**BIOGER**

**IRCCS INRCA INSTITUTIONAL BIOBANK FOR RESEARCH ON AGEING**

**INFORMED CONSENT FOR THE STORAGE OF BIOLOGICAL MATERIAL AT BIOGER INSTITUTIONAL BIOBANK**

**INFORMATIVE NOTE**

Dear Sir or Madam,

before giving your authorization for the conservation of your biological material in BioGer Institutional Biobank, or as a legal representative of a third party, it’s crucial you receive proper information on this process.

Storing material in a biobank means depositing, therefore entrusting samples of human origin and their related data to an organized structure, which manages the collection, preservation and release activities of these samples according to a code of good use and correct behavior, in oder to support the advancement of scientific research on biomedicine.

Biobanks are crucial institutions for scientific research, as they guarantee high qualitative standards in the aforementioned activities, which are collectively defined as “biobanking”. Moreover, biobanks offer a public service for the collectivity and act as guarantors of donors’ rights. Hence, thank to biobanking, donors are both beneficiaries and agents of the research process and their contribution is vital to the advancement of scientific knowledge.

That is why we request your support and your permission to incorporate to BioGer Biobank your biological materials and their associated data or the ones of the person you legally represent, so that it can be used in biomedical research.

This informative note aims to provide you with the necessary information to fully understand what storing your samples at Bioger implies, describing the activities, services and rules of BioGer.

Your participation is completely voluntary. You may refuse to participate or withdraw your consent at any time after signing, without having to explain the reason and it does not adversely affect the care you are currently receiving, or will receive in future at IRCCS INRCA.

The physician will collect your consent after answering your questions and providing you with the necessary information. You can request further information directly to BioGer biobank staff using the contacts enclosed at the end of this document.

For the purpose of a conscious and free provision of your consent, this note provides detailed information on each section of the informed consent form, so that independently from one another, you can decide whether or not according your consent to each of them.

**A. WHAT ARE SAMPLES?**

Samples are human cells, tissues, biological liquids, including derivable molecular fractions (proteins, RNA; DNA, etc), coming from subjects who are healthy or affected by a disease.

**B. WHAT ARE BIOBANKS FOR RESEARCH?**

Biobanks for research are non-profit service units aimed at collecting, preserving and releasing samples of human biological material in accordance with donors’ rights. Biobanks are institutions regulated by specific laws and codes and used for diagnosis and research purposes. Biobanks for research preserve donors’ samples and the related personal, clinical, biological data that are crucial to scientific research.

To ensure the respect of donors’ privacy rights, biobanks operate under the strict supervision of ethics and legal committees ensuring the respect of national and European laws (further information on the topic are provided in section H.

**C. HOW LONG ARE SAMPLES AND RELATED DATA PRESERVED?**

Biological samples are stored at BioGer as long as their quality is considered suitable to the purposes they are used for in order to obtain reliable results, and in general for a period that ranges between 7 and 25 years.

**D. HOW CAN THE SAMPLES BE USED?**

Samples stored in the biobank, such as blood and biological liquid, can be used to extract genetic material (DNA/RNA) to be stored along with the original samples.

To which extent can the samples be used?

Samples and related data can be used for scientific research in geriatric and gerontological pathologies.

Can the samples be transferred to Third Party?

Biological samples stored in BioGer can be released to Institutions which operates in the biomedical research field with nonprofit purposes. Sample release is possible only when researcher’s formal request receives a positive evaluation from IRCCS INRCA Scientific Director/Advisory Board.

In case of authorization, parts of your sample can be transferred to researchers operating in national and international research institutes, in accordance with articles 44-50, Chapter 5 of the European Regulation on General Data Protection (GDPR)[[1]](#footnote-1),[[2]](#footnote-2).

How are samples released?

Samples and related data can be released only after being pseudoanonymised in order to protect the privacy of donors. Sample release is regulated by the Material and Data Transfer Agreement, a contract between the Institute that hosts the biobank and the receiving organization in which rules and parties’ rights are defined, in compliance with the terms of your consent. This procedure applies to the release of your samples to Third Parties located in areas adopting EU Regulation 2016/679 (GDPR). Should you give your specific authorization, portions of your samples can be transferred to Third Parties who are located in areas in which the GDPR is not adopted and rights are not guaranteed[[3]](#footnote-3).

However, it would be impossible to associate the identity and personal data of the donor to the sample.

Can the use of samples generate any profit?

It is possible that potential business benefits of discoveries can be realized as a result of biomedical research conducted on biosamples (e.g. patents on diagnostic tools). Adherence to biobanking does not imply any financial burden on your part, nor does it provide any economic compensation for you or the biobank.

**E. WHICH ARE THE BENEFITS FOR THE DONOR AND THE COMMUNITY?**

Results issuing from the research on the samples could contribute to the understanding of molecular mechanisms that are at the basis of pathologies affecting the elderly or could help develop therapeutic strategies, advancing the knowledge on ageing and age-related pathologies.

**F. CAN I RECEIVE INFORMATION ON THE RESULTS OF RESEARCH?**

In the event that investigations on the samples provide secondary or unattended data that could be clinically or genetically relevant to you and interesting for your health, you can decide whether you want these data communicated to you. Moreover, you can choose whether to be informed about the overall results of the researches that have used your samples through: scientific publications, reports, or newsletters.

**G. WHAT ARE THE PROCEDURES FOR THE USE OF PERSONAL DATA?**

To guarantee the confidentiality of personal data, BioGer biobank adopts the following procedures in compliance with the current regulations:

1. An identification code is assigned to each sample, therefore your name will not be associated with your sample. The code is what will be used by researchers, thus preventing Third Parties from identifying the donor;
2. Only the BioGer Manager, and personnel authorized in writing by the BioGer Manager, may relate the sample code to the donor’s identity and their sensitive information (personal, clinical etc).
3. Data procession (also electronically) of such information will take place in a controlled way so as to prevent their use by unauthorized people. Therefore, encryption and access passwords will be protected and safeguarded to prevent access from those who have not been formally authorized by the biobank;
4. Although the results of research conducted with samples are published in scientific journals or presented at scientific congresses, your identity will not be revealed. In those studies samples and data will be presented only anonymously and / or in aggregate form, i.e. there will be no possibility to associate the sample with the donor’s identity.

You have the right to access your data.

The Data Controller body, which is responsible for the processing of personal data related to the samples stored in BioGer, is IRCCS INRCA, located in Via Santa Margherita, 5 – Ancona (inrca.protocollo@actaliscertymail.it). The Data Protection Officer (DPO) can be contacted at:

dpo@morolabs.it;

morolabs@legalmail.it (CEM).

Fabrizia Lattanzio - IRCCS INRCA Scientific Director, is the Scientific Director of BioGer (direzionescientifica@inrca.it ).

**H. WHO FINANCES THE BIOBANK?**

Biobank activities are financed by IRCCS INRCA, National Institute of Health and Science on Ageing located in Ancona, Via S. Margherita 5.

**I. WHAT HAPPENS IN CASE OF TERMINATION OF THE BIOBANK?**

In case of termination of the activities of the biobank, the samples stored in BioGer can be transferred to another biobank that is part of the IRCCS Network on Ageing, deleted or anonymized, according to donor’s specific consent. The donor will be notified with a communication of the termination of the activity of the biobank.

**L. CAN I CANCEL MY CONSENT, MODIFY MY AUTHORIZATION OR TRANSFER MY SAMPLES?**

Samples donation to the biobank is completely voluntary and altruistic. You can withdraw your consent at any time after the signing of the informed consent. Seemingly, at any time you will be able to communicate any changes of opinion regarding what was declared.

Should you ask the biobank to withdraw your consent, your biological samples will be destroyed and their associated data will bewithdrawn from the biobank. You may also ask the biobank to transfer your personal data to another Data Controller or to anonymize the samples, in which cases the relationship between your personal data (that reveals your identity) and your biological samples and associated clinical data will be eliminated. The effects of such cancellation or anonymization will not be retroactive and will not include research results already obtained.

The Biobank will notify any Third Party to which the portions of your sample were transferred and will ask them to destroy their samples.

If you wish to withdraw your consent, you must send the request in writing to the Director of the Biobank, at the above address.

**M. CONSEQUENCES OF CONSENT WITHDRAWAL**

Neither the refusal to donate your sample to the biobank, nor the withdrawal of your consent, as reported in section L, will involve any form of discrimination or adversely affect the care you presently receive at IRCCS INRCA or will need in future.

Please, notify the biobank about any change in your address or contact information, in order to allow future communications.

For further information you can contact the BioGer Manager at: bioger@inrca.it

***The original informed consent form, dated and signed, must be delivered along with the biological sample to BioGer - IRCCS INRCA Institutional Biobank, Via Fossatello 2, Località Castelferretti, Comune di Falconara Marittima (AN) - 60015.***

**BIOGER**

**IRCCS INRCA INSTITUTIONAL BIOBANK FOR RESEARCH ON AGEING**

**AUTHORIZATION FOR STORAGE OF BIOLOGICAL MATERIAL IN BIOGER INSTITUTIONAL BIOBANK**

**INFORMED CONSENT**

|  |
| --- |
| I, the undersigned |
| Born in *(place)* | **DOB** |
| Home Address | **ZIP Code** |
| City | **State**  | **Phone n.** |
| E-mail  |

After reading and understanding the information contained in the "Informative Note", of which I received a copy, and after having my questions answered with the additional information I needed,

**I DECLARE TO:**

**1. Storage**

I authorize I do not authorize

the conservation in the aforementioned biobank of the biological material and derivates:

Blood

Urine

Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Collected on (YYYY/MM/DD): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

At the Operating Unit/ Recruiting Centre: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

For the purposes of the Project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**2. Use**

I authorize I do not authorize

the use of said biological material stored in BioGer for future studies or scientific research on ageing and age-related pathologies and to be contacted for further information;

**3. Release**

I authorize I do not authorize

the possible release of the aforementioned biomaterial to Third Parties in countries which adopt

the European Regulation on general data protection (GDPR) to be used for scientific research on ageing and age-related pathologies;

I authorize I do not authorize

the possible release of the aforementioned biomaterial to Third Parties in countries which **do not** adopt the European Regulation on general data protection (GDPR) to be used for scientific research on ageing and age-related pathologies;

I authorize I do not authorize

the possible release of the pseudoanonymized biomaterial to Institutions operating in the field of biomedical research on ageing and age-related pathologies;

**4. Processing of Personal data**

I authorize I do not authorize

the processing of my personal and sensitive data for research purposes.

**5. Licenses and Patents**

I authorize I do not authorize

the patenting of possible invention or finding, developed by Third Parties operating in the biomedical field as a result of using the biological sample. I am aware that I won’t obtain any reimbursement or financial right.

**6. Result communication**

I authorize I do not authorize

the researchers to contact me to provide relevant and applicable information for my state of health, resulting from research.

I want to be:

Personally contacted

Informed by a third party

Specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**7. Contact**

I authorize I do not authorize

being contacted by the biobank to renew or change my consent options,if the biobank needs a new specific authorization or the research purposes change.

**8. Termination of Activity**

In case of termination of the activities of the BioGer biobank:

I authorize the destruction of the biological material

I authorize the researchers to contact me to express my preference, independently of consent to section 7

**9. Processing of sensible data according GDPR 2016/679**

Having acquired the information related to the processing of personal and sensitive data according to art. 13 of GDPR 2016/679 and in particular those related to the processing of personal and medical data according to art.4 par 1.

I authorize I do not authorize

the processing of my personal and sensitive data for the research activities reported in the Informative Note.

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Physician that has received the consent:**

**Name and Surname \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Department / Institute \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Phone/Fax \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**E-mail\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PLEASE HAND IN COPY OF THIS INFORMATIVE NOTE AND INFORMED CONSENT TO THE SIGNATORY**

**PLEASE DELIVER THE BIOMATERIAL TO BIOGER ALONG WITH THE ORIGINAL SIGNED FORM OF THE INFORMED CONSENT (EXCEPT FOR THE INFORMATIVE NOTE)**

1. Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

<https://eur-lex.europa.eu/legal-content/IT/TXT/HTML/?uri=CELEX:32016R0679> [↑](#footnote-ref-1)
2. Italian Decree no. 101/2018, implementing Regulation no. 679/2016 (GDPR)

<https://www.gazzettaufficiale.it/eli/id/2018/09/04/18G00129/sg> [↑](#footnote-ref-2)
3. Transfer of personal data towards Extra-Europe Countries.

[https://www.garanteprivacy.it/home/provvedimenti-normativa/normativa/normativa-comunitaria-e-intenazionale/trasferimento-dei-dati-verso-paesi-terzi#1](https://www.garanteprivacy.it/home/provvedimenti-normativa/normativa/normativa-comunitaria-e-intenazionale/trasferimento-dei-dati-verso-paesi-terzi%22%20%5Cl%20%221) [↑](#footnote-ref-3)