**AGREEMENT BETWEEN LA FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO LA PAZ, HOSPITAL UNIVERSITARIO LA PAZ, ................................. (PRINCIPAL INVESTIGATOR) AND ………..…………………… (SPONSOR) FOR THE CONDUCT OF THE CLINICAL TRIAL ENTITLED: "………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………...…...."**

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

In Madrid, on …of ………………., 2023

**BY AND BETWEEN**

**(\*) To be adapted according to the specific situation of the parties to the agreement.**

On the one part, Mr/Ms ................................... with tax number / ID no. ..................... acting on behalf of ..............................................., (the “**SPONSOR**”), with registered office at .............................. of .......................... and with Tax Code no./VAT NUMBER/ID. no. ...................., being empowered for this act by virtue of power of attorney no. , duly registered in the Mercantile Register of ................................ , granted before the Notary Public of the Notaries Association of Mr..................................... on ........................

On the other part, Mr/Ms/.................................... with tax number / ID no. ..................... as legal representative of ........................... (name of the **CRO**) with registered office at .............................. of .......................... and Tax Code no./VAT NUMBER/ID. no. .................... (hereinafter **CRO)** acting for and on behalf of the **SPONSOR**, authorised for this purpose, in accordance with the powers of attorney issued at ....................., dated ...................., before the notary Mr/Ms.................................. This does not relieve the **SPONSOR** of its responsibilities under **RD 1090/2015 of 4 December**, which regulates clinical trials on medicinal products, the Ethics Committees for Research with medicinal products and the Spanish Clinical Trials Registry (hereinafter **RD 1090/2015 of 4 December**).

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

On the other part, Ms Ana Coloma Zapatero, with tax number 29.151.547-J, acting on behalf of the **FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO LA PAZ**, (“**FIBHULP**”), with registered address at Paseo de la Castellana, nº 261, Madrid (28046) and with tax code no. G83727057, in accordance with the powers of attorney issued in Madrid, dated 26 December 2018, before the notary Mr Miguel García Gil, with record no. 2324.

On the other part, Mr Rafael Pérez-Santamarina Feijóo, with tax number 35.243.627-Z, acting for and on behalf of the **SERVICIO MADRILEÑO DE SALUD** (“**SERMAS**”), for the **HOSPITAL UNIVERSITARIO LA PAZ** (the “**HOSPITAL**”), with registered address at Paseo de la Castellana, nº 261 in Madrid (28046), in accordance with **RESOLUTION 342/2021, of 13 September**, of the Vice-Ministry of Health Care and Public Health and Directorate General of the Madrid Health Service.

And on the other part Mr/Ms ......................, with tax number ..................... acting in his/her own name and right (the “**PRINCIPAL INVESTIGATOR**”), with address, for notification purposes, at the **..................... SERVICE** of the **HOSPITAL** located at Paseo de la Castellana, nº 261, Madrid (28046)

The Parties (“**THE PARTIES**”) acknowledge that they have the mutual capacity to be bound by this Agreement.

**THEY STATE**

Whereas the **SPONSOR** is interested in carrying out the **CLINICAL TRIAL** described in **CLAUSE ONE** of the Agreement.

Whereas the **CRO** as the legal representative of the **SPONSOR** may make payments on its behalf.

Whereas, in accordance with the provisions of its Statutes, the **FIBHULP** is responsible for the development of research, innovation and knowledge management, guided by the principle of legality, ethical principles and professional ethics, which include the management of clinical trials carried out in the **HOSPITAL**.

Whereas, for the management and coordination of biomedical research carried out at **HOSPITAL LA PAZ (HULP)**, on 19 April 2020, the **COMMUNITY** **OF MADRID** through the **HEALTH** **COUNCIL**, the **SERVICIO MADRILEÑO DE SALUD** (**SERMAS)** and the **FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO LA PAZ (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 **HOSPITAL UNIVERSITARIO LA PAZ (HULP)** and the **INSTITUTO DE INVESTIGACIÓN SANITARIA DEL HOSPITAL UNIVERSITARIO LA PAZ**.

This agreement includes a commitment by the **FOUNDATION (FIBHULP)** to use the standard agreement 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 agreement.

Based on the foregoing, they hereby agree to enter into this Agreement in accordance with the following:

**CLAUSES**

**ONE. - PURPOSE**

* 1. The purpose of this Agreement is to carry out the **TRIAL** entitled “............................................................................................................................................................................................................” (henceforth “**TRIAL**”) with protocol code .................. (henceforth “**PROTOCOL**”), which will be carried out mainly in the premises of the **HOSPITAL** identified in the Recitals of this agreement, without prejudice to the fact that for organisational reasons, any technique or visit may be carried out in an outside premises, identified in **ANNEX I** of this agreement, under the direction and responsibility of Dr. ................................, who will act as the **PRINCIPAL INVESTIGATOR** of the **TRIAL**.

The **TRIAL** will be carried out in accordance with the content specified in the **PROTOCOL**, **version** ......... **and date** ......, coinciding with the updated favourable opinion of the Ethics Committee for Research with Medicines (“**CEIm**”) of the **HOSPITAL** ........................... dated ...........

**TWO. - START AND DURATION**

* 1. The Agreement shall enter into force on the date of its signature and shall remain in force until the end of the **TRIAL**, without prejudice to the provisions of **CLAUSE NINE**.For these purposes, the **TRIAL** shall not be deemed to be completed until the Parties have fulfilled all their obligations under this Agreement.
  2. The **TRIAL** shall not commence under any circumstances until mandatory approval has been granted by the **SPANISH AGENCY FOR MEDICINES AND HEALTH PRODUCTS** (“**AEMPS**”) in accordance with **ROYAL DECREE 1090/2015** (**RD 1090/2015**), the relevant **CEIm** and any other approval that may be required under applicable laws or regulations.The effectiveness of this agreement, the **version** Protocol ... **and date** ..., is conditional upon the granting of the above approvals.
  3. The intended duration of the **TRIAL** is ... **months**, as specified in the **PROTOCOL**.

**THREE. - APPLICABLE LEGISLATION**

* 1. Legislation on clinical trials:
     1. **Law 10/2013 of 24 July**, which transposes into Spanish law **Directives 2010/84/EU of the European Parliament and 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 the prevention of the entry of falsified medicinal products into the legal supply chain, and amends **Law 29/2006 of 26 July** on guarantees and rational use of medicinal products and medical devices.
     2. **Royal Legislative Decree 1/2015, of 24 July**, approving the revised text of the Law on guarantees and rational use of medicinal products and medical devices.
     3. **Royal Decree 1090/2015 of 4 December**, regulating clinical trials on medicinal products, ethics committees for research on medicinal products and the Spanish Clinical Trials Registry (hereinafter, “**RD 1090/2015**”).
     4. **Decree 39/1994 of 28 April** regulating the competences in the field of clinical trials with medicinal products of the Community of Madrid.
     5. **Royal Decree 192/2023 of 21 March** on the regulation of medical devices.
     6. **European Regulation 2017/745** on medical devices (including active implantables) and **European Regulation 2017/746** on in vitro diagnostic medical devices.
  2. **Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016** on the protection of individuals 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 the Protection of Personal Data and the guarantee of digital rights, as well as the rest of the regulations in force on the protection of personal data that may be applicable.
  3. **Law 41/2002, of 14 November**, basic law regulating patient autonomy and rights and obligations regarding clinical information and documentation.
  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 biomedical research purposes and the treatment of biological samples of human origin, for biological samples of human origin obtained directly or indirectly as part of the **TRIAL** and, in particular, if they are to be used for biomedical research purposes after completion of the study.
  5. **Law 1/1998, of 2 March**, on Foundations of the Community of Madrid. Pursuant to Article 23, the trustees may enter into contracts with the **FIBHULP**, either in their own name or in the name of a third party, with the prior authorisation of the Protectorate of Foundations.
  6. **Law 53/1984 of 26 December** on the incompatibilities of staff in the service of the Public Administrations and **Royal Decree 598/1985, of 30 April**,on incompatibilities of staff in the service of the State Administration, the Social Security and dependent Entities, Bodies and Companies.
  7. The ICH (International Conference of Harmonisation Guideline) Standards for Good Clinical Practise (GCP): **GCP E6(R2**).
  8. Basic ethical principles set out in internationally recognised recommendations, including the **Declaration of Helsinki** as updated.
  9. Ethical standards and national and international anti-corruption laws contained in the **OECD Convention adopted on 21 November 1997**, which are also contained in the **Foreign Corrupt Practises Act (FCPA)** and which may be applicable to some or all of **PARTIES** this agreement.
  10. Notwithstanding the foregoing, the **PARTIES** undertake to respect and comply at all times with the laws in force at the time of signing this Agreement and during its term. Should the relevant legislation be amended during the development of this Agreement, it shall automatically be deemed to apply to the aforementioned Agreement, unless the relevant legislation establishes a different transitional regime for its application.

**FOUR. - OBLIGATIONS OF THE PARTIES**

* 1. The **PARTIES** undertake to fully perform the services provided for in this Agreement, in accordance with the provisions thereof and in the **PROTOCOL**.
  2. The obligations of **PARTIES** are also:
     1. To cooperate in the monitoring visits of the **TRIAL** to be carried out by: **(1)** the **CEIm**, **(2)** the monitors and auditors acting at the request of the **SPONSOR** and (3) the competent authorities when they carry out inspection activities. These visits, with the exception of inspection visits, shall be announced at least one week in advance, unless otherwise agreed by the **PARTIES**. During these monitoring visits, surveillance and audits, technical and organisational measures are taken to ensure maximum compliance with the regulations on the protection of personal data.
     2. The **PRINCIPAL INVESTIGATOR**, the **SPONSOR**, the monitors and the auditors shall comply with the internal rules of the **HOSPITAL** and the **FIBHULP** provided by these bodies and with the indications on the development of the **TRIAL** provided by the **CEIm** in charge of the monitoring.
     3. The **PARTIES** shall not enter into any agreements or conditions among themselves or with third parties outside the present document in connection with the execution of the **TRIAL** which hinder, restrict, exclude, contravene or prevent the fulfilment of the respective obligations assumed or which imply the assumption of other obligations contrary to the applicable regulations. To this end, each of the **PARTIES**, as of the date of this Agreement, state that they are not a party to any agreement or understanding that provides for any of the foregoing agreements or conditions. In particular, by virtue of this clause, the **PARTIES** agree that no consideration other than that provided for in this Agreement may be agreed or paid. Excluded from this prohibition are costs for meetings held for the purpose of organising and monitoring the implementation of the **TRIAL**, as well as those for the purpose of analysing or publishing the results of the **TRIAL** (presentations or scientific publications).
  3. The obligations of the **SPONSOR** are, in addition to those provided for in the applicable regulations, to provide continuous support to the **PRINCIPAL INVESTIGATOR** and to provide it and the **CEIm** with any new relevant information on the medicinal product investigated.
  4. The **FIBHULP** is responsible for the financial management of this **TRIAL**, receiving the payments made on behalf of the **SPONSOR /CRO** and distributing them in accordance with the provisions of **ANNEX I**.
  5. The **PRINCIPAL INVESTIGATOR** undertakes to keep custody of the patient identification codes. The **SPONSOR** and the **PRINCIPAL INVESTIGATOR** and the **HOSPITAL** undertake, within the limits of their responsibilities, to keep the essential documents of the **TRIAL** for the period and under the conditions laid down in the legislation in force.
  6. It is also the responsibility of the **PRINCIPAL INVESTIGATOR** to select the members of the research team and support staff for the **TRIAL**, who may be individuals, companies or other entities with the appropriate material and human resources to carry out the **TRIAL**. **ANNEX II** contains a list of the members of the research team at the time of signing of this agreement. Any change in the Research Team must be notified to the **CEIm** in accordance with the regulations.

**FIVE. - FINANCIAL ASPECTS**

* 1. The amount of this **TRIAL** was originally estimated at... **EUROS**, VAT not included (**€**.....................) (hereinafter **TRIAL BUDGET**).

This amount was calculated on the basis of a cost of ... **EUROS** (**€**...........................) per evaluable subject, as set out in the Financial Report of the **TRIAL** (**ANNEX I**), which sets out all the economic aspects of the said **TRIAL**. This amount in no way implies any obligation or incentive for the **HOSPITAL**, the **FIBHULP** and/or the **PRINCIPAL INVESTIGATOR** to recommend, prescribe, purchase, use or consent to the use of any product of the **SPONSOR**.

In addition, the **SPONSOR** will pay the amount of **TWO THOUSAND EUROS** **(€2,000)** in a one-off, non-refundable payment as administrative and contract management costs upon signing of this Agreement.

* 1. The amount to be paid by the **SPONSOR /CRO** during the execution of the **TRIAL** shall be determined by applying **ANNEX I** and shall be paid to **FIBHULP** in the payments set out below:
     1. The remainder of the Budget for the **TRIAL** shall be paid at least every six months in accordance with the table of amounts per visit per recruited patient contained in **ANNEX I** until the entire amount constituting this Budget has been paid. For this purpose, the **SPONSOR /CRO** and the **PRINCIPAL INVESTIGATOR** shall maintain the **FIBHULP** informed every six months
     2. These payments are considered to be payments on account, subject to the settlement of the final amount of the **TRIAL**

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* 1. The final amount to be paid by the **SPONSOR /CRO** for the execution of the **TRIAL** shall be determined on the basis of the activity actually carried out for the execution of the **TRIAL** (hereinafter, **FINAL AMOUNT**). The **FINAL AMOUNT** shall be calculated as follows:
     1. Within a maximum of (3) **three months** after the completion of the **TRIAL** at the **HOSPITAL**, the **SPONSOR /CRO** and the **PRINCIPAL INVESTIGATOR** shall notify the **FIBHULP** in writing of the total number of: **(1)** subjects recruited and evaluated, **(2)** visits actually made, **(3)** adverse events encountered, and **(4)** any tests, analyses, examinations, consultations or hospitalisations that were of an extraordinary nature, whether or not included in the financial report (**ANNEX I**).
     2. As soon as possible after the submission of the information referred to in the previous point, **FIBHULP** will calculate, issue and notify the **SPONSOR /CRO** of the settlement of the final amount with the final statement of the process, as well as claim any outstanding amounts, if any, to be paid within one **(1) month**, without the need for any further request. Upon settlement of the final payment, the economic obligations of the **SPONSOR** shall be deemed to be fulfilled.
  2. All payments must be made against presentation of the invoice to which VAT is applied in accordance with the applicable regulations on the date of issue and on behalf of the **SPONSOR** or the established **ECONOMIC RESPONSIBLE PARTY** (tax data):

|  |  |
| --- | --- |
| **ENTITY RESPONSIBLE FOR ISSUING/PROCESSING INVOICES** | |
| **NAME** |  |
| **TAX No/ VAT NUMBER/ ID** |  |
| **ADDRESS** |  |
| **FINANCIAL ENTITY RESPONSIBLE FOR RECEIVING INVOICES** | |
| **NAME** |  |
| **ADDRESS** |  |

**(\*) In order for the FIBHULP to issue invoices for the costs listed in the economic report (ANNEX \_1), the SPONSOR /CRO must inform the FIBHULP in writing of the total amount to be invoiced and provide a detailed breakdown of the visits and procedures carried out. To do so, it will send en email to** [**ensayosclinicos@idipaz.es/**](mailto:ensayosclinicos@idipaz.es/) [**administracioneecc@idipaz.es**](mailto:administracioneecc@idipaz.es)

**(\*\*) FIBHULP will in no case be responsible for accessing the platform to register, upload documentation or issued invoices**

**(\*\*\*) If it is necessary to include a purchase order number or a purchase order in the invoices, this must be indicated, as well as the procedure to be requested by FIBHULP.**

* 1. Payments to **FIBHULP** shall be made by bank transfer, at the payer's expense, to:

|  |  |
| --- | --- |
| **ACCOUNT HOLDER** | Fundación para la Investigación Biomédica  del Hospital Universitario La Paz (FIBHULP) |
| **TAX NO./VAT NUMBER** | ESG83727057 |
| **BANKING INSTITUTION** | Caixabank, S.A  C/ Alcalá, 391  28027 Madrid |
| **IBAN** | ES47 2100 4065 1322 0009 2143 |
| **SWIFT** | CAIXE SBB |

* 1. Payments made by the **SPONSOR /CRO** to **FIBHULP** will be settled in full by the **SPONSOR** and **FIBHULP** will be responsible for payment of any amounts due to the trial investigators.

**(\*) Insert item 5.7 only if applicable (ASSIGNMENT OF EQUIPMENT)**

* 1. The **PARTIES** agree that if the **HOSPITAL** does not have the necessary equipment to adequately carry out the **TRIAL**, the **SPONSOR** will make it available free of charge and on a temporary basis to the **HOSPITAL** and will transfer its use directly or through a third party. Likewise, the **SPONSOR** shall bear the costs and be responsible for the delivery, installation, maintenance, calibration and removal of the equipment, as well as for the training of the personnel who are to use it, if necessary. The **HOSPITAL**, the **FIBHULP** or the **PRINCIPAL INVESTIGATOR** are under no circumstances responsible for the maintenance or loss of the equipment.

The equipment consists of the following components:

* .......................................................................
* .......................................................................

The Equipment is always the property of the **SPONSOR** or a third party and bears an appropriate marking. The Equipment may only be used for the purpose of the **TRIAL** and must be returned to the **SPONSOR** or a third party

when the **TRIAL** is completed at no cost whatsoever for the **HOSPITAL** or **FIBHULP**.

Upon receipt of a request for return, the **INVESTIGATOR** will make the **EQUIPMENT** available for collection by the **SPONSOR** or the third party designated by the **SPONSOR**.

At the end of the **TRIAL**, the **SPONSOR** may cede the Equipment free of charge to the **HOSPITAL** or **FIBHULP**, for which purpose the necessary documents will be formalised.

Should it become apparent during the course of the **TRIAL** and after the signing of this agreement that additional equipment is required, the **PARTIES** will sign an addendum containing the equipment provided, subject to the terms and conditions set out in the previous paragraphs.

**SIX. -INSURANCE AND LIABILITIES**

**6.1.** The **SPONSOR** has taken out a liability insurance policy which complies in all respects with the provisions of **RD 1090/2015**. The said policy, No. ..........................., has been taken out with the insurance company ................................, and is in force as the **SPONSOR** is up to date with the payment of premiums.

**6.2.** The said insurance policy also includes the **PRINCIPAL INVESTIGATOR**, its employees and the **HOSPITAL** and **FIBHULP** in its coverage (a copy of the policy or certificate thereof is attached).

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

* 1. **CONFIDENTIALITY.** - The **PARTIES** undertake to use all means at their disposal to ensure the **CONFIDENTIALITY** of the information provided for and received during the implementation of the **TRIAL**, as well as the personal data of the persons recruited for it, in order to comply with all the requirements set out in the applicable regulations. Exceptions to this confidentiality obligation will be made for information that: **(i)** it be publicly known; (ii) was already known to the **PRINCIPAL INVESTIGATOR** or **FIBHULP** at the time of disclosure; or (iii) disclosure is required by law.
  2. **DATA PROTECTION**. - All **PARTIES**, insofar as they access and process personal data of the persons belonging to the **TRIAL**, shall take appropriate measures to protect them and prevent access by unauthorised third parties. The Parties undertake to strictly comply with the provisions of **Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016** on the protection of individuals with regard to the processing of personal data, on the free movement of such data and repealing **Directive 95/46/ EC** (General Data Protection Regulation), **Organic Law 3/2018 of 5 December** on the protection of personal data and the guarantee of digital rights. The aforementioned legal provisions shall also apply to the personal data contained in this agreement.

The **HOSPITAL**, the **PRINCIPAL INVESTIGATOR** and **FIBHULP** will appropriately segregate the personal data of the individuals participating in the **TRIAL** so that they are not identified or identifiable by the **SPONSOR /CRO** (if applicable). Only the monitors and/or the representatives designated by the **SPONSOR /CRO**, auditors and the competent authorities will have access to the personal data of the **TRIAL** subjects to the extent permitted by informed consent and in the performance of their professional duties.

The **PARTIES** signatories to this agreement mutually undertake to:

• Access personal data only when essential for the proper conduct of the project.

• To process the data exclusively for the fulfilment of the purpose of the agreement.

• If one of the parties considers that the other party is in breach of the **GDPR**, the **Organic Law 3/2018, of 5 December, on the Protection of Personal Data and Guarantee of Digital Rights (LOPD-GDD)** or other EU or Member State data protection provisions, it shall inform the other party without delay in order to arrange for immediate correction.

• Assume responsibility in the event of using the data for a purpose other than fulfilling the purpose of this contract, communicating them, or using them in violation of the provisions of the current regulations, and be personally liable for any infringements committed.

• Prohibit access to personal data by any employee under their responsibility who does not need to know them for the provision of the services.

• Not disclose, transfer, assign, or otherwise communicate personal data, whether verbally or in writing, through electronic means, paper, or computer access, even for the purpose of storage, to any third party, unless there is prior authorisation or instruction to do so.

• Maintain a record of all categories of processing activities carried out in compliance with this contract, containing the information required by **Article 30.2** of the **GDPR** and **section 31** of the **LOPDGDD**.

• Ensure that persons authorised to process personal data receive the necessary training on data protection.

• Assist each other in carrying out data protection impact assessments where appropriate.

• Assist each other in conducting prior consultations with the supervisory authority where appropriate

• Provide the other party with all information necessary to demonstrate compliance with its obligations and conduct audits or inspections carried out by the other party to verify proper compliance with this agreement.

• To adopt and apply the security measures set out in this agreement in accordance with the provisions of **Article 32 of the GDPR** that ensure the security of personal data and prevent its alteration, loss, processing or unauthorised access, taking into account the state of the art, the nature of the data stored and the risks to which they are exposed, whether caused by human action or by the physical or natural environment.

• Appoint a data protection officer and communicate his/her identity and contact details to the other party and comply with all provisions of **Articles 37, 38 and 39 of the GDPR** and **sections 35** to **37** of the **LOPDGDD**.

• In the event that either party is required by applicable Union or Member State law to transfer or provide access to personal data under the responsibility of the other party to a third party, it shall inform the other party of that legal requirement in advance, unless prohibited for reasons of public interest.

• In the event that the processing includes the collection of personal data, the procedures corresponding to the collection of the data shall be established, especially with regard to the reliable identification of users, the duty of information and, where appropriate, obtaining the consent of those affected, guaranteeing that these instructions comply with all the legal and regulatory prescriptions required by current data protection legislation.

• Monitor the other party's processing and data protection regulations.

* 1. **SECURITY MEASURES AND SECURITY BREACHES**. - Taking into account the state of the art, the costs of implementation and the nature, scope, circumstances and purposes of the processing, as well as the risks to the rights and freedoms of

natural persons of varying likelihood and severity, the parties shall implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk including, where appropriate:

1. pseudonymisation and encryption of personal data;
2. the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services, and the availability and accessibility of personal data in a timely manner in the event of a physical or technical incident.
3. a procedure for periodically reviewing, evaluating and assessing the effectiveness of the technical and organisational measures to ensure the security of the processing.
4. a catalogue of security measures recognised in regulations or standards on information security.

In assessing the adequacy of the level of security, the parties shall take into account the risks arising from the processing of data, in particular as a result of accidental or unlawful destruction, loss or alteration of, or unauthorised disclosure of or access to, personal data transmitted, stored or otherwise processed. The **PARTIES** will allow and contribute to audits, including inspections, of the other party.

Similarly, in the event of a change in the regulations data protection or other related regulations applicable to the processing covered by this agreement, the parties guarantee the implementation and maintenance of other security measures that may be required, without this implying any change in the terms of this agreement.

In the event of a personal data breach in the information systems used by the Parties for the provision of the Services, they shall notify each other without undue delay, and in any event within a period not exceeding 24 working hours, of the personal data security breaches under their responsibility that have come to their attention, together with all relevant information for the documentation and notification of the incident in accordance with the provisions of **Article 33.3 of the GDPR**.

In such case, each Party shall, to the extent applicable to it, notify the Data Protection Authority and/or the Data Subjects of the Data Security Breach in accordance with the provisions of the applicable regulations.

* 1. **RIGHT OF INFORMATION.** - Each of the **PARTIES** is hereby informed that the contact details of a professional nature will be processed by the other party for the purpose of the administration of this Agreement, the basis of the processing being the execution thereof. The data will be kept for the duration of the contractual relationship and until the expiry of the obligations arising therefrom. The **PARTIES** will not disclose the data to third parties, unless there is a legal obligation to do so. Similarly, the **PARTIES** may at any time exercise their rights of access, rectification, restriction, erasure, opposition, non-submission to automated individual decisions (including profiling) and portability in relation to its personal data, by contacting the data protection officers of the **PARTIES**:

**DETAILS OF THE HOSPITAL'S DATA PROTECTION OFFICER:**

**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**

**DETAILS OF THE FIBHULP DATA PROTECTION OFFICER:**

**AlaroAvant, S.L.**

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

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

**DETAILS OF THE SPONSOR'S DATA PROTECTION OFFICER:**

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The **PARTIES** may also file a complaint with the Spanish Data Protection Agency.

Should any of the **PARTIES** wish to transfer Personal Data of the signatories outside the **European Economic Area (EEA)** or Switzerland, this will only be done if permitted by applicable **EEA** law, based on the legal mechanisms of the transfer and with the prior consent of the other **PARTIES**.

**EIGHT. - INVESTIGATIONAL MEDICAL DEVICES**

**8.1**. The **SPONSOR** shall supply the medical devices investigated, including comparators, free of charge, under the terms established in **RD 1090/2015**.

**8.2**. The medical device being investigated shall be supplied through the **HOSPITAL**'s ........................... **SERVICE**, dispensed in a controlled manner and in accordance with the guidelines of the **PROTOCOL**.

**8.3.** The medical device investigated will not be made available to investigators until a positive **CEIm** report has been received.

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

**▪ AMENDMENT**

* 1. Any amendment to the provisions of this Agreement must be in writing and signed by the Parties as an **ADDENDUM**. In any event, the amendment must comply with the provisions of Article **26 of RD 1090/2015**.

**▪ CANCELLATION OR SUSPENSION**

* 1. The **TRIAL** may be cancelled or suspended by one of the Parties in any of the situations provided for in section **27 of RD 1090/2015** and in the following cases:
     1. In the event of breach of the material obligations assumed by any of the **PARTIES**.
     2. In the event of breach or defective performance of the other obligations accepted by one of the **PARTIES**, unless such breach is remedied within **fifteen (15) days** of the other Party's written notice of such performance.
     3. By mutual agreement between the **PARTIES**, expressed in writing.

**▪ TERMINATION OR END OF THE AGREEMENT**

* 1. Termination or suspension of the execution of the **TRIAL** will allow the termination of the Agreement by the Party that has not breached its contractual obligations.
  2. The **PARTIES** shall ensure the safety of the subject at the end of the trial, as well as the continuity of the treatment, and shall therefore continue to provide the trial treatment to the subjects in compliance with the provisions of **Royal Decree 1015/2009 of 19 June** regulating the availability of medicinal products in special situations. If there is a request from 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 investigated/treated in the trial.

**TEN. - RESULTS AND PUBLICATIONS**

* 1. The entirety of the data, the results of the **TRIAL**, as well as all works and industrial and/or intellectual property rights derived therefrom, are the property of the **SPONSOR**, and the Parties shall be subject to the provisions of the applicable legislation. This circumstance does not prevent the **PRINCIPAL INVESTIGATOR** and **FIBHULP** from using the results in the context of their professional activity. Respecting the industrial and/or intellectual property rights of the **SPONSOR** and complying with 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 **TRIAL** is completed. This publication will be made in publicly available scientific media, preferably in scientific journals.
  3. If the final results of the **TRIAL** have not been submitted for publication by the **SPONSOR**, the **PRINCIPAL INVESTIGATOR** may publish these data, discoveries or inventions for professional purposes and in scientific journals and publications, mentioning at least the **SPONSOR** according to the following criteria: **Studies involving non-marketed products**: within the first year of their approval and marketing in any country; **Trials conducted after marketing**: within one year of the completion of the **TRIAL**, unless publication in a peer-reviewed medical journal is mandatory or contrary to 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, if nothing is specified, at least **forty-five (45) days** before the date of submission to the scientific journal and at least **twenty (20) days** before in the case of an abstract. In any case, the **PRINCIPAL INVESTIGATOR** may only use these data with the express written permission of the **SPONSOR**.

**ELEVEN: - ANTI-CORRUPTION CLAUSE**

* 1. The Anti-Corruption Policy provides that all employees of the **PARTIES** and all third parties acting for or on behalf of the **PARTIES** shall have no interest or obligation that prevents them from performing their duties under this Agreement in an ethical and proper manner and that all activities shall be conducted in strict compliance with these ethical standards and applicable laws. The **PARTIES** consider integrity and transparent conduct to be essential and have a zero tolerance policy towards all corrupt practises.
  2. The employees of the **PARTIES** and any third parties acting on behalf of the **PARTIES** must not, under any circumstances, directly or indirectly, contact or authorise payments of any kind to any of the stakeholders involved in the **TRIAL** in order to gain an improper advantage or unduly influence decision-making. “Payments” include payments or promises to pay in kind and/or cash and any other offer of goods or services.
  3. **FIBHULP** shall keep a reliable record of all economic transactions resulting from this Agreement and shall provide the **SPONSOR**, upon written request, with the relevant documentation to enable verification of compliance with the obligations contained in this document.
  4. The **PARTIES** agree that the compensation offered (i) is fair compensation with respect to services rendered in accordance with their expertise; (ii) is not an inducement for or in exchange for past, present or future prescriptions, purchases, recommendations, use, obtaining preferred formulary status or dispensations of any product of the **SPONSOR** or is in any way contingent upon similar activity; and (iii) does not involve any change in the judgement of the **PRINCIPAL INVESTIGATOR** and the **HOSPITAL** with respect to the advice and care of each of the Subjects.

**TWELVE: - JURISDICTION**

* 1. To resolve any disagreement in the application or interpretation of the provisions of this Agreement, the **PARTIES**, expressly waiving any other jurisdiction to which they may be entitled, submit to the jurisdiction of the courts of the place where the **HOSPITAL** is located in the **COMMUNITY OF MADRID**.
  2. If a copy of this Agreement is in another language, the Spanish version shall prevail.

In witness whereof, the **PARTIES** sign this document on three counterparts, each equally binding

For the **SPONSOR**, For the **CRO** in the name and on behalf of the **SPONSOR**

**(only if acting for and on behalf of the Sponsor)**

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

## For FUNDACIÓN DE INVESTIGACIÓN BIOMÉDICA

## DEL HOSPITAL UNIVERSITARIO LA PAZ (FIBHULP)

Ms. Ana Coloma Zapatero

## For HOSPITAL UNIVERSITARIO LA PAZ

Dr. Rafael Pérez-Santamarina Feijoó

For the **PRINCIPAL INVESTIGATOR**

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

**ANNEX 2. LIST OF MEMBERS OF THE COLLABORATING TEAM**

|  |  |  |
| --- | --- | --- |
| **COLLABORATORS** | **SERVICE** | **National ID No. (DNI)** |
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**(\*) In order to receive financial remuneration for work done in the study, it is necessary to appear as a collaborator on this list and to be personnel contracted by HULP or FIBHULP.**