and liquid nitrogen tanks) and in paraffin.

The data generated by investigations carried out on BCTO BioBank material are collected in a database at the IGB. The IT platform takes into account the different roles in the management of the biobank and guarantees access to the data exclusively to authorized parties.

The data can be made available to the scientific community with the methods and times agreed with the applicant following approval by the Scientific Committee of the Biobank of a formal request.

The human biological material and the data connected to it are managed by the Management Committee in accordance with established and documented operational specifications which reflect the resolution of the Federico II Ethics Committee and operate in accordance with current regulations regarding quality and respect for privacy.

### Biosafety

Handling human tissue carries a risk of exposure to probable infectious agents. Therefore, to minimize these risks, it is necessary that all those who use the material archived in the BCTO BioBank consider the samples as potentially infectious. Those responsible for the acquisition of materials and the Researchers who receive them for study purposes therefore assume full responsibility for informing and training all personnel who will use the material regarding biological risk, and for implementing all possible preventive measures.



## Sample collection

The tissues come from patients who have given their informed consent to donate. Collection and management of sample data:

The data relating to the samples present in the BCTO BioBank are managed in compliance with the regulations in force by the Management Committee. To guarantee the confidentiality of personal data, BCTO BioBank provides that:

1. the samples are anonymized by assigning an alphanumeric code and, therefore, no one will be able to connect the sample with the identity of the person;

2. the connection between the code, the identity of the depositor and the related information (clinical, genetic, genealogical, etc.) can only be made by the BCTO BioBank Manager, or by personnel explicitly authorized by him in writing;

3. access to the information systems, where the data is recorded, is controlled using security measures suitable to prevent their dissemination or use by unauthorized parties. In particular, access will be controlled by double personalized passwords assigned by the Scientific Manager of BC-Tiss&Org BioBank to authorized personnel;

4. any research results published in journals or communicated at scientific conferences do not contain information such as allowing the patient's identity to be traced, as the samples are transferred and used exclusively in coded form and, under the constraint of the recipient not to publish such information.

BCTO BioBank recognizes the right of access to their data to people affected by breast cancer who participated in the project in accordance with EU Directive no. 679/2016.

### Use of samples

How to access materials:

Samples may be provided to Researchers only as part of Research Projects authorized by an Ethics Committee.

The samples can be transferred, in coded form, to researchers working at national and international research institutes after the evaluation of the proposed project by the Scientific Committee of the BCTO BioBank.

Institutions interested in accessing biomaterials must submit an application to the Head of the BCTO BioBank, accompanied by a description of the Research Project they intend to carry out on the requested material.

The application must specify the Researcher Responsible for the Project (Principal Investigator, PI), with the curriculum vitae and summary description of the Project attached, according to a format that will be defined with the standard operating procedures (SOP) of the BCTO BioBank.



The type and quantity of samples you intend to request must be specified in the document. Furthermore, a commitment will be signed to acknowledge, in a possible publication, the provenance of the samples from the BCTO BioBank.

The transfer of materials will not be possible without a precise definition of their use. The PI must attach a copy of the approval of the Ethics Committee relating to the Project he intends to propose.

In the Material Transfer Agreement, (MTA) the PI must sign the commitment to use the samples only for the purposes indicated in the request and approved by the BCTO BioBank, not to use the samples for commercial purposes, nor to transfer them to third parties for such purposes.

Furthermore, the PI will undertake to send the Biobank a final report with the results obtained and to acknowledge, in possible publication, the origin of the samples from the BCTO BioBank.

A contribution may be requested from the PI to partially cover the costs of set-up, conservation and storage, to be paid for by the research project underlying the request, according to methods and rates that will be defined with the BCTO BioBank SOPs.

## **Project Evaluation:**

The Research Projects are presented to the Scientific Director of BCTO BioBank.

The Scientific Committee of the BCTO BioBank will evaluate the acceptance of the projects based on the proponent's CV, the originality of the research, the validity of the study design and the expected results.

The BCTO BioBank Scientific Committee is made up of 5 members:

-the Scientific Manager;

-two members belonging to the hospital structure supplying the biological material (for acceptance upon invitation of the Scientific Manager);

-two researchers/teachers from Research Institutions/Universities (for acceptance upon invitation of the Scientific Responsible).

The two members belonging to the hospital structure supplying the material and the researchers/teachers from Research Institutions/Universities must be renewed or replaced every two years.

## **Quality Control:**

The BCTO BioBank quality system includes both quality control activities of materials and procedures, and constant updating of staff, through tutoring and training methods.



## **Cessation of activity**

If for any reason Biobank ceases its activity, the stored sample and related data will be transferred to another Biobank. The depositor will be notified of the change in placement with written communication.

The communication will contain an indication of the address of the Biobank to which samples and data are transferred and an explicit indication of the possibility of being able to revoke your consent.

## The BCTO BioBank website within the CRB-IGB website

The BCTO BioBank has a dedicated page within the CRB-IGB institutional website, where the public and patients can find the contact information of the Biobank Manager, the description of the activities and the sample path within the Biobank, and the list of the main publications in which the Biobank is mentioned.

## Financing

The BCTO BioBank operates without profit or direct economic interest and is supported by the infrastructure of the Biological Resources Center of the IGB-ABT, CNR. Liberal donations from Foundations and non-profit organizations and funding from future research projects can contribute to the functioning of the Biobank.

### References

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- Mollaki V. Ethical Challenges in Organoid Use. BioTech (Basel). 2021; 10(3): 12. doi: 10.3390/biotech10030012.

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