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

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

In Madrid, on …………………..

**BY AND BETWEEN**

**(\*) Change depending on the specific circumstances of the parties**

Of the one part, Mr/Ms.…………………..…………holder of Tax ID/ID No. ……………………….acting in the name and on behalf of ……………………………………….., (hereinafter, the **SPONSOR**), with registered office at ……………………………………….., and holder of CIF/VAT NUMBER/ID No. .................... being empowered for this act by deed of power of attorney No ………………., duly registered at the ………………. Companies Registry, executed before the Notary of the ……………………… Notarial Association, Mr/Ms. ................................... dated …………..

Of the one part, Mr/Ms. …………………………………. (name of the CRO's legal representative), holder of Tax ID/ID No. ……………………….as legal representative of …………………..……………… (CRO name), with registered office at ………………………….….……(CRO’s full address) and holder of CIF/VAT NUMBER/ID ………………..,(hereinafter, the **CRO**) acting in the name and on behalf of the **SPONSOR** (Full name, address and Tax ID Code of the SPONSOR - pharmaceutical laboratory, scientific company, or legal person), (hereinafter, the **SPONSOR**) authorised for this purpose under powers of attorney issued in ……………….. on ……………..(date), before the Notary, Mr/Ms……………………..

There is no exemption from the **SPONSOR**’s liability under **Royal Decree 1090/2015, of 4 December**, regulating clinical CLINICAL TRIAL with medications, Research with medications’ Ethics Committees and the Spanish Clinical CLINICAL TRIAL Registry (hereinafter, **RD 1090/2015, of 4 December**).

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

Of the other, Ms. Ana Coloma Zapatero, holder of Tax ID No. 29.151.547J, acting in the name 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**, under 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.

Of the other, Mr. Rafael Pérez-Santamarina Feijóo, holder of Tax ID 35.243.627-Z, acting in the name and on behalf of the **MADRID HEALTH SERVICE** (hereinafter, **SERMAS**), for **LA PAZ UNIVERSITY HOSPITAL** (hereinafter, **HOSPITAL**), with registered office at Paseo dela Castellana, 261, Madrid (28046), in accordance with **RESOLUTION 385/2020, of 11 June**, of theDeputy Ministerfor Health Care, under powers of attorney in matters of procurement and economic-budgetary management.

And of the other part, Mr/Ms ………………………, holder of Tax ID No. ………………..acting in their own name and on their own behalf (hereinafter, the **LEAD INVESTIGATOR**), with address for the purposes of notifications at the **……………………. SERVICE** in the **HOSPITAL** located at Paseo de la Castellana, nº 261 de Madrid (28046)

Based on the above statements, the **PARTIES** have decided to formalize this Contract, in accordance with the following:

**THEY STATE**

That the **SPONSOR** is interested in carrying out the **CLINICAL TRIAL** described in the **FIRST CLAUSE** of the Contract.

**(\*) Change depending on the specific circumstances**

That the **CRO**, as the **SPONSOR**’s representative, may make payments in its name.

That the **FIBHULP**, in accordance with the provisions of its Statutes, is attributed the role of developing research, innovation and managing know-how, inspired by the principle of legality and the principles of ethics and professional conduct, which form a part of managing the clinical **CLINICAL TRIAL** carried out at the **HOSPITAL**.

Whereas forthe management and coordination of biomedical research carried out at **LA PAZ UNIVERSITY HOSPITAL (HULP)**, on 19th April 2020, the **COMMUNITY OF MADRID** through the **HEALTH COUNCIL**, the **MADRID HEALTH SERVICE** (**SERMAS)** and the **FOUNDATION FOR BIOMEDICAL RESEARCH OF LA PAZ UNIVERSITY HOSPITAL,** (**FIBHULP),** signed the current General Collaboration Agreement for the management and coordination of biomedical research and innovation carried out at the **HOSPITAL UNIVERSITY LA PAZ (HULP).**As per clause 3c) of the above agreement, **FIBHULP** is responsible for the economic management for research activity of the **LA PAZ UNIVERSITY HOSPITAL (HULP)** and the **HEALTH RESEARCH INSTITUTE OF THE LA PAZ UNIVERSITY HOSPITAL.**

This agreement includes a commitment by the **FOUNDATION (FIBHULP)** to use the standard contract for clinical trials and the effective management thereof. As a result, employer self-appointments for the conducting of clinical trials are covered by this agreement and must use this standard contract

The **PARTIES** mutually acknowledge that they have the necessary capacity to be bound by this Contract (hereinafter, the **PARTIES**)

**clauses**

**ONE. - PURPOSE**

* 1. The purpose of this Contract is to carry out the trials entitled**“…………………………………………………………………………….....”** (hereinafter, the **CLINICAL** **TRIAL**) with protocol code……………………(hereinafter, the **PROTOCOL**), which will be carried out within the **HOSPITAL**, without prejudice to the fact that for organizational reasons a technique or visit may take place outside it, as identified in **APPENDIX I** to this contract, under the management andat the liability of its **LEAD INVESTIGATOR**.
  2. The **CLINICAL TRIAL** will be carried out in accordance with the content specified in the **PROTOCOL**, in the version …………….and with the date……………… matching those included in the updated favourable opinion from the Research with Medications Ethics Committee (hereinafter, the **CEIm**) of the .................. **HOSPITAL** dated ………………..

**TWO. - COMMENCEMENT AND TERM**

* 1. This Contract will come into force on the day it is signed and will endure until the end of the **CLINICAL TRIAL**, without prejudice to the provisions of **CLAUSE NINE**. For this purpose, the **CLINICAL TRIAL** will not be understood to be finalized until the **PARTIES** have performed all their obligations arising under this Contract.
  2. The **CLINICAL TRIAL** will not, in any case whatsoever, commence until the **CEIm** has issued the relevant favourable opinion and the mandatory authorization is issued by the **SPANISH MEDICATIONS AND HEALTHCARE PRODUCTS AGENCY** (hereinafter **AEMPS**) under the terms of **ROYAL DECREE 1090/2015,** and any other authorization which, as appropriate, may be required by the applicable legislation. The effectiveness of this contract is subject to obtaining the aforementioned authorizations.
  3. The planned term for the **CLINICAL TRIAL** is **…… months**, as provided for in the **PROTOCOL.**

**THREE.- APPLICABLE REGULATIONS**

* 1. Legislation on clinical trials:
     1. **Law 10/2013, of 24 July**, bringing **Directives2010/84/EU of the European Parliamentand of the Council, of 15 December 2010,** on pharmacovigilance, and **2011/62/EU of the European Parliament and of the Council, of 8 June 2011**, on prevention of the entry into the legal supply chain of falsified medicinal products, into the Spanish legal system, and amending **Law 29/2006, of 26 July,** on the guarantees and rational use of medicines and healthcare products.
     2. **Royal Legislative Decree 01/2015, of 24 July,** approving the combined text of the Guarantees and rational use of medicines and healthcare products act.
     3. **Royal Decree 1090/2015, of 4 December,** regulating clinical trials with medications, Research with Medications Ethics Committees and theSpanish Clinical Trials Registry (hereinafter, **RD1090/2015**).
     4. **Decree 39/1994, of 28 April,** regulating the powers of the Madrid Community with respect to clinical trials with medications.
     5. **Royal Decree** [**1591/2009, of 16 October**](http://www.aemps.gob.es/legislacion/espana/productosSanitarios/docs/Directiva_93-42-CEE/rcl_2009_2105.pdf)regulating medical devices
     6. [**Royal Decree 1616/2009, of 26 October**](http://www.aemps.gob.es/legislacion/espana/productosSanitarios/docs/Directiva_90-385-CEE/rcl_2009_2106.pdf), regulating active implantable medical devices
  2. **Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016**, relating to the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing **Directive 95/46/EC (General Data Protection Regulation)**, and **Organic Law 3/2018, of 5 December**, on Personal Data Protection and guarantee of digital rights, along with the remainder of current regulations relating to personal data protection which may be applicable.
  3. **Law 41/2002, of 14 November**, on basic regulation of patient autonomy and on the rights and obligations with regard to clinical information and documentation.
  4. **Law 14/2007, of 3 July**, on Biomedical Research, and **Royal Decree 1716/2001, of 18 November**, establishing the basic requirements for Biobank authorization and operation for the purposes of biomedical research and processing biological samples of human origin, and regulating the operation and organization of the National Biobank Registry for biomedical research, biological samples of human origin,and processing biological samples of human origin, which have been obtained, directly or indirectly, as a result of the **TRIALS** and, in particular, as long as they are going to be used for the purpose of biomedical research once the trials have ended.
  5. **Law 1/1998, of 2 March**, on Foundations in the Madrid Community. In accordance with article 23, patrons may engage with the Foundation, either in their own name or on behalf of a third party, with prior authorisation from the Foundations Protectorate.
  6. **Law 53/1984, of 26 December**, on incompatibilities for personnel in the service of Public Authorities, and **Royal Decree 598/1985, of 30 April**, on incompatibilities for personnel in the service of the Government and Social Security, and the Bodies, Organizations and Enterprises coming under them.
  7. The **ICH Standard** (International Conference of Harmonization Guideline) for Good Clinical Practice (GCP): **GCPE6 (R2).**
  8. Basic ethical principles provided for in internationally accepted recommendations, including the **Declaration of Helsinki**, in its updated version
  9. Ethical standards and the national and international anti-corruption legislation contained in the **OECD Convention,** signed on **21 November 1997**, and also included in the **Foreign Corrupt Practices Act (FCPA),** which may be applicable to one or all of the **PARTIES** to this contract
  10. Without prejudice to the foregoing, the **PARTIES** undertake, at all times, to respect and comply with the legislation applicable on signature of this Contract and during its term. If, during its performance, the relevant regulations are amended, they will automatically be understood to apply to the Contract, unless the relevant regulation provides for a transitory regime with a different application.

**FOUR.- PARTIES' OBLIGATIONS**

* 1. The **PARTIES** are under the obligation to perform the services provided for in this Contract in their entirety, in accordance with its content and that of the **PROTOCOL.**
  2. Furthermore, the **PARTIES** obligations include:
     1. Collaborating in visits monitoring the **CLINICAL TRIAL** made by: **(1)** the **CEIm**, **(2)** monitors and auditors acting on instructions from the **SPONSOR** and **(3)** the relevant authorities, when they make inspections. These visits, apart from inspections, will be notified a minimum of one week in advance, unless a different time frame is agreed by the **PARTIES.** When such follow up, monitoring and audit visits are paid, such technical or organizational measures will be taken as ensure the maximum respect for the legislation on personal data protection.
     2. The **LEAD INVESTIGATOR**, the **SPONSOR** and the monitors and auditors will observe the internal procedural rules of the **HOSPITAL** and the **FOUNDATION**, which will be provided by the latter, and also the indications on the performance of the **CLINICAL TRIAL** given by the **CEIm** responsible for monitoring them.

The **PARTIES** may not agree, amongst themselves or with third parties unrelated to this document, in relation to the performance of the **CLINICAL TRIAL**, agreements or terms unrelated to this one which obstruct, qualify, except, contravene or prevent performance of the respective obligations undertaken, or which involve undertaking others which are contrary to the applicable regulations. For this purpose, each one of the **PARTIES** declares that, at the date of this Contract, they are not a party to any agreement or pact which includes any of the agreements or terms referred to previously. In particular, under this Clause, the **PARTIES** accept that they may not agree or pay considerations of any kind other than those provided for in the Contract. The costs of the meetings held to organize and supervise performance of the **CLINICAL TRIAL,** and those for analyzing or publishing their results (presentations or scientific publications) are excluded from this prohibition.

* 1. Apart from those provided for in the applicable regulations, the **SPONSOR’s** obligations are to give continuous support to the **LEAD INVESTIGATOR** and provide it and the **CEIm** with any new, relevant information which appears about the medication under investigation.
  2. The **FIBHULP’s** obligation is the financial management of these **CLINICAL TRIAL**, receiving the payments made on account by the **SPONSOR/CRO** (choose whichever is appropriate) and distributing them in accordance with the provisions of **APPENDIX I.**
  3. The **LEAD INVESTIGATOR** undertakes to safeguard the identification codes of the subjects included. The **SPONSOR**, the **LEAD INVESTIGATOR** and the **HOSPITAL**, depending on their responsibilities, undertake to keep the essential documents for the **CLINICAL TRIAL** for the time and under the conditions provided for in current legislation.
  4. The **LEAD INVESTIGATOR** is also responsible for selecting the members of the investigation team and support staff for the **CLINICAL TRIAL,** which may be made up of natural persons and/or trading companies, or any other kind, who have the appropriate material and human resources to carry them out. **APPENDIX II** attached sets out a list of the members of the investigation team at the time this contract is signed. Any change to the investigation team must be notified to the **CEIm** in accordance with current regulations

**FIVE.- FINANCIAL ASPECTS**

* 1. The cost of these **CLINICAL TRIAL** has been initially budgeted at **……………. EUROS**, not including VAT, **(€……………….)** (hereinafter, the **CLINICAL TRIAL BUDGET**).

This amount has been determined by applying the cost of…**………………….……..EUROS (€………………………)** per evaluable patient, in accordance with the provisions of the Financial Memorandum for the **CLINICAL TRIAL (APPENDIX I),**which specifies all their financial aspects. This amount does not, in any case whatsoever, include an obligation or inducement for the **HOSPITAL**, the **FIBHULP**, and/or the **LEAD INVESTIGATOR** to recommend, prescribe, buy, use or arrange the use of any of the **SPONSOR’s** products

Furthermore, on signature of this contract, the **SPONSOR** will pay the amount of **2.000 Euros**, in a one-off, non-refundable payment, by way of administrative and contractual management costs

* 1. The amount to be paid by the **SPONSOR/CRO** during performance of the **CLINICAL TRIAL** will be calculated by applying **APPENDIX I** and must be paid to the **FIBHULP** in the payments set out below:
     1. The **CLINICAL TRIAL** budget will be paid, at least, every six months in accordance with the details in the amounts table by visit and subject signed up included in **APPENDIX I,** until the total amount of the Budget has been paid. For that purpose, the **SPONSOR/CRO** (choose as appropriate) and the **LEAD INVESTIGATOR** will report to the **FIBHULP** every six (6) months
     2. These payments are considered to be payments on account, pending payment of the definitive total for the **CLINICAL TRIAL**
  2. The definitive total to be paid by the **SPONSOR/CRO** for performing the **CLINICAL TRIAL** will be calculated based on the work effectively carried out to perform the **CLINICAL TRIAL** be calculated as follows:
     1. Within a maximum of three (3) months after termination of the **CLINICAL TRIAL** at the **HOSPITAL**, the **SPONSOR/CRO** and the **LEAD INVESTIGATOR** will notify the **FIBHULP** in writing of the total number of: **(1)** subjects signed up and assessed, **(2)** visits effectively paid, **(3)** incidents occurring, and **(4)** any hospital test, analysis, exploration, appointment or stay of an extraordinary nature which may have occurred, whether or not they are reflected in the Financial Memorandum (**APPENDIX I**).
     2. As soon as possible after the information referred to in the previous paragraph has been notified, the **FIBHULP** will calculate, issue and notify the **SPONSOR/CRO** in a final invoice for the trials, the amount of the definitive total and, if necessary, claim the amounts pending payment, which must be paid within one (1) month, without the need for a subsequent request. Once the final payment is made, it will be understood that the **SPONSOR’s** financial obligations have concluded.
  3. All payments must be made on submission of the invoice, to which VAT will be added in accordance with the applicable law on the date it is issued on, in the name of the **SPONSOR**, or **FINANCIAL MANAGER** designated:

|  |  |
| --- | --- |
| **INVOICES WILL BE ISSUED TO** | |
| **NAME** |  |
| **CIF/VAT NUMBER/ ID** |  |
| **ADDRESS** |  |
| **INVOICES WILL BE SENDED TO** | |
| **NAME** |  |
| **ADDRESS** |  |
| **INVOICES WILL BE PAYED FOR** | |
|  |  |
|  |  |

(\*) In order for **FIBHULP** to issue the invoices corresponding to the costs detailed in the **budget (ANNEX\_1)**, the **SPONSOR/CRO** must inform **FIBHULP** in writing of the total amount to be invoiced, detailing the breakdown of the visits and procedures that have been carried out. To do so, he/she shall send an e-mail to [**ensayosclinicos@idipaz.es**](mailto:ensayosclinicos@idipaz.es)

**(\*\*)** If it is necessary to include an order or purchase order number in the invoices, this must be indicated, along with the procedure for the **FIBHULP** to request it

* 1. Payments to the **FIBHULP** will be made by bank transfer, with charges payable by the sender, to:

|  |  |
| --- | --- |
| **HOLDER** | Fundación para la Investigación Biomédica  del Hospital Universitario La Paz (FIBHULP) |
| **TAX ID CODE** | 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** (choose as appropriate) to the **FOUNDATION** will be full settlements for the former, with the **FIBHULP** being responsible for payment the amounts that, as appropriate, are payable to the **CLINICAL TRIAL** researchers.

**(\*) Include point 5.7 only if applicable**

* 1. The **PARTIES** agree that, if the **HOSPITAL** lacks the necessary equipment for adequate performance of the **CLINICAL TRIAL,** the **SPONSOR** will provide the **HOSPITAL** with it, free-of-charge and assigning its use, either directly or via a third party. Furthermore, the **SPONSOR** will pay the cost, and arrange the supply, installation, maintenance, calibration and removal of the equipment, and training personnel in operating it, if necessary. The **HOSPITAL**, the **FIBHULP** and the **LEAD INVESTIGATOR** will, in no case, be liable for its maintenance or its eventual loss.

The equipment will consist of the following components:

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

The Equipment will remain the property of the **SPONSOR,** or a third party, and will carry the relevant identification to show this. The Equipment may only be used to perform the **CLINICAL TRIAL** and, when they have ended, will be returned to the **SPONSOR**, or a third party, at no cost to the **HOSPITAL** or the **FIBHULP**

When the **LEAD INVESTIGATOR** receives a request for return, they will make the Equipment available to the **SPONSOR**, or the third party appointed by it to collect it.

On termination of the **CLINICAL TRIAL**, the **SPONSOR** may assign the Equipment to the **HOSPITAL**, or the **FIBHULP**, free-of-charge, for which purpose such documents as are necessary will be formalized.

In the event that additional needs for equipment are detected during performance of the **CLINICAL TRIAL**, subsequent to the signature of this contract, the **PARTIES** must sign an addendum including the equipment made available, respecting the terms and conditions set out in the previous paragraphs.

**SIX. - INSURANCE AND LIABILITIES**

**6.1.-** The **SPONSOR** has taken out a civil liability insurance policy which, in all its aspects, complies with the provisions of **RD 1090/2015**. The policy, No ..……….., was arranged with the insurance company ……………………….. and is current, as the **SPONSOR** is up-to-date with the premiums.

**6.2.-** The policy also explicitly includes the **LEAD INVESTIGATOR**, their collaborators, and the **HOSPITAL** and the **FIBHULP** within its coverage (a copy of the policy or certificate of it is attached).

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

* 1. **CONFIDENTIALITY**.- The **PARTIES** undertake to use all available means to guarantee the **CONFIDENTIALITY** of the information provided for performance of the **CLINICAL TRIAL,** and obtained during its performance, and of the personal data of the subjects signed up for them, for the purpose of complying with all the requirements provided for in the current regulations. The following information is excepted from this confidentiality undertaking: **(i)** which is in the public domain, **(ii)** which was known by the **PARTIES** prior to it being disclosed, or **(iii)** which must be disclosed under legal imperative.
  2. **DATA PROTECTION**. - All the **PARTIES,** in as far as they process the personal data of the **CLINICAL TRIAL’** subjects, must take the necessary measures to protect them and prevent access to them by unauthorized third parties. The **PARTIES** are under the obligation to rigorously observe the provisions of **Regulation (EU) 2016/679, of the European Parliament and of the Council, of 27 April 2016**, and **Organic Law 3/2018, of 5 December**, on Personal Data Protection and the guarantee of digital rights. Furthermore, the aforementioned legislation will be applicable to the personal data contained in this contract.

The **HOSPITAL**, the **LEAD INVESTIGATOR** and the **FIBHULP** will suitably process the personal data of the subjects taking part in the **CLINICAL TRIAL** in such a way that they cannot be identified by the **SPONSOR** and CRO (if appropriate). They will only access the personal data of the **CLINICAL TRIAL’** subjects, where they are identified, in as far as permitted by the informed consent, and in the exercise of their professional duties, of the monitors and/or representatives appointed by the **SPONSOR** and **CRO** (if appropriate), the auditors and competent authorities.

The **PARTIES** signing this contract mutually undertake to:

• Solely access the personal data when this is essential for proper performance of the project

• Process the data for the sole purpose of performing the purpose of the contract

• If any of the parties considers that another breaches the **GDPR**, the **LOPDGDD**, or any other provision relating to data protection in the European Union or the member states, it will immediately notify the others, for the purpose of prompt rectification.

• Assume the relevant liability in the event that the data are used for a purpose other than the performance of the purpose of this contract, they are communicated or they are used in breach of the stipulations in the current regulations, responding for the breaches they may have incurred personally.

• Not to allow access to personal data by any employee it is responsible for who does not need to know them to provide the services.

• Not to disclose, transfer, assign, or in any other way communicate the personal data, whether verbally or in writing, by electronic means, on paper or by computer access, not even for their storage, to any third party, unless there is prior authorization or instruction to do so.

• Keep a register of all the categories of treatments carried out in performing this contract, containing the information required by article**30.2** of the **GDPR** and **31** of the **LOPDGDD.**

• Ensure the necessary training in relation to personal data protection for the persons authorized to process personal data.

• Give mutual support in carrying out impact assessments relating to data protection, when appropriate.

• Give mutual support in carrying out prior consultations with the Supervisory Authority, when appropriate.

• Make all the information needed available to the other party to demonstrate compliance with its obligations, and to carry out the audits and inspections carried out by the other party for the purpose of verifying the proper performance of this contract.

• Take and apply the security measures stipulated in this contract, in accordance with the provisions of article **32** of the **GDPR**, to ensure the security of the personal data and prevent their unauthorized alteration, loss, processing or access, taking into account the level of technology, the nature of the data stored and the risks they are exposed to, whether from human actions or the physical or natural environment.

• Designate a data protection officer and notify their identity and contact details to the other party, and comply with all of the provisions of articles **37, 38** and **39** of the **GDPR** and **35** to **37** of the **LOPDGDD.**

• In the event that either of the parties must transfer or allow access to personal data which are the responsibility of the other to a third party under European Union Law, or of the Member states, which is applicable, it will notify the other of this legal requirement beforehand, unless this is prohibited on grounds of public interest.

• In the event that the processing includes personal data gathering, the relevant procedures for data gathering will be set up, particularly in relation to proven identification of the users, the duty to report and, as appropriate, obtaining consent from the affected parties, ensuring that these instructions comply with all the legal and regulatory provisions required by current regulations on data protection.

•Supervise processing and compliance with data protection regulations by the other party.

**7.3 SECURITY MEASURES AND SECURITY BREACHES**.- Taking into account the level of technology, the application costs, and the nature, scope, context and purposes of the processing, along with the variable risks of probability and severity for the rights and freedoms of natural persons, the parties will take such technical and organizational measures as are appropriate to ensure a security level which is in line with the risk, which, as appropriate, includes, amongst others, the following:

1. Personal data pseudonymisation and encoding;
2. The capacity to ensure permanent confidentiality, integrity, availability and resilience in the processing systems and services, along with rapid availability and access to the personal data en the event of a physical or technical incident.
3. A conventional verification, evaluation and assessment process of the effectiveness of the technical and organizational measures to ensure secure processing.
4. A catalogue of security measures recognized by information security regulations or standards.

When assessing the suitability of the security level, the parties will take into account the risks involved in data processing, particularly as a result of the accidental or unlawful destruction, loss or alteration to the personal data sent, stored or processed in another way, or the unauthorized communication of, or access to, such data. The **PARTIES** will allow audits, and inspections, by the other party and contribute to them.

Furthermore, in the event that the current regulations on data protection, or other related regulations which are applicable to the processing which is the purpose of this contract, are amended, the parties guarantee to implement and maintain any other security measures which may be required of them, without this involving any amendment to the terms of this contract.

In the event of a breach of the security of the personal data on the computer systems used by the parties to provide the Services, they should notify each other, without undue delay, and, at any event, within a maximum of 24 working hours, of the breaches of the security of the personal data held by them that they are aware of, together with all the relevant information to document and notify the incident in accordance with the provisions of **article 33.3** of the **GDPR**.

In this case, each party, to the extent that it concerns them, must notify data security breaches to the Data Protection Authority and/or the parties concerned in accordance with the provisions of the current regulations.

* 1. **RIGHT TO INFORMATION. -** Each one of the **PARTIES** is informed that the professional contact details will be processed by the other party for the purpose of managing this contract, with the basis for processing being its execution. The data will be stored during the time that the contractual relationship lasts and until the eventual liabilities arising from it have lapsed. Furthermore, the **PARTIES** will not assign the data to third parties, except where there is a legal obligation to do so. Moreover, the **PARTIES** may, at any time, exercise their right of access, rectification, restriction, erasure, objection and portability with respect to their personal data, by writing to the **PARTIES’** data protection officers:

**DATA PROTECTION OFFICERS’ CONTACT (HOSPITAL)**

**Comité PDP de la Consejería de Sanidad de la Comunidad de Madrid**

Plaza Carlos Trías Bertrán nº7 (Edificio Soluble) Madrid 28020 **protecciondedatos.sanidad@madrid.org**

**DATA PROTECTION OFFICERS’ CONTACT (FIBHULP)**

**AlaroAvant, S.L**.

Avda. de Brasil 17, 7C, 28020, Madrid

**[dpo.fiblapaz@alaroavant.com](mailto:dpo.fiblapaz@alaroavant.com)**

**DATA PROTECTION OFFICERS’ CONTACT (SPONSOR)**

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**DATA PROTECTION OFFICERS’ CONTACT (CRO)**

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The **PARTIES** may also submit a claim to the Spanish Data Protection Agency.

If one of the **PARTIES** wishes to transfer the signatories’ Personal Data outside the **European Economic Area (EEA)** or Switzerland, this may only be done where permitted by the applicable legislation in the **EEA,** based on the legal mechanisms for transfer or with prior authorization from the other **PARTIES** affected.

**EIGHT. - INVESTIGATIONAL medical devices**

**8.1**. The **SPONSOR** will supply the investigational medical devices free-of-charge, including those for comparison, under the terms provided for in **RD1090/2015.**

**8.2**. The investigational medicinal product will be supplied via the **HOSPITAL’S …………………… SERVICE** and dispensed on a controlled basis, in accordance with the guidelines in the **PROTOCOL**.

**8.3.** The investigational medicinal product will not be made available to the **HOSPITAL** or the **LEAD INVESTIGATOR** until the favorable report from the **CEIm**

**NINE. - AMENDMENT, CANCELLATION OR SUSPENSION, AND TERMINATION OF THE CONTRACT.**

**▪ AMENDMENT**

* 1. Any amendment to the provisions of the Contract be made in writing and be signed by the **PARTIES** as an **ADDENDUM** to it. At any event, the amendment will take into account the provisions of **article 26** of **RD 1090/2015.**

**▪ CANCELLATION OR SUSPENSION**

* 1. The **CLINICAL TRIAL** may be cancelled or suspended by one of the **PARTIES** in any of the situations provided for in **article 27** of **RD 1090/2015**, and also in the following cases:
     1. Due to breach of the essential obligations undertaken by one of the **PARTIES.**
     2. Due to breach or defective performance of the remaining obligations undertaken by another of the **PARTIES**, as long as such breach is not rectified within fifteen **(15) days** from when the other Party informs it of the breach in writing.
     3. By mutual agreement between the **PARTIES**, stated in writing.

**▪ TERMINATION OF THE CONTRACT**

* 1. The discontinuation or suspension of performance of the **CLINICAL TRIAL** will allow termination of the Contract by the Party who is not in breach of their contractual obligations.
  2. The **PARTIES** will guarantee the safety of the subject at the end of the trial, as well as the continuity of the treatment, so they will continue to provide the treatment of the trial to the subjects in compliance with the provisions of **Royal Decree 1015/2009, of June 19,** regulating the availability of medications in special situations. If there is a request by the **CEIm** for continuation of treatment, the **PARTIES** shall agree on the supply taking into account the feasibility of production and the efficacy and safety data of the drug under investigation / treatment of the trial.

**TEN. - RESULTS AND PUBLICATIONS**

* 1. All of the data, the results of the **CLINICAL TRIAL,** and all of the work and industrial and intellectual property rights arising from it, belong to the **SPONSOR**, with the **PARTIES** being subject to the provisions of the applicable legislation.This circumstance will not prevent the **LEAD INVESTIGATOR** and the **FIBHULP** from using the results in their non-commercial professional research and teaching activities, safeguarding the **SPONSOR’s** industrial and intellectual property rights and respecting the provisions of the **PROTOCOL.**
  2. In accordance with the provisions of **RD 1090/2015**, the **SPONSOR** undertakes to publish the results obtained, whether positive or negative, once the **TRIALS** have ended. This publication will take place in publicly accessible scientific media, preferably in scientific journals
  3. If the final results of the **CLINICAL TRIAL** are not submitted for publication by the **SPONSOR**, the **LEAD INVESTIGATOR** may, for professional purposes and in scientific journals and publications, make such data, discoveries or inventions known, with, at least, a mention of the **SPONSOR**, in accordance with the following criteria: **Clinic Trials with products not on the market:** in the first year after their authorization and marketing in any country; **Clinic Trials performed after marketing:** in the year following the end of the **CLINICAL TRIAL**, unless it compromises publication in a medical journal subject to peer review or contravenes national legislation.

The **SPONSOR** must receive a copy of the text proposed for publication and/or dissemination for review, in accordance with the provisions of the **PROTOCOL** and, in the event that no indications are made in that respect, at least forty-five **(45) days** before the despatch date to the scientific journal and, at least, twenty (**20) days** before hand in the event that it is a summary. At any event, the **LEAD INVESTIGATOR** may only use the data with prior, express, written authorization from the **SPONSOR.**

**ELEVEN.- ANTI-CORRUPTION CLAUSE**

* 1. The anti-corruption policy provides that none of the **PARTIES’** employees, and any third party acting for them or in their name, may have any interest or commitment which comes into conflict with, or prevents them from, performing their obligations under this Contract. All work must be carried out with strict respect for, and compliance with, the applicable ethical standards and legislation. The **PARTIES** consider that behaving with integrity and transparency is essential, with a zero tolerance policy towards any corrupt practices.
  2. The **PARTIES’** employees, and any third party acting in their name, will not make payments of any kind, under any circumstances, either directly or indirectly, to any of the **PARTIES** taking part in the **CLINICAL TRIAL** for the purpose of obtaining an unfair advantage or unduly influencing any decision making. This concept includes payments, or promises to pay, in kind and/or in cash, and any other offer of goods or services.
  3. The **FIBHULP** will accurately record all financial transactions arising from this Contract and will, when requested to do so in writing, make the relevant documentation available to the **SPONSOR** allowing verification of compliance with the commitments included in this document.
  4. The **PARTIES** agree that the consideration provided for **(i)** is, in their experience, a just consideration in relation to the services provided; **(ii)** is not an incentive for, or in exchange for, past, present or future prescriptions, purchases, recommendations, use, obtaining a preferential formulaic status or dispensations of any of the **SPONSOR’s** products, or, in any way, conditional or any other similar activity; and **(iii)** does not involve an impairment to the judgment of the **LEAD INVESTIGATOR** and the **HOSPITAL** in relation to advising and caring for each one of the Subjects.

**TWELVE.- JURISDICTION**

* 1. For the resolution of any dispute about the application or interpretation of the provisions of this Contract, the **PARTIES,** expressly waiving any other jurisdiction which may correspond to them, submit to the jurisdiction of the courts and tribunals of the area in the **MADRID COMMUNITY** where the **HOSPITAL** is located
  2. In the event that a copy of this Contract is available in another language or tongue, the Spanish version will prevail.

In witness whereof, the **PARTIES** sign this document in 3 and for a single purpose.

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

(only in the event that it acts in the name and on behalf of the Sponsor)

Mr/ Ms. ……….…….. Mr/ Ms. ……….……..

## On behalf of FOUNDATION FOR BIOMEDICAL RESEARCH

## OF LA PAZ UNIVERSITY HOSPITAL (FIBHULP)

Ms. Ana Coloma Zapatero

## On behalf of LA PAZ UNIVERSITY HOSPITAL

Dr. Rafael Pérez-Santamarina Feijóo

The **LEAD INVESTIGATOR**

Dr. ...........................................

**APPENDIX 2.- LIST OF THE RESEARCH TEAM MEMBERS**

|  |  |  |
| --- | --- | --- |
| **COLLABORATORS** | **SERVICE** | **DNI**  **(National ID document No)** |
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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**