MATERIAL TRANSFER AGREEMENT (MTA)

number	

Madrid, ……., 20--

The scope of this agreement is to establish the agreement between the researcher, Dr. …….. at …….. (hereinafter the Researcher) and of Hospital Universitario Ramón y Cajal-IRYCIS Biobank (hereinafter the Transferor) for the transfer of patient samples obtained by the deposit agreement named as …….. The agreement establishes:

1. REASON FOR THE SAMPLES TRANSFERING

The Researcher agrees to the use the samples provided by the Transferor in the research project named as …….. (hereinafter the Researcher Project) already positively evaluated by the Ethical and Scientific Committees linked to the Biobank.

2. REQUESTED SAMPLES

Under the mentionated project the Transferor agrees to send to the Researcher …….. together with associate clinical data of the samples.

The Biobank declares that obtaining samples was performed according to all safety and confidentiality guarantees provided by the applicable law (Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal; Ley 14/2007, de Investigación Biomédica; Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica; RD 1716/2012 de biobancos y demás normativa aplicable).

3. RESEARCHER AGREES

Researchers are committed to using only the samples in the above investigation, being forbidden to use it for any other purpose than that stipulated in the project referred to in paragraph 1.

For the objectives of the research team and the study to be performed, samples ceded were dissociated, and not exist in any case the possibility of identifying the patient.

The objectives for which samples are required

a. .....

b. .....

c. .....

Researchers will use only the samples provided by the Biobank to comply with the objectives mentioned in the previous point.

If a surplus sample occurs, researchers can not give it to another researcher or research group.

Researchers must notify the Biobank any changes occurring in the research objective for which samples requested

That in case of surplus of solid samples, they shall be maintained and returned to the Biobank in the same condition as they where sent. In the event of surplus of liquid samples they shall be destroyed. Exceptionally, if there were a new project in which the samples could be used, these may not

be used without prior request to the Biobank and approved for use by the Scientific and Ethics Committees.

Research must ensure traceability of the samples according to the information provided in the delivery note (RG-BIOB-85).

To inform the Transferor about any validated clinically relevant data that could help to source subject and/or his family. This commitment is assumed under the provisions of Biomedical Research Law (Ley 14/2007, de Investigación Biomédica).

In case the source subject withdraws consent for the use of their samples, Transferor will communicate this event to Researcher which shall immediately stop any usage of the samples from such subject. Results already obtained will not be affected.

That according to intellectual contributions, material and economic custodians of the samples in the Biobank, Dr……, and in accordance with the Policy Authoring Biobank publications defined in Annex 1, as part of this agreement, the publications resulting from the project will be governed by the regime of (tick the appropriate) ☐ Cooperation, ☐ Reciprocity WITHOUT shared authorship of publications, ☐ Reciprocity WITH shared authorship of publications, ☐ Outsourcing, ☐ Depository and applicant match (equivalent scheme of cooperation), ☐ *Not applicable.*

To mention the origin of the requested samples in accordance with Annex 1 in all derivated papers thereof, in paragraphs Material and Methods and Acknowledgements, according to the interaction regime described in Annex 1.

Failure to apply the authorship policy, the source of the samples should be included in all papers published in the Material and Methods section as Model 1 in Annex 1.

4. EVALUATION AND MONITORING

According to Royal Decree 1716/2011 the Biobank will make available the information regarding the use of the samples for the source subjects unless the samples had been anonymized.

The Transferor reserves the right to request the Researcher reports about the use of samples and obtained results. The results may be published on the website of IRYCIS (www.irycis.org/biobanco.htm) if this does not interfere in the protection of industrial property rights or trade secret on the results of the project.

5. BREACH OF COMMITMENTS BY THE RESEARCHER

In case of non-compliance of any term agreeded in Section 3, the Biobank Scientific Committee will be inform and further actions will be taken.

6. PLANNING OF SAMPLES SUPPLY

The Biobank is committed to complete the preparation and sending of the samples requested within one month from the signing of this agreement.

Shipment of samples will be paid by researchers at the date agreed. The Biobank will not pay for the costs of sending the samples to the researcher.

7. COMPENSATION FOR EXPENSES

The Biobank will be countervailed by the production process cost (collection, processing, storage, and supply of biological material) and management by the FIBioHRC costs (15% if the cost is borne by external researchers to the

institution), ensuring no cost impact on the sample itself and the lack of profit in the process.

SAMPLE COST CONCEPT	**Amount in € (excluding VAT)**
Sample cost	**0 €**
Production process and sample management FIBioHRC costs	**€**
Packaging and sending cost	**€**
TOTAL (excluding VAT)	**€**

The FIBioHRC will manage this income as a financial contribution towards the expenditures generated in achieving the objectives of the Biobank.

Both parties agree the previous terms described and accept the responsibilities of action by signing this document, in Madrid, on ....., 20_ _.

Researcher Dr.:	Biobank Dr. Fernando Liaño García Director of Biobank

This authorship policy is based in the policy applied in Pais Vasco Research Biobank-OEHUN.

CONTRIBUTIONS OF THE PARTIES

The purpose of this Annex is the embodiment of the contributions of the depositary of the samples in the Biobank face to identify the ownership of research results as well as derivatives of the authors and / or inventors, as appropriate. It shall identify the regime governing interaction between the depositary and the applicant for the Biobank samples.

As stated in the policy guidelines of authorship, the signatories of an article must have made a significant contribution and have an active presence in at least one of the phases of the research.

A. Intellectual input and experimental. (Put an X in the aspects that has participated each of the parties)

Concept	The Custodian	The Applicant
Generation of question		
Defining assumptions and objectives		
Clinical design and / or experimental		
Discussion, writing and critical review of the manuscript		
Participation in data collection		
Contribution and sample collection		
Preparation / processing of samples		
Performing experiments		
Other (training, etc.)		

B. Providing means. (Indicate the means that each party makes available to the project)

Concept	The Custodian	The Applicant
Research team		
Goods and services (consumables, equipment, laboratory services, etc..)		
Contribution of external funding, jointly or individually (also include applications submitted pending announcement)		

AUTHORSHIP POLICY OF PUBLICATIONS

One of the main purposes of the research, is publishing the results in scientific journals. At the request of the Biobank materials, different states originating exchange of material between the Depository and the Applicant under the rules of interaction:

a) Cooperation
b) Reciprocation
   I. WITHOUT shared authorship of publications
   II. WITH shared authorship of publications

Forms of interaction:

a) **Cooperation**: in which Applicant and actively collaborate Depositary recognizing the other a set of skills and powers based on complementarity and subsidiarity in the study: the question generation, design, provision and collection of biological material, search funding, results analysis, article writing, etc. (as shown in the previous section). In this case, the intellectual property of the results in publications that are generated as a result of the execution and implementation of the project will be shared between Applicant and Depositary. The publications are added the forms in the model presented in this Annex 1.

b) **Reciprocation** in which Applicant and Depositary consider collaboration in the project as an exchange relationship that depends on the importance of the contribution of samples and associated data.

I. WITHOUT shared authorship of publications: In this case the number of samples is limited and / or related information is not particularly relevant, so that the contribution of the Custodian will be reflected only in sections of Methods and Acknowledgements of articles derived. In these publications, the formulas are added in model 2 presented in this annex.

II. WITH shared authorship of publications: In this case, the number of samples and / or relevant clinical information to be included at the Depositary, as co-author of arising. If the request is of tissue samples and the pathologist had to review cases to include new information or samples, was also added to the list of authors. In these publications, the formulas are added in model 1 presented in this Annex 1.

As a general rule for the two forms of collaboration, technicians or managers Biobank not entitled to authorship of publications. In exceptional circumstances and provided the Biobank has actively participated in the project studio or performing tasks beyond own assignment of the samples, you can contemplate the possibility of including Biobank staff as co-author.

c) **Subcontracting**: in which the contribution of samples and associated data is considered as a service in which the Depositary is compensated financially for their time to patient selection and collection of samples and associated data. Thus, the Depositary shall not be included in the items derived from the study of the samples provided. The publications are added the forms in the model presented in this Annex 1.

For cooperation and reciprocity schemes with shared authorship of publications is taken into account:

- When a party wishes to use the partial or final results, in part or in its entirety, as an article for publication, conference, etc., must seek the agreement of the other party in writing, by email or letter. The other part shall reply within a period not exceeding 60 days, communicating its approval, disapproval or reservations about the information contained in the article or conference. After that time no response, unauthorized dissemination means requested.
- The order of the authors in the publications will be agreed between the parties, who are committed to the strict compliance of the above analysis, with special attention to avoid early disclosure of those results can be protected by patent.

TEXT TO BE INCLUDED IN THE PUBLICATIONS IN SECTION MATERIAL AND METHODS OF ARTICLES

MODEL 1

In **Material and Methods** section:

- **Spanish:** “Las muestras biológicas y los datos asociados de los pacientes incluidos en el estudio fueron recogidas, procesadas y cedidas por el Biobanco del Hospital Universitario Ramón y Cajal-IRYCIS integrado en la Plataforma de la Red Nacional de Biobancos Hospitalarios (RetBioH; www.redbiobancos.es) siguiendo procedimientos normalizados de trabajo y con la aprobación del Comité de Ética y del Comité Científico”.
- **English:** “Samples and data from patients included in this study were provided by the Hospital Universitario Ramón y Cajal-IRYCIS Biobank integrated in the Spanish Hospital Platform Biobanks Network (RetBioH; www.redbiobancos.es) and were processed following standard operation procedures with appropriate approval of the Ethical and Scientific Committees”.

In **Acknowledgements**:

- **Spanish:** “Agradecemos la generosa aportación de los pacientes en el estudio y la colaboración del Biobanco del Hospital Universitario Ramón y Cajal-IRYCIS integrado en la Plataforma de la Red Nacional de Biobancos Hospitalarios (RetBioH; www.redbiobancos.es)”.

- **English:** "We want to particularly acknowledge the patients enrolled in this study for their participation and the Hospital Universitario Ramón y Cajal-IRYCIS Biobank integrated in the Spanish Hospital Platform Biobanks Network (RetBioH; www.redbiobancos.es) for its collaboration".

MODEL 2

In **Material and Methods** section:

- **Spanish:** "Las muestras biológicas y datos asociados de los pacientes incluidos en el estudio fueron obtenidas por el Dr._____ en el Hospital_____.

El Biobanco del Hospital Universitario Ramón y Cajal-IRYCIS integrado en la Plataforma de la Red Nacional de Biobancos Hospitalarios (RetBioH; www.redbiobancos.es) ha sido el responsable de la recogida, procesamiento y cesión de las muestras biológicas y los datos asociados de los pacientes incluidos en el estudio, siguiendo procedimientos normalizados de trabajo y con la aprobación del Comité de Ética y del Comité Científico".

- **English:** "Samples and data from patients were obtained by Dr._____from _____ Hospital. The Hospital Universitario Ramón y Cajal-IRYCIS Biobank integrated in the Spanish Hospital Platform Biobanks Network (RetBioH; www.redbiobancos.es) processed and released the samples and associated data following standard operation procedures with appropriate approval of the Ethical and Scientific Committees".

In **Acknowledgements**:

- **Spanish:** "Agradecemos la generosa aportación de los pacientes su participación en el estudio y a la colaboración del Biobanco del Hospital Universitario Ramón y Cajal-IRYCIS integrado en la Plataforma de la Red Nacional de Biobancos Hospitalarios (RetBioH; www.redbiobancos.es)".

- **English:** "We want to particularly acknowledge the patients enrolled in this study for their participation and the Hospital Universitario Ramón y Cajal-IRYCIS Biobank integrated in the Spanish Hospital Platform Biobanks Network (RetBioH; www.redbiobancos.es) for its collaboration".