By,

Mr. José Vicente Cervera Zamora, Scientific Director of the Hospital Universitario y Politécnico La Fe’s biobank (Valencia), hereinafter **“BIOBANCO LA FE”**, and ID number 25.400.036-D.

And *(only you must complete the option that corresponds),*

Mr./Mrs      , hereinafter **“RECIPIENT”**, linked to Hospital Universitario y Politécnico La Fe (Valencia) and/or researcher of Hospital La Fe’s Health Research Institute (IIS-La Fe), with ID number**[[1]](#footnote-1)**

Mr./Mrs      , hereinafter **“RECIPIENT”**, linked to       with ID number**[[2]](#footnote-2)**

**STATE THAT:**

1. Hospital Universitario y Politécnico La Fe as owner of BIOBANCO LA FE, is an organization belonging to the *Conselleria de Sanidad* (Generalitat Valenciana). As reference Health Department serves the area’s health needs and others departments or communities.
2. BIOBANCO LA FE, in accordance with the provisions of *Law 14/2007, of 3 July, on biomedical research* and Royal Decree *1716/2011, of 18 November, establishing the basic requirements of authorization and functioning of biobanks for biomedical research and the management of human biological samples, and regulating the functioning and organization of the National Registry of Biobanks for biomedical research,* is a non-profit **public establishment** that stores human biological samples for biomedical research and/or diagnosis extension. Its purpose is the management, collection, processing and preservation of biological samples for being used in approved clinical trials/research projects and/or to complete diagnostic tests in case that there is not remaining material in the medical file.
3. BIOBANCO LA FE is part of **National Registry Biobanks,** reference **B.0000723**, (<https://www.isciii.es/QueHacemos/Servicios/BIOBANCOS/Paginas/RegistroNacionalBiobancos.aspx>).

It is a member of Biomodels and Biobanks Platform ISCIII[[3]](#footnote-3). 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.

1. The RECIPIENT **gives credit to be researcher on biomedical research and/or the doctor** in charge of the patient’s treatment.
2. The RECIPIENT **has requested samples and/or associated information** from BIOBANCO LA FE, according to the biobank’s model, for carrying out the research project/clinical trial entitled

or extension of the diagnostic test needed, having the competence, experience and resources to be able to take it.

1. BIOBANCO LA FE **has capacity to supply the required samples** and the associated information. This agreement is formalized so that BIOBANCO LA FE transfers to RECIEPIENT the samples and associated information described in the ***“Quality report”*, sent to the samples,** and/or other document referred to the cases or their seudonimization. The samples’ application is evaluated by the Ethics and Scientific Committees to which BIOBANCO LA FE is assigned with the positive report of Scientific Director. In case of a Committees’ negative inform, it must be sent the corrections before the samples’ shipment.
2. In accordance with the above and the current regulations, the parties agree to sign this Agreement, taking into account with the following clauses:

**FIRST. OBJECT**

The objective of this Agreement is to establish the **conditions for the samples’ transfer** and associated information from BIOBANCO LA FE to the RECIPIENT, for being used in approved research projects/clinical trials and/or to complete diagnostic tests in case that there is not remaining material in the medical file.

They are part of this Agreement: ***“Formal application”*** (current version), document of **project research/clinical trial** for which the samples, ***"Quality report"*** provided by BIOBANCO LA FE to RECIPIENTE and ***"Budget"*** which sets the provided services’ items.

**SECOND. BIOBANCO LA FE’S OBLIGATIONS**

BIOBANCO LA FE undertakes to comply with the following **obligations:**

1. Obtaining and supplying of the biological material and associated information shall comply with all **guarantees** of safety, security and confidentiality laid down in the **applicable regulations** *(Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 on the protection of natural persons with regard to the processing of personal data and the free circulation of these data, Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, Law 14/2007, of July 3, on biomedical research, Royal Decree 1716/2011, of November 18, which establishes the basic requirements for authorization and operation of biobanks for the purposes of biomedical research and the treatment of biological samples of human origin and Law 41/2002, of November 14, basic regulation of patient autonomy and rights and obligations in this area. of clinical information and documentation, Law 10/2014, of December 29, on Health of the Valencian Community, as well as its regulatory developments).*
2. To provide both samples and associated information **seudoniminized from data that identifies the donor**, to protect the donor’s identity and to fulfill the legal requirements for the transfer, with the exception of the diagnosis extension application.
3. To deliver the biological material and associated information to the RECIPIENT in **optimal conditions for experimental use**, according to the BIOBANCO LA FE’s quality standards, although its suitability for a specific purpose cannot be guaranteed, nor can any other guarantee, implied or explicit, be given.
4. To supply the biological 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.
5. Once the material is transferred, BIOBANCO LA FE **will not assume any liability for the use** the RECIPIENT makes of the supplied biological samples or associated information, as all duties and responsibilities described in this Agreement, cannot be held responsible for misuse of the transferred material and/or associated information.
6. If BIOBANCO LA FE takes on responsibility of hiring to shipping company, it will have to guarantee the appropriate transport of material according to quality standards. BIOBANCO LA FE **will not be liable for damage caused during transport of the MATERIAL.**

**THIRD. RECIPIENT’S OBLIGATIONS**

The RECIPIENT undertakes to comply with the following **obligations:**

1. **To use the supplied biological samples and associated information**, in biomedical research or to complete diagnostic tests, exclusively for carrying out the presented project/clinical trial which was previously evaluated by the Ethics Committee or for complementary **diagnostic tests** referred to in the application.

In event of a substantial change in the project/clinical trial’s development that affects the use of the material and associated information, the RECIPIENT must inform BIOBANCO LA FE the use of the material and/or clinical data. Biobank will decide expressly about the use of samples and associated information.

1. To safeguard and **ensure the traceability** of the samples and associated information.
2. **Not to give the biological samples and clinical data to third parties**, researchers and/or institutions, directly or indirectly, not referred to in the project, evaluated favorably, and not for commercial purposes.
3. To guarantee the **confidentiality** of the samples, data and associated information at all times.
4. To assume **responsibility for the proper and safe handling** of the biological samples and associated information under appropriate biosafety and information security 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.

1. To inform BIOBANCO LA FE 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.
2. **To mention the origin of the biological samples and associated information** in all scientific communications and publications resulting from the research, through the following formulas, being able to use others as long as the reference and name of BIOBANCO LA FE is contemplated:

***In “Materials and Methods” and/or “Acknowledgements”:***

“*Samples and data from patients included in this study were provided by the Biobanco La Fe (B.0000723) and they were processed following standard operating procedures with the appropriate approval of the Ethics and Scientific Committees*”.

1. **To send copies of all published communications and scientific articles** to the BIOBANCO LA FE once the results derived from the use of the samples and data associated information have been published.
2. BIOBANCO LA FE **reserves the right to obtain reports** from the RECIPIENT regarding the use of the samples and associated information, and to keep track of the results obtained with them to ensure the right of confidentiality and privacy of the donors.
3. Upon completion of the research 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 BIOBANCO LA FE, which may request their return if they are rare samples or if there is a small amount of them, at the technical biobank’s discretion.
4. To cover the **expenses incurred** by BIOBANCO LA FE according to the sent ***“Budget”***, as well as shipping costs, including costs generated by specific packaging for transport.
5. If the RECIPIENT takes on responsibility of hiring to shipping company, it will have to guarantee the appropriate transport of material according to quality standards. BIOBANCO LA FE **will not be liable for damage caused during transport of the MATERIAL.**
6. **To comply with BIOBANCO LA FE’s internal Regulations** regarding transfers, material and associated shipments. These aspects are already contained in the clauses of this Agreement.

**FOURTH. CONFIDENTIALITY**

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

The RECIPIENT must obtain the **NON-REIDENTIFICATION** commitment, attached as Annex A, from all the people who are going to use the samples and associated information.

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

**FIFTH. INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS**

If the RECIPIENT makes an invention, that can be patented or not, as the result of using the samples applied for and within the framework of the cited project, **he/she should inform the BIOBANCO LA FE Scientific Direction confidentially and irrefutably.** The RECIPIENT shall hold the industrial and/or intellectual property rights that may arise from the results of the research of the RECIPIENT’s institution.

The **copyright/patent rights of any invention deriving from the cited project/clinical trial** must be determined by mutual agreement between the RECIPIENT’s Institution and the BIOBANCO LA FE’s Institution after considering the role and contribution of all the parties involved according to regulations. The intellectual contribution of each will be respected in any case.

**SIXTH. 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 BIOBANCO LA FE, 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.

**SEVENTH. TERM AND TERMINATION**

This Agreement shall enter into force **on the date of the last signature** of the signatories. This Agreement may be terminated:

* 1. Following completion of the project/research for which the biological samples/clinical data was requested.
  2. By mutual agreement of the parties. The agreement must be established in writing.
  3. Closure, dissolution or liquidation of any of the entities/institutions that have signed this Agreement.
  4. This Agreement may be resolved by either party with immediate effect through notification in writing, unless the breaching party to remedy their acts within the period of 30 days of receipt of the notification, if the clauses of the contract or of the applicable legal regulations are violated.

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.

**EIGHTH. 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 the formal application linked to this document.

**Signed:**

**Date:**

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**ANNEX A: Commitment to non-reidentification of the researchers of [RECIPIENT]**

with ID number       responsible for the research/test project

**I COMMIT** that no person from the research team will develop any activity aimed at the re-identification of the donor subjects of the samples provided in execution of the tasks object of this contract. The rest of the members of the research team undertake the same terms by signing this document.

And to this end we express it in       *[Place]* to       *[Date]*

**Signed (RECIPIENT):**

**Signed (researches team):**

1. Only for RECIPIENTS linked to Hospital La Fe and IIS-La Fe. [↑](#footnote-ref-1)
2. Only for RECIPIENTS linked to different center to Hospital La Fe and/or IIS-La Fe. [↑](#footnote-ref-2)
3. Instituto de Salud Carlos III. [↑](#footnote-ref-3)