

## AGREEMENT FOR THE TRANSFER OF HUMAN BIOLOGICAL SAMPLES AND/OR ASSOCIATED CLINICAL DATA FOR BIOMEDICAL RESEARCH

By and between,

Mr. /Ms. (name of the legal representative of the institution of the recipient), in the name and on behalf of (name of the institution) located at (full address of the recipient institution) and Tax Identification Number (tax identification number), by virtue of the attributes and powers conferred and granted, and

The researcher (name of the researcher) (hereinafter RECIPIENT), affiliated to (name of the institution) (hereinafter XXXX), with National Identity Card Number (National Identity Card Number), as parties of the second part.

And,

Mr. /Ms. (name of the legal representative of the institution of the recipient), in the name and on behalf of (name of the institution) located at (full address of the recipient institution) and Tax Identification Number (tax identification number), by virtue of the attributes and powers conferred and granted, and

The researcher (name of the researcher) (hereinafter RECIPIENT), affiliated to (name of the institution) (hereinafter XXXX), with National Identity Card Number (National Identity Card Number), as parties of the second part.

### RECITALS

- I. XXXXXXXX, is a nonprofit scientific entity, whose primary purpose is to encourage, to promote and to develop scientific and technical health and biomedical research in Valencia Region.
- II. The BIOBANK, in accordance with the provisions of Law 14/2007, of 3 July, on Biomedical Research and its development, is a non-profit public/ private establishment (strike out as appropriate), that stores human biological samples for biomedical research.
- III. The BIOBANK is a member of the National Biobank Network Platform – ISCIII. This platform is a harmonious cooperative framework for the benefit of the Scientific Community to promote the increase of scientific production of excellence in Biomedicine, while guaranteeing the rights of patients and donors in terms of donation, management and transfer of biological samples and associated information, within the framework of the ethical and legal standards in force.
- IV. BIOBANK is a member of the ISCIII Biomodels and Biobanks Platform and the Valencian Biobanking Network. This platform, promoted by CIBERER, with the ultimate aim of making high quality biological samples available to the international scientific community for the development of biomedical projects. Among its functions is to process applications form for access to biological samples and its information associated from users of the network who meet the requirements for it.
- V. The RECIPIENT has requested samples and/or associated data from the BIOBANK (ANNEX I, request for samples) for carrying out the research project (**project name**), hereinafter PROJECT (ANNEX II), and has the expertise and resources required to carry out said project.

- VI. The BIOBANK has the capacity to supply the samples required for the PROJECT, and this agreement is formalized so that the BIOBANK may transfer the samples and/or associated data (hereinafter MATERIAL) described in Annex III to the RECIPIENT, after a favorable evaluation of the aforementioned transfer by the ethical and scientific committees attached to the BIOBANK, and with a favorable report from the Scientific Director of the Biobank.
- VII. In accordance with the above, and in accordance with current regulations, the parties agree to sign this agreement in accordance with the following:

## **TERMS AND CONDITIONS**

### **1. OBJECTIVE**

The objective of this Agreement is to establish the conditions for the transfer of the MATERIAL and DATA by the **BIOBANK** to the RECIPIENT, for the execution of the presented PROJECT.

ANNEX I, with the request for samples; ANNEX II, the PROJECT for which the samples have been requested; ANNEX III, regarding the samples and information to be provided to the RECIPIENT; and Annex IV, with a comprehensive budget of the services to be rendered by the **BIOBANK** are integral parts of this Agreement. (Include reference to other specific annexes existing at the time of signing the agreement).

### **2. OBLIGATIONS OF THE **BIOBANK****

The BIOBANK undertakes to comply with the following obligations:

- I. The procurement and supply of the MATERIAL and DATA shall comply with all guarantees of safety, security and confidentiality laid down in the applicable regulations (ORGANIC LAW 15/1999, of 13 December, on the Protection of Personal Data, LAW 14/2007, of 3 July, on Biomedical Research, and BASIC LAW 41/2002, of 14 November, governing patient autonomy and the rights and obligations concerning clinical information and documentation, and their implementing regulations).
- II. To provide both samples and associated information dissociated from data that identify the donor (encoded or anonymized, as indicated in Annex II), to protect the identity of the donor and to fulfill the legal requirements for said transfer.
- III. To deliver the MATERIAL to the RECIPIENT in optimal conditions for experimental use, although its suitability for a specific purpose cannot be guaranteed, nor can any other guarantee, implied or explicit, be given.
- IV. To supply the MATERIAL for free, and only to pass on to the transfer the costs of obtaining, maintaining, handling, shipping and other similar expenditure related to the samples, as detailed in the budget accepted by the RECIPIENT and included in ANNEX IV.
- V. Once the material is transferred, the BIOBANK will not assume any liability for the use the RECIPIENT makes of the supplied MATERIAL, as all duties and responsibilities described herein are also transferred, and the BIOBANK cannot be held responsible for misuse of the transferred material and clinical data.
- VI. The BIOBANK will not be liable for damage caused during transport of the MATERIAL.

### **3. OBLIGATIONS OF THE RECIPIENT**

The RECIPIENT undertakes to comply with the following obligations:

- I. To use the supplied MATERIAL exclusively for carrying out the presented PROJECT, which was previously evaluated by its relevant Ethics Committee. In the event of a substantial change in the

development of the PROJECT that affects the use of the MATERIAL, the RECIPIENT must inform the BIOBANK, which will expressly decide on the authorization of the new use of the MATERIAL.

- II. To safeguard and ensure the traceability of the samples.
- III. Not to give the MATERIAL to other researchers and/or institutions who are not included in the initial PROJECT.
- IV. To guarantee the confidentiality of the samples and data at all times.
- V. To assume responsibility for the proper and safe handling of the MATERIAL under appropriate biosafety conditions and by trained personnel in the RECIPIENT's laboratory in order to ensure appropriate risk containment. The transferred MATERIAL may contain viruses, latent viral genomes and other infectious agents.
- VI. To inform the BIOBANK and ensure access to the corresponding data, if in the course of the research a finding relevant for the health of the donor or his/her relatives is obtained.
- VII. To mention the origin of the MATERIAL in all communications and scientific publications resulting from the research using the aforementioned samples and/or data, with the following formulations in conjunction:

**In Materials and Methods:**

*"Samples and data from patients included in this study were provided by the Biobank XXXXX, integrated in the ISCIII Biomodels and Biobanks Platform (PT23/XXXXX) and in the Valencian Biobanking Network and they were processed following standard operating procedures with the appropriate approval of the Ethics and Scientific Committees".*

**In Acknowledgements:**

*"We want to particularly acknowledge the patients and the Biobank XXXXX integrated in the ISCIII Biomodels and Biobanks Platform (PT23/XXXX) and in the Valencian Biobanking Network for their collaboration".*

- VIII. To send copies of all published communications and scientific articles to the BIOBANK once the results derived from the use of the samples and/or data have been published.
- IX. The BIOBANK reserves the right to obtain reports from the RECIPIENT regarding the use of the samples and data, and to keep track of the results obtained with them to ensure the right of information of the donor.
- X. Upon completion of the PROJECT or termination of the contract, the Researcher shall DESTROY surplus samples used for said purpose as directed by said institution or RETURN them to the BIOBANK, which may request their return if they are rare samples or if there is a small amount of them.
- XI. To cover the expenses incurred by the BIOBANK according to the previously accepted budget included in Annex IV, as well as shipping costs, if any, within 30 days after issuance of the invoice.

- XII. To contract a shipping company that ensures proper transport of the MATERIAL, complies with the quality standards and has the authorization and approval of the BIOBANK. The BIOBANK does not assume responsibility for any damage that may occur during transport.
- XIII. To comply with the internal Regulations of the BIOBANK regarding transfers. These aspects are already contained in the clauses of this Agreement.

#### **4. CONFIDENTIALITY and DATA PROTECTION**

Each party shall undertake not to disclose without permission of the other party any scientific information or techniques belonging to the other party to which they may have had access, provided that such information is not in the public domain.

This obligation shall remain in force regardless of the term of this agreement and for as long as said information shall be kept confidential.

#### **5. INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS**

The contribution of the BIOBANK to this Research PROJECT is limited to the provision of samples and data. The recipient shall hold the Industrial and/or Intellectual Property rights that may arise from the results of the research.

The contribution and collaboration of the providing institution in the generation of knowledge shall be regulated in a specifically prepared collaborative document between the parties involved.

#### **6. BREACH OF COMMITMENTS / DISPUTE RESOLUTION**

The parties undertake to resolve amicably any disagreement that may arise from the implementation of this Agreement.

In the case of conflict because of differences in the interpretation or implementation of this Agreement, or any issues that may arise from the application, implementation and effects of this Agreement, the parties agree to submit to the competent court of the domicile of the BIOBANK, to the exclusion of any other court or jurisdiction.

The parties agree to submit to the specifically applicable legislation. This Agreement shall be governed by Spanish law.

#### **7. TERM AND TERMINATION**

This AGREEMENT shall enter into force on the date of the last signature of the signatories.

This Agreement may be terminated:

- a) Following completion of the PROJECT for which the MATERIAL was requested.
- b) By mutual agreement of the parties.
- c) Closure, dissolution or liquidation of any of the entities/institutions that have signed this Agreement.
- d) Breach of the obligations under this contract.

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Notwithstanding the termination of this Agreement for any reason, the obligations of the signatories regarding confidentiality, return or destruction of surplus MATERIAL, acknowledgment of the source, return of results and all obligations established by applicable law shall not cease.

## 8. PARTIAL INVALIDITY

If at any time any of the provisions of this Agreement becomes illegal, invalid or unenforceable, the remaining provisions shall remain fully effective.

In witness whereof, for all pertinent purposes, confirming and ratifying the content of this Agreement, with a promise of strict compliance faithful to the content, the parties sign in duplicate for a single purpose.

| On behalf of the BIOBANK:            | On behalf of the RECIPIENT Institution:  |
|--------------------------------------|------------------------------------------|
| Legal Representative of the Biobank: | Legal Representative of the Institution: |
| Signed: (Name and Surname)           | Signed: (Name and Surname)               |
| Scientific Director of the Biobank:  | Principal Investigator of the Project:   |
| Signed: (Name and Surname)           | Signed: (Name and Surname)               |

## ANNEXES:

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|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| <b>ANNEX I:</b>   | Sample request form.                                                                                                                         |
| <b>ANNEX II:</b>  | PROJECT for which the samples are requested.                                                                                                 |
| <b>ANNEX III:</b> | Comprehensive description of the samples and information to be provided to the RECIPIENT, including the type of dissociation of information. |
| <b>ANNEX IV:</b>  | Comprehensive budget of the services to be provided by the BIOBANK.                                                                          |
| <b>ANNEX V:</b>   | Ethical committies.                                                                                                                          |