**CONTRACT BETWEEN THE FOUNDATION FOR BIOMEDICAL RESEARCH OF LA PAZ UNIVERSITY HOSPITAL, LA PAZ UNIVERSITY HOSPITAL, .................................... (PRINCIPAL INVESTIGATOR) AND ………………………….… (SPONSOR) FOR PERFORMANCE OF THE CLINICAL TRIAL: “…………………………………………………………………………………………………………………………………………………………………....“**

|  |  |  |  |
| --- | --- | --- | --- |
| **PROTOCOL CODE** |  | **HULP CODE** |  |

In Madrid, on .............. 2019

**BY AND BETWEEN**

**(\*) Adjust according to the specific situation of the parties to the contract**

On the one party, Mr/Ms ................................., holder of Tax ID/ID No. ………………………., for and on behalf of ……………...................…, (full name of **SPONSOR ENTITY**) with registered office at ……………………….......................... (full address of the **SPONSOR**), and holder of VAT NUMBER No. .................... (hereinafter referred to as the **SPONSOR).**

On the other party, Mr/Ms .................................., holder of Tax ID/ ID No. ………………………., for and on behalf of ……………… full name of **CRO**), with registered office at ……………………….........................., (full address of the **CRO**) and holder of VAT NUMBER No. .................... (hereinafter referred to as the **CRO).**

On the other party, Mr/Ms………………..…………………… (name of the legal representative of the **CRO**), holder of Tax ID/ID No.………………..as legal representative of …………………………(name of the **CRO**), with registered office at ………………………….….……(full address of the **CRO**) and holder of VAT NUMBER………………..,(hereinafter, the **CRO**), acting for and on behalf of the **SPONSOR** ……………………. (full name of the **SPONSOR** **ENTITY**), authorised to this end, pursuant to the powers of attorney issued in ………………..., on ……………….., in the presence of the notary public ……………….………….. The **SPONSOR** is not exonerated from the liability that affects this party pursuant to **RD 1090/2015**, regulating clinical trials with drugs.

**(\*) The Delegation of the Sponsor in the CRO must be notarised or bear the Hague Apostille.**

On the other party, Ana Coloma Zapatero, holder of Tax ID No. 29.151.547-J, acting for and on behalf of the **FOUNDATION FOR BIOMEDICAL RESEARCH OF LA PAZ UNIVERSITY HOSPITAL**, (hereinafter, **FIBHULP**), with registered office at Paseo de la Castellana, 261, Madrid (28046) and holder of VAT NUMBER G83727057, authorised for the purpose in accordance with the powers of attorney issued in Madrid, on 26 December 2018, in the presence of the notary public, Miguel García Gil, under his record number 48.

On the other party, Rafael Pérez-Santamarina Feijóo, holder of Tax ID No.: 35.243.627-Z, acting for and on behalf of **LA PAZ UNIVERSITY HOSPITAL** (hereinafter, **HOSPITAL**), by virtue of and in accordance with the agreements by and between the **FIBHULP** and the **HOSPITAL.**

On the other party, Mr/Ms…………………, holder of Tax ID No., …………………….., acting in their own name and on their own behalf (hereinafter, **PRINCIPAL INVESTIGATOR**), with domicile for notification purposes at the **…………………. DEPARTMENT** of the **HOSPITAL** located at Paseo de la Castellana, 261, Madrid (28046)

The Parties mutually recognise their capacity to enter into and be bound by this Contract (hereinafter **THE PARTIES**).

**STATE**

Whereas the **SPONSOR** wishes to perform the **CLINICAL TRIAL** described in **CLAUSE ONE** of the Contract.

Whereas the **CRO**, as legal representative of the **SPONSOR** may make payments on its behalf; and the signature of the **CRO** will not be required to amend other points of the Contract in which this party is not involved.

Whereas the **FIBHULP,** pursuant to the provisions set out in the prevailing Agreement signed on **17 June 2009** with **SERVICIO MADRILEÑO DE SALUD (SERMAS)**, has -among other duties- the management of clinical trials undertaken at **LA PAZ UNIVERSITY HOSPITAL**

Whereas, pursuant to the agreement signed between **LA PAZ UNIVERSITY HOSPITAL** and the **BIOMEDICAL RESEARCH FOUNDATION OF LA PAZ UNIVERSITY HOSPITAL** for the performance of clinical studies it corresponds to the **(FIBHULP)** to arrange the contracting and performance of the clinical trials undertaken at **LA PAZ UNIVERSITY HOSPITAL.**

The **PARTIES** declare their will, even though it is not part of the content of this contract, to facilitate the reciprocal fulfilment of the different obligations and needs of the signatories, in order to achieve the objectives proposed in the study.

Based on the foregoing, they enter into this Contract in accordance with the following:

**CLAUSES**

**ONE.- PURPOSE**

* 1. The purpose of this Contract is the performance of the **CLINICAL TRIAL** under **..................................................................................................………………………………………………………….........…………..”** (hereinafter **TRIAL**) with protocol code …………………… (hereinafter **PROTOCOL**), which will be undertaken fundamentally at the areas of the **HOSPITAL** identified in the Recitals of this contract, under the management and responsibility of Dr. .…………………………., who will act as **PRINCIPAL INVESTIGATOR** of the same.
  2. The **TRIAL** will be conducted in accordance with the content specified in the **PROTOCOL**, **version**……... **and dated** ……., with the favourable updated opinion of the Ethics Committee for Research with Medicinal Products (hereinafter **ECRmp**) of the .................. **HOSPITAL** dated ………………..

**TWO.- START, DURATION AND VALIDITY**

* 1. This Contract will come into force on the date of signing, and will remain valid until finalisation of the **TRIAL**, without prejudice to the provisions set out in **CLAUSE TEN.** For these purposes, the **TRIAL** will not be considered finalised until the parties have fulfilled all their obligations under this Contract.
  2. The **TRIAL** will not commence under any concept until the mandatory authorisation has been issued by the **SPANISH AGENCY FOR MEDICINES AND MEDICAL DEVICES** (hereinafter **AEMPS**) in accordance with the terms of **Royal Decree 1090/2015**, **of the corresponding ECRmp,** and any other authorisation which may be required under applicable legislation and regulations**.** The effectiveness of this contract, **version protocol ... and date ...**, is subject to obtaining the aforementioned authorisations. The Parties undertake to ensure that the **TRIAL** is performed in accordance with the terms of the **PROTOCOL.**
  3. The scheduled duration of the **TRIAL** is …… months, as set out in the **PROTOCOL.**

**THREE.- APPLICABLE REGULATIONS**

* 1. The Parties undertake to respect. and comply with applicable legislation upon signing this **CONTRACT** and throughout the duration thereof, and to expressly observe ethical principles and standards, particularly the following:
     1. **Law 10/2013, of 24 July,** through which **Directives 2010/84/EU** and **2011/62/EU** are incorporated into the Spanish legal system
     2. **Royal Legislative Decree 1/2015, of 24 July**, approving the consolidated text of the Law on guarantees and the rational use of medicines and health products.
     3. **Royal Decree 1090/2015, of 4 December**, regulating clinical trials with medicinal products, the Ethics Committee for Research with medical products and the Spanish Register of Clinical Studies (hereinafter **RD 1090/2015).**
     4. **Decree 39/1994, of 28 April**, regulating clinical trials with medicinal products in the Community of Madrid.
  2. **Regulation (EU) 2016/679 from the European Parliament and the Council of 27 April 2016** on the protection of natural persons with regard to the processing of personal data and the free movement of such data, and which repeals **Directive 95/46/EC** (General Data Protection Regulation) and **Organic Law 3/2018, of 5 December,** on the protection of Personal Data and guarantee of digital rights
  3. **Act 41/2002, of 14 November**, governing the Basic Aspects of Patients’ Autonomy
  4. **Law 14/2007, of 3 July**, on Biomedical Research, and **Royal Decree 1716/2011, of 18 November**, which establishes the basic requirements for the authorisation and operation of Biobanks for the purpose of biomedical research and the treatment of biological samples of human origin, for biological samples of human origin that have been obtained as a result of the **TRIAL** directly or indirectly and especially whenever they are going to be used for biomedical research purposes once the trial has finished.
  5. **Law 1/1998, of 2 March**, on Foundations of the Community of Madrid. In accordance with article 23, employers may contract with the foundation, either on their own behalf or on behalf of a third party, following prior authorisation from the Protectorate of Foundations.
  6. The **ICH standards (International Conference of Harmonization Guideline)** the Best Clinical Practices (BCP): GCP E6(R2).
  7. Basic ethical principles established in the internationally accepted recommendations, including the **Declaration of Helsinki** in its updated version.
  8. The deontological standards and national and international anti-corruption legislation, set out in the **OECD Convention adopted on 21 November 1997**, also set out in the **Foreign Corrupt Practices Act (FCPA)** that may be applicable to one or all **PARTIES** to this contract.

Notwithstanding the foregoing, the **PARTIES** undertake at all times to respect and comply with applicable legislation on signing this Contract and during the validity thereof. If the pertinent regulations are modified during contract validity, they will automatically be applied to the aforementioned Contract.

**FOUR.- OBLIGATIONS OF THE PARTIES**

* 1. The **PARTIES** are obliged to full performance of the provisions set out in this Contract, in accordance with the provisions set out herein and in the **PROTOCOL**. Each Party will fulfil its own obligations in accordance with the legislation indicated under **CLAUSE THREE**. The obligations, duties and functions set out in **RD1090/2015** for each of the Parties constitute, for all intents and purposes, obligational content in this Contract, whereby any non-compliance will be considered a breach of this Contract.
  2. In addition, the Parties have the following obligations:
     1. To collaborate in the **TRIAL** monitoring visits carried out by: **(1)** the **ECRmp**, **(2)** the monitors and auditors acting on the instructions of the **SPONSOR** and **(3)** the competent authorities, whenever they perform inspections. At least one week’s notification will be given for these visits, unless agreed otherwise between the Parties. During these inspection, monitoring and audit visits, the necessary technical and organisational measures will be implemented to ensure the maximum respect for personal data protection legislation.
     2. To ensure the **PRINCIPAL INVESTIGATOR**, the **SPONSOR**, the monitors and auditors observe the internal rules of the **HOSPITAL** and of the **FIBHULP**, as well as any instructions on the performance of the **TRIAL** given by the **ECRmp** in charge of monitoring.
     3. With regard to performance of the **TRIAL**, not to enter into any agreements or unconnected terms that make it difficult or contravene or which prevent compliance with the respective obligations assumed or which involve the assumption of others that are contrary to applicable regulations. In this regard, the Parties declare that, on the date of this Agreement, they are not party to any agreement or contract which contradicts this Agreement. In particular, by virtue of this Clause, the Parties accept that no considerations of any kind can be agreed or paid except those specified in this Contract. This prohibition does not include expenses incurred with regard to meetings held to organise and supervise the **TRIAL**, or any held to analyse or disseminate its findings (scientific presentations or publications).
  3. In addition to the obligations provided for by applicable legislation, the **SPONSOR** will support the **PRINCIPAL INVESTIGATOR** and provide this party and the **ECRmp** with all new relevant information regarding the medicinal product under research.
  4. The **FIBHULP** is responsible for the economic management of this **TRIAL**, and will receive the payments made on behalf of the **SPONSOR/CRO** and distribute them in accordance with the provisions set out in **APPENDIX I.**
  5. The **PRINCIPAL INVESTIGATOR** hereby undertakes to safeguard the patient identification codes. The **SPONSOR** and the **PRINCIPAL INVESTIGATOR** hereby undertake to safeguard the essential **TRIAL** documents for the time and under the conditions established in current legislation.
  6. The **PRINCIPAL INVESTIGATOR** is responsible for selecting the members of the research team and the **TRIAL** support personnel, which may consist of individuals, commercial entities or other organisations that have the necessary material and human resources for the performance of the trial. Attached as **APPENDIX II** is the list of members of the research team at the time of signing this contract. Any change to the research team must be reported to the **ECRmp** in accordance with current regulations.
  7. Likewise, the **PARTIES** must comply with any other obligation that may correspond to them, according to their status, pursuant to applicable legislation, regardless of whether or not it is set out in this contract.

**FIVE.- ECONOMIC ASPECTS**

* 1. The amount of this **TRIAL** has initially been budgeted at **………………………………..…EUROS** excluding VAT (€…………………) (hereinafter, **TRIAL BUDGET**).
  2. This amount has been determined by applying the cost of…**………………….……..EUROS** (€………………………) per evaluable patients, as set out in the Economic Report of the **TRIAL** (**APPENDIX I**), which specifies all economic aspects of the same. Under no circumstances does this amount include an obligation or inducement to the **HOSPITAL,** the **FIBHULP** and/or **PRINCIPAL INVESTIGATOR** to recommend, prescribe, purchase, use or arrange the use of any product of the **SPONSOR.**
  3. The amount to be paid by the **SPONSOR/CRO** during the performance of the **TRIAL** will be established in accordance with the terms of **APPENDIX I**, and be paid to the **FIBHULP** as specified hereunder:
     1. On the signing of this contract, the **SPONSOR** will pay the amount of **€2,000,** as a one-off non-refundable payment to cover the administrative and contractual management expenses of the same.
     2. The remainder of the **TRIAL** Budget will be paid at least every six months, in accordance with the table of amounts per visit and patient recruited included in **APPENDIX I**, until full payment of the amount constituting this Budget. To this end, the **SPONSOR/CRO** and the **PRINCIPAL INVESTIGATOR** will provide the **FIBHULP** with six-monthly reports.
     3. These payments are considered payments on account, dependent on settlement of the definitive **TRIAL** amount.
  4. The definitive amount to be paid by the **SPONSOR/CRO** for performance of the **TRIAL** will be determined in accordance with the activity effectively carried out for the performance of the **TRIAL** (hereinafter the **DEFINITIVE AMOUNT**). The **DEFINITIVE AMOUNT** will be calculated as follows:
     1. Within a maximum term of three (3) months as from termination of the **TRIAL** in the **HOSPITAL**, the **SPONSOR/CRO** and the **PRINCIPAL INVESTIGATOR** will notify the **FIBHULP** in writing of the total number of: (i) patients recruited and evaluated, (ii) actual visits carried out, (iii) incidents arising, along with (iv) all extraordinary tests, analyses, examinations, consultations or hospital admissions, whether or not they are included in the Economic Report (**APPENDIX I**).
     2. As soon as possible following communication of the information referred to in the previous point, the **FIBHULP** will calculate, issue and notify the **SPONSOR/CRO** -through a final billing of the trial- of settlement of the definitive amount, as well as, where appropriate, claiming any outstanding payments, which must be paid within a deadline of one (1) month, without the need for any subsequent payment demand. With settlement of the final payment, the economic obligations of the **SPONSOR** will be understood as concluded.
  5. All payments will be made against the corresponding invoice, to which VAT will be applied in accordance with the regulations in force at the time of issue, in the name of the **SPONSOR** or **THE PAYMENT CONTROLLER** established(tax details):

|  |  |
| --- | --- |
| **CONTROLLER OF INVOICE ISSUANCE** | |
| **NAME** |  |
| **CIF/VAT NUMBER/ ID** |  |
| **ADDRESS** |  |
| **CONTROLLER OF INVOICE SENDING** | |
| **NAME** |  |
| **ADDRESS** |  |

**(\*)** The **SPONSOR/CRO** must notify the amount to be billed in writing for the visits/procedures that have been conducted, giving a breakdown of these, so that the **FOUNDATION (FIBHULP)** can issue the invoices corresponding to the costs detailed in the **Economic Report (APPENDIX\_1)**. To this end, an email will be sent to [**ensayosclinicos@idipaz.es**](mailto:ensayosclinicos@idipaz.es)

* 1. Payments to the **FIBHULP** will be made by bank transfer, with the expenses borne by the payer, to:

|  |  |
| --- | --- |
| **TITLE** | Foundation for Biomedical Research  of La Paz University Hospital |
| **CIF/VAT NUMBER** | ESG83727057 |
| **BANK:** | La Caixa  Av. de la Institución Libre de Enseñanza, 18  28037 Madrid |
| **IBAN** | ES47 2100 4065 1322 0009 2143 |
| **SWIFT** | CAIXE SBB |

* 1. Payments made by the **SPONSOR/CRO** to the **FIBHULP** will release the former from all obligations with regard to the same. The **FIBHULP** will pay any amounts due to the trial investigators.

**(\*) Include point 5.8 only if applicable**

* 1. The **PARTIES** agree that if the **HOSPITAL** lacks the equipment necessary to adequately perform the **TRIAL**, the **SPONSOR** will provide this to the **HOSPITAL** on a free of charge and temporary basis, either directly or through a third party.

The **SPONSOR** will be in charge of the supply, installation, maintenance and removal of the same. In no case will the **HOSPITAL**, the **FIBHULP** or the **RESEARCHER** be responsible for its maintenance or potential loss

The equipment will consist of the following components:

* …………………………………………………………………..……
* ………………………………………………………………………..

The **EQUIPMENT** will always be the property of the **SPONSOR** or of a third party and will carry the corresponding identification in that regard.

The **EQUIPMENT** must only be used to conduct the **TRIAL**, and on finalisation of this will be returned to the **SPONSOR** or to a third party at no cost whatsoever for the **HOSPITAL** or the **FIBHULP**

When receiving a request to return the equipment, the **PRINCIPAL INVESTIGATOR** will place the **EQUIPMENT** at the disposal of the **SPONSOR** or the third party designated by the latter for collection.

On finalisation of the **TRIAL** the **SPONSOR** may transfer the **EQUIPMENT** to the **HOSPITAL** or to the **FIBHULP** free of charge, in which case the appropriate documents will be formalised.

In the event that additional equipment needs are detected during performance of the **TRIAL** and after signing this contract, the **PARTIES** must sign an addendum that includes the equipment made available, respecting the conditions and terms indicated in the preceding paragraphs.

**SIX.- Insurance and liabilities**

**6.1.** The **SPONSOR** has taken out a public liability insurance policy that complies with all aspects of the provisions set out in **RD1090/2015**. Said policy, number................... , which has been taken out with the insurance company …………………………………….., covers damages for which the person conducting the **TRIAL** that is the subject matter of this Contract is liable, and it remains in force as the **SPONSOR** is up-to-date in payment of the premiums.

**6.2.** This policy also explicitly includes the **PRINCIPAL INVESTIGATOR**, their collaborators and the **HOSPITAL** and the **FIBHULP** (a copy of the policy or certificate is attached).

**SEVEN.- PERSONAL DATA CONFIDENTIALITY AND PROTECTION GUARANTEES.**

* 1. The Parties hereby undertake to do everything in their power to ensure the **CONFIDENTIALITY** of the information provided and obtained during the course of the **TRIAL**, along with all personal information on the subjects recruited for the TRIAL, in compliance with the requirements of current legislation. This confidentiality obligation does not include information that: (i) is in the public domain, (ii) was already known to the **PRINCIPAL INVESTIGATOR** or **FIBHULP** at the time it was revealed, or (iii) which had to be revealed pursuant to a court order.
  2. All Parties, to the extent that they have access to and process personal information on the **TRIAL** subjects, must take the necessary measures to protect this data and prevent access by non-authorised third parties. The parties are obliged to strictly observe the provisions set out in **Regulation (EU) 2016/679 from the European Parliament and the Council, of 27 April 2016**, on the protection of natural persons with regard to personal data processing and the free movement of such data, and which repeals **Directive 95/46/EC** (General Data Protection Regulation), **Organic Law 3/2018, of 5 December,** governing Personal Data Protection and the guarantee of digital rights and the[...]. Said legislation will also apply to the personal data contained in this contract.

In accordance with the provisions of **article 28** of the **General Data Protection Regulations**, in the event that the **FIBHULP**, for the economic management of the clinical trials covered by this contract, accesses personal data that are part of data processing activities that are the responsibility of the joint data controllers, the stipulations set out hereunder will apply.

By means of this clause, the **FIBHULP** is empowered, as data processor, to process the personal data necessary for the economic management of the clinical trials that are the subject of this contract on behalf of those joint data controllers.

In this regard, data for which the joint data controllers are responsible, and to which the **FIBHULP** could have access for the economic management of clinical trials, would be the following:

**▪ CATEGORIES OF DATA SUBJECTS:** Clients, Suppliers, Employees.

**▪ DATA TYPES:** Identification data, Contact data, Employment details, Commercial information.

For the economic management of clinical trials, the **FIBHULP** may access and process the personal data indicated above, for which the joint data controllers are responsible, solely for the purpose of fulfilling the services covered by this contract and always in accordance with the instructions given by the joint data controllers (if the **FIBHULP** considers that any of the instructions violates the General Data Protection Regulation or any other data protection provision of the Union or of the Member States, the **FIBHULP** will immediately inform the joint data controllers). The joint data controllers must provide the **FIBHULP** with the databases that are the object of the service. The joint data controllers hereby guarantee that the data included in these databases have been obtained and are processed legitimately.

The processing of such data will mainly consist in the collection of the data provided by the joint data controllers, the registration of the same in the systems of the **FIBHULP**, their conservation and storage, as well as their destruction or, at the request of the joint data controllers, return.

The joint data controllers are responsible for facilitating data subjects with the right to information at the time of collecting their data.

For its part, both the **FIBHULP** and its staff, properly trained in data protection, are required:

• To maintain the due confidentiality and duty to secrecy with respect to data that are the object of the provision of the service, as well as not to disclose the data to third parties, unless it has the express authorisation of the joint data controllers in the legally admissible cases. If the **FIBHULP** needs to transfer personal data to a third country or to an international organisation, pursuant to European Union law or the laws of any Member State, it will inform the joint data controller about such a legal requirement in advance, unless prohibited by laws for important reasons of public interest;

• Introduce the necessary security measures to: guarantee the confidentiality, integrity, availability and resilience of the data-processing systems and services; restore the availability and access to personal data quickly in case of a physical or technical incident; verify, evaluate and assess, on a regular basis, the effectiveness of the technical and organisational measures implemented to guarantee the security of data processing; encrypt personal data

• Maintain a record of the data-processing activities carried out by the **FIBHULP** on behalf of the joint data controllers;

• Assist the joint data controllers in the event of potential requests by data subjects to exercise data protection rights (access, rectification, erasure, objection, data portability and restriction on the processing of data, and not to be the object of individualised automated decisions [including profiling]);

• Notify the joint data controllers as expeditiously as possible and in any case within a deadline of 24 hours of any security breaches of the data under its charge, so that the joint data controllers have sufficient time to inform, if necessary, the AEPD or the data subjects;

• Support the joint data controllers, when appropriate, in carrying out the impact assessments related to data protection and in carrying out the prior consultations with the supervisory authority;

• Provide the joint data controllers with all information required to demonstrate compliance with their data protection obligations and allow the joint data controllers or auditor authorised by them to perform inspections or audits.

• Not perform any subcontracting for the economic management of the trials, except the auxiliary services necessary for the normal operation of the services of the **FIBHULP**. If it is necessary to subcontract any data processing, this fact must be previously disclosed in writing to the joint data controllers, with one week’s notice, indicating the data processing to be subcontracted and clearly and unambiguously identifying the subcontractor company and its contact information. The subcontracting may be carried out if the joint data controllers do not declare their objection within the established deadline. The subcontractor, who will also hold the status of data processor, is likewise obliged to comply with the obligations set out in this document for the **FIBHULP** and the instructions given by the joint data controllers. It is up to the initial data processor to regulate the new relationship so that the new data processor is subject to the same conditions (instructions, obligations, security measures, etc.) and with the same formal requirements as the initial data processor, with regard to the appropriate processing of personal data and guaranteeing the rights of the data subjects affected. In the case of non-compliance by the sub-processor, the initial data processor will remain fully liable with the joint data controllers for compliance with the obligations.

* 1. **THE PRINCIPAL INVESTIGATOR** and the **FIBHULP** will appropriately disassociate the personal data of the subject taking part in the **TRIAL**, so that they cannot be identified or be identifiable by the **SPONSOR/CRO**. Access to personal data of the **TRIAL** subjects will only be gained to the extent permitted in the Informed Consent, and in the exercise of their professional duties, by the monitors and/or representatives designated by the **SPONSOR/CRO**, and the pertinent auditors and authorities
  2. Each of the **PARTIES** is hereby informed that the professional contact data will be processed by the other party in order to manage this Contract, with the performance of the contract serving as the basis for processing. The data will be stored during the time that the contractual relationship exists and until any potential liabilities arising therefrom are time-barred. In addition, the **PARTIES** will not transfer the data to third parties, except under legal obligation. Likewise, the **PARTIES** may at any time exercise their right to access, rectification, restriction, erasure, objection, and data portability, with respect to their personal data, and may do so at the address of the other party that appears in the heading of this Contract. They may also file a claim with the Spanish Data Protection Agency (AEPD).

**EIGHT.- Investigational medicinal products**

**8.1**. The **SPONSOR** will supply the investigational medicinal product, including comparison and placebo products, free of charge, in accordance with the terms of **RD 1090/2015.**

**8.2**. The investigational medicinal product will be supplied through the **HOSPITAL’s** **PHARMACY DEPARTMENT** and dispensed in a controlled manner in accordance with the **PROTOCOL** directives.

**8.3.** The investigational medicinal product will not be made available to the investigators until the TRIAL has received the favourable **ECRmp** report and has been authorised by the **AEMPS.**

**NINE. MANAGEMENT OF SAMPLES**

* 1. The **SPONSOR** undertakes to ensure that management, storage and use of biological samples obtained from the trial subjects is carried out in accordance with the provisions of **Law 14/2007** on Biomedical Research and its legislative implementation in Spain.
  2. The **SPONSOR** undertakes to comply with the requirements of **Royal Decree 65/2006, of 30 January**, which establishes requirements for the import and export of biological samples

**TEN. MODIFICATION, CANCELLATION, FINALISATION OR SUSPENSION AND RESOLUTION OF THE CONTRACT.**

**▪ MODIFICATION**

* 1. Any modification to the terms of the Contract must be made in writing and signed by the Parties, as an **ADDENDUM** to the same. In any case, any such amendments will be carried out in compliance with the terms of **Art.26 of Royal Decree 1090/2015.**

**▪ CANCELLATION OR SUSPENSION**

* 1. The **TRIAL** may be cancelled or suspended by any of the Parties in any of the cases contemplated under article **27 of Royal Decree 1090/2015** and in the following cases:
     1. Failure by any of the Parties to satisfy their fundamental responsibilities.
     2. Non-compliance or defective execution of the remaining obligations assumed by another Party unless remedied within a term of fifteen (15) days as from the date notification of breach is submitted by the other Party
     3. By mutual agreement between the parties, stated in writing.
     4. This contract will be valid until all the **STUDY** payments have been made

**▪ RESOLUTION OR FINALISATION OF THE CONTRACT**

* 1. Termination or suspension of the **TRIAL** will permit the Party not in breach of their contractual obligations to terminate the Contract.
  2. The Parties will guarantee the safety of the subject when the **TRIAL** is completed, and the continuity of their treatment and compliance with current legislation on the matter. In addition, the **SPONSOR** will provide investigational medicinal products not authorised in Spain for that symptom or condition of use, or which are not commonly used in the centre for said symptom.

**▪ OBLIGATIONS FOLLOWING CONTRACT TERMINATION**

* 1. The content of **CLAUSES SEVEN** and **ELEVEN** will remain in force even when this contract has finalised or terminated.

**ELEVEN.- FINDINGS AND PUBLICATIONS**

* 1. All data, the findings of the **TRIAL**, along with all works and industrial and/or intellectual property rights deriving from same are owned by the **SPONSOR**, the Parties being bound by the terms of applicable legislation. This will not prevent the **PRINCIPAL INVESTIGATOR** and the **FIBHULP** from using the findings in their professional activities. Safeguarding the industrial and/or intellectual property rights of the **SPONSOR** and respecting what is established in the **PROTOCOL**.
  2. In accordance with the terms of Royal Decree 1090/2015, upon finalisation of the **TRIAL** the **SPONSOR** undertakes to publish the findings, whether they be positive or negative. This publication will preferably take place in publicly available scientific journals
  3. If the final results of the **TRIAL** are not submitted for publication by the **SPONSOR**, the **PRINCIPAL INVESTIGATOR** may disseminate the data, discoveries or inventions for professional purposes in scientific journals and publications, with at least a reference to the **SPONSOR** in accordance with the following criteria:
* **Trials with non-marketed products:** in the first year following authorisation and marketing in any country;
* **Post-marketing trials:** in the year following finalisation of the **TRIAL**, unless publication has been agreed with the peer-reviewed medical journal or contravenes national legislation.
  1. In this event, the **SPONSOR** must receive a review copy of the text proposed for publication and/or dissemination in accordance with what is established in the **PROTOCOL** and in the event of not specifying anything in this regard, at least forty five (45) days before the day on which it is sent to the scientific journal and at least twenty (20) days beforehand in the case of an abstract. In any case, the **PRINCIPAL INVESTIGATOR** may only use the data having first received the express written consent of the **SPONSOR**.

**TWELVE. ANTI-CORRUPTION CLAUSE**

* 1. The anti-corruption policy sets out that all employees of the **SPONSOR** and of any third party that acts on behalf of the same, or in their name, cannot have any interest or undertaking that enters into conflict or which prevents them from performing their obligations in this Contract in an ethical and appropriate way, as well as ensuring that all activities carried out respect and comply strictly with such ethical standards and with any applicable legislation
  2. The **PARTIES** consider integral and transparent conduct to be essential, as well as a zero tolerance policy with regard to any corrupt practice.
  3. Employees of the **SPONSOR**, and any other third party that acts on behalf of the same will not enter into contracts or authorise, under any concept, whether directly or indirectly, payments of any kind to any of the **TRIAL** participants for the purpose of obtaining an unfair advantage or unduly influencing the taking of any decision. The concept of “payments” includes payments or payment promises, payments in kind and/or in cash, as well as any other offer of goods or services.
  4. The **FIBHULP** will keep a reliable record of all economic transactions arising from this Contract and furnish the **SPONSOR**, on written request, with the corresponding documentation to check compliance with the undertaking set out in this document.

**THIRTEEN. JURISDICTION**

* 1. For ruling on any discrepancy arising with regard to the application or interpretation of the provisions set out in this Contract, the Parties hereby submit to the jurisdiction of the courts of the Community of Madrid where the Centre is based, with express waiver to any other jurisdictional privilege to which they may be entitled.
  2. Whenever copies of this Contract are available in other languages, the Spanish version will prevail.

In witness whereof, the Parties sign this document on three counterparts and for a sole purpose

For the **SPONSOR**, For the **CRO** for and on behalf of the **SPONSOR**

(only if acting for and on behalf of the sponsor)

Mr/Ms ………………….. Mr/Ms …………………

For the **FOUNDATION FOR BIOMEDICAL RESEARCH**

**OF LA PAZ UNIVERSITY HOSPITAL (FIBHULP)**

Signed: Ms Ana Coloma Zapatero

## For LA PAZ UNIVERSITY HOSPITAL

Signed: Rafael Pérez-Santamarina Feijóo

For **THE PRINCIPAL INVESTIGATOR**

Mr/Ms ...........................................

**APPENDIX 2.- LIST OF COLLABORATING RESEARCHERS**

|  |  |
| --- | --- |
| **NAME AND SURNAME(S)** | **NATIONAL ID CARD NUMBER** |
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**(\*) To be able to receive economic compensation for work conducted in the study it will be necessary to appear as a contributor in this contract**