**AGREEMENT BETWEEN THE LA PAZ UNIVERSITY HOSPITAL FOUNDATION FOR BIOMEDICAL RESEARCH, …………..………….. (INVESTIGATOR) AND ………………………… (SPONSOR) FOR THE CONDUCT OF THE CLINICAL TRIAL "………………………………………………………………………..……...."**

**(Protocol Code, Foundation Code Number)**

Madrid, on..... ………2017

**BEING ASSEMBLED**

**(\*) Set according to specific situation of the parties**

On the one party, Mr/Ms/Mrs ........................…and Mr/Ms/Mrs …......................., with Tax Identity Number .................. and …………….. acting respectively on behalf and in representation of …………..................… (hereinafter the **SPONSOR**), with Tax Identity Code ……………… and registered address ………………………………………….. , duly authorised to execute this document by virtue of a deed of power of attorney duly registered with the Companies Register of …………………….., authorised by the Notary Public Mr/Ms/Mrs …………………………….., of the Notary Association of ……………………on ………………. (date), number …………. of his/her records, with VAT number ………………;

On the other party, Mr/Ms/Mrs ........................… (name of the legal representative of the**CRO**), with Tax Identity Code ........................…,acting as legal representative of ........................…(name of the **CRO**), and with registered address ........................… (full address of the **CRO**), ........................… (town/city and post code), with Tax Identity Code/VAT number........................…**,** (hereinafter **CRO**);

On the other party, Mr/Ms/Mrs ...............................… (name of the legal representative of the**CRO**), with Tax Identity Code........................…,acting as legal representative of ........................…(name of the **CRO**), and with registered address........................…(full address of the **CRO**), ........................…(town/city and post code), with Tax Identity Code/VAT number........................…**,**(hereinafter **CRO**), acting on behalf and in representation of the**SPONSOR**…………..................… (full name of the sponsoring entity–pharmaceutical laboratory, scientific association/entity, corporate person), (hereinafter **SPONSOR**), authorizsed to execute this document by virtue of a deed of power of attorney duly registered with the Companies Register of ........................…, authorised by the Notary Public Mr/Ms/Mrs........................…, of the Notary Association of ........................… on ........................…This is without prejudice of the Sponsor’s responsibility under RD 1090/2015;

On the other party, Mrs Ana Coloma Zapatero, with Tax Identity Number 29151547-J, acting on behalf and in representation of the **LA PAZ UNIVERSITY HOSPITAL FOUNDATION FOR BIOMEDICAL RESEARCH**, (hereinafter **FOUNDATION**), with registered address Paseo de la Castellana nº 261 inMadrid (28046), with VAT number G83727057, duly authorised to execute the present document by virtue of the power of attorney authorised in Madrid on 15 January 2010 by the Notary Public of Madrid, Mrs Carmen Boulet Alonso, with number 48 of her record;

On the other party, Mr Rafael Pérez-Santamarina Feijóo, acting on behalf and in representation of **LA PAZ UNIVERSITY HOSPITAL** (hereinafter **HOSPITAL**), by virtue of the agreements between the **FOUNDATION** and the **HOSPITAL**;

And on another party, Mr/Ms/Mrs .....................................*,* with Tax Identity Number ........................., acting on his/her own behalf and representation (hereinafter **PRINCIPAL INVESTIGATOR**), with domicile for notification purposes the .................................. Service of the **HOSPITAL** with address at Paseo de la Castellana nº 261 inMadrid (28046).

The Parties mutually acknowledge their capacity to enter into, and the binding force of, this Agreement (hereinafter **the Parties**),

**THEY STATE**

That **SPONSOR** expresses its interest in conducting the **CLINICAL TRIAL**described in the First Clause of the Agreement.

That the **CRO**, as the **SPONSOR**’S legal representative, is authorised to carry out payments on behalf of the **SPONSOR**, and that the **CRO**’s signature is not required for the amendment/change of all other aspects of the Agreement in which the **CRO** is not directly involved.

Thataccording to the provisions of the Agreement signed on **17 June 2009** between the **FOUNDATION** and the **SERMAS**, the **FOUNDATION**’s functions are, among others, the management of any **CLINICAL TRIAL**s to be conducted at **LA PAZ UNIVERSITY HOSPITAL**;

Also, that by virtue of the agreement between **LA PAZ UNIVERSITY HOSPITAL** and the **LA PAZ UNIVERSITY HOSPITAL FOUNDATION FOR BIOMEDICAL RESEARCH** for the development of **CLINICAL TRIAL**s, it is **FIBHULP**’s responsibility to enter into the required agreements and to effectively execute any **CLINICAL TRIAL**s to be conducted at **LA PAZ UNIVERSITY HOSPITAL**.

Now, therefore, the Parties express their desireto execute this Agreement according to the following:

**cLAUSES**

**ONE.- OBJECT**

* 1. The purpose of this Agreement is to conduct a **CLINICAL TRIAL** under the title “..........................................................................................................................” (hereinafter the **CLINICAL TRIAL**) with protocol code ..................... (hereinafter the **PROTOCOL**), to be conducted mainly within the **HOSPITAL**’spremises identified above, under the leadership and responsibility of Dr. ...............……… acting as **PRINCIPAL INVESTIGATOR** in said trial.
  2. The **CLINICAL TRIAL** shall be conducted according to the specifications detailed in the **PROTOCOL**, **version no.** ….................of ...........…. (date), i.e., the same as has been reported to the HOSPITAL.................................’s Clinical Research Ethics Committee(**CREC**) and with the Favourable Opinion of the **CREC** of reference (details of the **CREC** of reference) dated ..........................

**TWO.- START AND DURATION**

* 1. This Agreement is effective as of the date of execution and shall remain valid and in force until the **CLINICAL TRIAL** has been fully completed, without prejudice to the provisions of **CLAUSE TEN**. To such effects, the **CLINICAL TRIAL** shall only been considered as fully completed upon due execution by each Party of their respective obligations of this Agreement.
  2. The **CLINICAL TRIAL** shall not be initiated unless and until the mandatory permission of the Spanish Agency for Drugs and Health Products (‘Agencia Española de Medicamentos y Productos Sanitarios’) (hereinafter **AEMPS**) has been obtained in the terms provided by **Royal Decree 1090/2015**, and also until the authorizations of both the competent **CREC**, the **HOSPITAL** Management and any other, if any, required by law have been obtained. The effectiveness of this Agreement, with protocol version ……….... of date ………….. is subject to the authorisations above being obtained in due course. The Parties acknowledge that each of them is responsible for the execution of the **CLINICAL TRIAL** exactly as per the specifications contained in the **PROTOCOL.**
  3. The estimated duration of the **CLINICAL TRIAL** is …….... month(s), as specified in the **PROTOCOL**.

**THREE.- APPLICABLE LAWS**

* 1. The Parties agree to abide by and to respect at all times anyapplicable laws both upon the execution of this Agreement and at all times during its term. The applicable laws shall be in force with respect of the Agreement even if any of them is amended, which amendment shall be automatically applicable to the Agreement. The Parties also agree expressly to abide by the ethical principles and policies, and in particular:
     1. **Royal Decree 01/2015, of 24 July**, approving the revised text of the law on guarantees and the rational use of drugs under research and medicinal products;
     2. **Royal Decree 1090/2015, of 4 December**, governing the conduct of **CLINICAL TRIAL**s with medicinal products, the Clinical Research Ethics Committees (**CREC**s) and Spanish Clinical Trials Registry (hereinafter, **RD 1090/2015)**;
     3. **Law 14/2007, of 3 July,** on Biomedical Research;
     4. **Royal Decree** [**1591/2009, of 16 October**](http://www.aemps.gob.es/legislacion/espana/productosSanitarios/docs/Directiva_93-42-CEE/rcl_2009_2105.pdf)governing medical devices;
     5. [**Royal Decree 1616/2009, of 26 October**](http://www.aemps.gob.es/legislacion/espana/productosSanitarios/docs/Directiva_90-385-CEE/rcl_2009_2106.pdf), governing active implantable medical devices;
     6. **Decree 39/1994, of 28 April**, governing competencies in the field of **CLINICAL TRIAL**s with medicinal products of the Madrid Community;
     7. **Act 15/1999 of 13 December**, of Personal Data Protection, and **Act 41/2002, of 14 November**, governing the Basic Aspects of Patients’ Autonomy.
  2. **Act 15/1999, of 13 December**, of Personal Data Protection, and **Act 41/2002, of 14 November**, governing the Basic Aspects of Patients’ Autonomy.
  3. **Act 1/1998 of the Madrid Community, of 2 March**, of Foundations. Under its article 23, patrons may contract with the foundation either on their own behalf or on that of a third party, subject to obtaining prior authorisation from the Foundations Authority.
  4. The Parties agree also to comply with the rules on incompatibilities of the staff at the service of Public Administrations under **Act 53/1984, of 26 December**, and **Royal Decree 598/1985, of 30 April.**
  5. The Parties agree that the **CLINICAL TRIAL** shall be conducted under the Principles of the Helsinki Declaration and according to the International Conference of Harmonisation (ICH) Guideline for Good Clinical Practice; they shall comply also with the applicable deontological principles and the international and local anti-bribery and anti-corruption laws, in particular those adopted under the OECD Convention of 21 November 1997, the Foreign Corrupt Practices Act, and any other that may be applicable to the Parties of the Agreement.

**FOUR.- DUTIES OF THE PARTIES**

* 1. The contracting parties are bound to fully implement all clauses of this Agreement in its own terms, as well as those of the **PROTOCOL**. Each party shall comply with their respective obligations as per the legislation indicated in **CLAUSE THREE**. Each party’s obligations, duties and functions under **RD 1090/2015** are deemed binding content of the present Agreement, and consequently any violation thereof shall be considered as non-compliance of the Agreement.
  2. The Parties are committed also to:
     1. Collaborating in the **CLINICAL TRIAL** follow-up visits conducted by: (i) the **CREC**, (ii) the monitors and auditors acting on behalf of the SPONSOR, and (iii) the competent authorities when conducting inspection interventions. There shall be at least a one-week notice prior to these visits (unless the Parties agree otherwise). Technical and organisational steps will be taken during these follow-up, monitoring, and audit visits to ensure full compliance with any applicable personal data protection statute.
     2. The **PRINCIPAL INVESTIGATOR**, the **SPONSOR,** the monitors and the auditors shall comply with both the **HOSPITAL** and the **FOUNDATION** internal rules andshall be notified by them, and with the instructions from the monitoring **CREC** about the execution of the **CLINICAL TRIAL**.
     3. Not entering into any agreements or commitments related to the implementation of the **CLINICAL TRIAL** that might result in exceptions or contradictions with its content. Therefore, each Party states that, at this date, none of them is a party in any agreement or pact that might contradict its content. In particular, by virtue of this Clause, the Parties agree that they shall in no event compromise or pay any compensation whatsoever other than those provided for in the Agreement, without prejudice to the expenses incurred for the attendance to/celebration of the meetings required to organise and supervise the execution of the **STUDY** and the meetings designed to analyse or make the **STUDY**’s results public (presentations or scientific publications).
  3. In addition to the obligations stated in the applicable norms, the **SPONSOR** shall provide constant support to the **PRINCIPAL INVESTIGATOR** and shall provide him/her and the **CREC** with any new information related to the drug under research that may be relevant.
  4. It is the **FOUNDATION**’s responsibility to manage the financial aspect of this **CLINICAL TRIAL**. To such effect, the **FOUNDATION** shall receive any payments made by the **SPONSOR/CRO** and shall distribute them according to the provisions of **SCHEDULE 1**.
  5. The **PRINCIPAL INVESTIGATOR** agrees to safeguard the patient identification codes. The **SPONSOR** and the **PRINCIPAL INVESTIGATOR** agree to maintain the essential documents of the **CLINICAL TRIAL** during the period and according to the conditions set forth by the laws currently in force.
  6. It is the **PRINCIPAL INVESTIGATOR**’S responsibility also to select the members of the research team and the support staff for the **CLINICAL TRIAL**. These can be either natural or legal persons, or organisations of a different nature;in any case, with adequate material and human resources for its implementation. Attached as **SCHEDULE 2** is a comprehensive list of the current members of the research team at the date of execution of this Agreement. Any change in the list of members of the research team shall be reportedto the **CREC** as per the laws in force.

**FIVE.- FINANCIAL ASPECTS**

* 1. The cost of the **CLINICAL TRIAL** has been initially estimated at ……………EUROS (VAT not included) (€……………) (hereinafter the **CLINICAL TRIAL BUDGET**).
  2. This cost has been determined by applying a cost of**............... EUROS (.............. €)** per subject to be evaluated, as established by the Financial Schedule attached as **SCHEDULE 1** to this Agreement,which specifies all economic aspects. This amount does not cover or provide for any obligation or commitment for the **HOSPITAL**, the **FOUNDATION** and/or the **PRINCIPAL INVESTIGATOR** to recommend, endorse, prescribe, purchase, use, or agree to the use of any of the **SPONSOR**’s products.
  3. The sum to be paid by the **SPONSOR/CRO** during the implementation of the **CLINICAL TRIAL** shall be set according to the specifications of **SCHEDULE 1**, and shall be paid to the **FOUNDATION** as detailed below:
     1. **€2,000** to be paid by Administrative Management of the present contract according to thatestablished in the **STUDY BUDGET (SCHEDULE 1);**
     2. The remainder of the **CLINICAL TRIAL** budget shall be paid, at least each semester, as detailed in the table of cost per visit and recruited patient included as in**SCHEDULE 1,** until the total cost of the budget is fully paid. The **SPONSOR** and the **PRINCIPAL INVESTIGATOR** shall report to the **FOUNDATION**trimestrally.
     3. These instalments shall be considered as partial payments, subject to the settlement of the final total expenses of the**CLINICAL TRIAL.**
  4. The final contribution of the **SPONSOR** for the implementation of the **CLINICAL TRIAL** shall be determined by the activities actually performed while conducting the **CLINICAL TRIAL** (“**Finalcost”**). Final cost shall be estimated as follows:
     1. Within a maximum of three (3) months from completion of the **TRIAL** at the **HOSPITAL**, the **SPONSOR/CRO** and the **PRINCIPALINVESTIGATOR** shall report in writing to the **FOUNDATION** the total number of (1) recruited and evaluated subjects, (2) actual number of visits, (3) resulting incidents, as well as (4) any tests, analyses, examinations, consultations or hospital stays of special nature that might have occurred, whether or not included in the Financial Schedule (**SCHEDULE 1**);
     2. As soon as possible after the information of the previous point has been reported, the **FOUNDATION** shall calculate and notify the **SPONSOR/CRO**of the final payment of the **CLINICAL TRIAL**, as well as the outstanding sums, if any, which shall be paid within one (1) month without further requirement. This settlement of the final payment shall be regarded to all effects as due compliance by the **SPONSOR** of his financial obligations**.**
  5. All payments shall be made upon the presentation of an invoice; the corresponding VAT shall be included as per current legislation at the time of payment, inthe name of the **SPONSOR** or the **ENTITY/PERSON IN CHARGE OF FINANCIAL ASPECTS** (invoicing details).

|  |  |
| --- | --- |
| **ENTITY IN CHARGE OF FINANCIAL ASPECTS (Invoicing Details)** | |
| **NAME** |  |
| **VAT NUMBER/ TAX ID NUMBER** |  |
| **REGISTERED ADDRESS** |  |

* 1. All payments to the Foundation shall be by bank transfer (with bank fees being paid by the payer) to:

**Beneficiary:**La Paz University Hospital

Foundation for Biomedical Research

**CIF/VAT Number/ TAX ID Number**: G 83727057

**Banking Entity**: La Caixa,

C/ Hermanos García Noblejas 18 (Madrid)

**Account Number:**2100 4065 13 2200092143

**IBAN:** ES47 2100 4065 1322 0009 2143

**SWIFT:** CAIXE SBB

* 1. Payments by the **SPONSOR/CRO** to the **FOUNDATION** shall be in full satisfaction by the former of its obligations, it being the **FOUNDATION**’s responsibility to pay the sums, if any, due to the researchers and/or the subjects of the trial.

**SIX.-INSURANCE AND LIABILITY**

The **SPONSOR** has a civil liability policy that meets all requirements under **RD** 1090/2015.This policy**,** number………………………., has been issued by the insurance company …………………………………….., and covers any damages arising from the participation of subjects in the **CLINICAL TRIAL** under this Agreement, and is fully effective, providedthe **SPONSOR** is up to date with the payment of all premiums. The coverage of this policy expressly includes the **PRINCIPALINVESTIGATOR** and his/her collaborators, the **HOSPITAL**, and the **FOUNDATION** (copy of the policy or certificate is attached).

**SEVEN.-CONFIDENTIALITY ASSURANCE AND PROTECTION OF PERSONAL DATA.**

* 1. To comply with all requirements under current legislation, the Parties agree to take all necessary steps within their means to ensure the confidentiality of the information collected for the implementation of the **CLINICAL TRIAL,** as well as the personal data of participants in the trial. Exceptions are: (i) public domain information, (ii) information previously known by the **PRINCIPAL INVESTIGATOR** or the **FOUNDATION** at the moment of disclosure, or (iii) mandatory disclosure of information enforced by law.
  2. All parties, insofar as they access and deal with personal data from the **CLINICAL TRIAL** participants, must take all necessary steps to protect these data and to prevent access by unauthorised third parties. The Parties are bound to the utmost strict observance of the provisions of **Act 15/1999 of 13 December 1999**, on Personal Data Protection, the regulation implementing said **Act (RD 1720/2007),** and **Act 41/2002, of 14 November 2002**, which regulates patient autonomy. The statutes above are applicable also to all personal data contained in this Agreement.
  3. The **PRINCIPAL INVESTIGATOR** and the **FOUNDATION** shall treat the personal data of any person participating in the **CLINICAL TRIAL** in a manner that they cannot be traced to and/or be used to identify any particular individual by the **SPONSOR/CRO**. Access to the personal data of any person participating in the **CLINICAL TRIAL** shall be granted, subject to the terms governing Informed Consent, solely to the monitors and/or representatives designated by the **SPONSOR/CRO**, auditors, and competent authorities, and strictly within the exercise of their respective professional duties.

**EIGHT.-MEDICAL DEVICE UNDER RESEARCH**

**8.1**. The **SPONSOR** shall provide, free of cost, the medical devices as per **RD 1090/2015** guidelines.

**8.2**. The medical device under research shall be supplied through the **HOSPITAL** Pharmacy Service and shall be administered in a controlled manner, as specified by the **PROTOCOL** guidelines.

**8.3.** The medical device under research shall not be available to researchers unless a favourable **CREC** report and the mandatory authorization of the **AEMPS** have been obtained.

**nine.- AMENDMENTS, TERMINATION, AND SUSPENSION OF THE AGREEMENT**

**amendments TOTHE AGREEMENT**

**9.1.** Amendments to the terms of the Agreement shall be in writing, duly signed by the Parties, and as an addendum thereto. In any case, amendments shall conform with the provisions of section **26, RD 1090/2015**.

**GROUNDS FOR TERMINATION OR SUSPENSION OF THE AGREEMENT**

**9.2.** Either Party may terminate or suspend the **CLINICAL TRIAL** if any of the circumstances envisaged by **section 27 RD 1090/2015** occur, and also in any of the following cases:

**9.2.1.** Breach by either Party of their essential obligations under this Agreement;

**9.2.2.** Breach or defective compliance by either Party of any of their obligations not considered essential, where this is not remedied within fifteen (15) days after the other Party’s requirement to comply, expressed in writing;

**9.2.3**. Mutual agreement of the Parties, expressed in writing.

**EFFECTS OF TERMINATION OF THE AGREEMENT**

* 1. Upon termination or suspension of the **CLINICAL TRIAL,** the Party not being in breach of its contractual obligations shall be entitled to rescind the Agreement.
  2. The Parties shall ensure the participants’ safety upon termination of the **CLINICAL TRIAL** for whatever reason, guaranteeing also the continuity of the treatment administered and compliance with the current laws governing the subject matter.

**OBLIGATIONS AFTER TERMINATION OF THE AGREEMENT**

* 1. The contents of the **SEVEN** and **ELEVEN CLAUSES** shall still survive the termination or suspension of this agreement.

**TEN.-RESULTS AND PUBLICATIONS**

* 1. All data and results obtained within the **CLINICAL TRIAL** as well as any derivative works and intellectual/industrial property rights arising therefrom are the property of the **SPONSOR**, and the Parties are bound to the provisions of the laws governing these issues. This does not preclude the right of the **PRINCIPAL INVESTIGATOR** and of the **FOUNDATION** to use the results in their respective professional activities subject to the **SPONSOR**’s intellectual/industrial property rights and to the terms of the **PROTOCOL**.
  2. Under the provisions of **RD 1090/2015**, upon completion of the **CLINICAL TRIAL,** the **SPONSOR** shall publish the results, whether positive of negative, in scientific media accessible to the public.
  3. If the **SPONSOR** has not published the **CLINICAL TRIAL** final results, the **PRINCIPALINVESTIGATOR** can disseminate any data, discoveries, or inventions through journals or scientific publications, making reference at least to the **SPONSOR**. This shall be conducted according to following criteria: Trials on non-marketed products: during the first year, once authorised and marketed in any country; Trials conducted after product has been marketed, during the following year after the completion of the Trial, except when there is a commitment to publish the results in a medical journal submitted to peer review, or if there is an infringement to national law. The **SPONSOR** shall receive for his/her review, a copy of the text proposed for publication and/or dissemination at least forty-five (45) days before it is submitted to a scientific journal and at least twenty (20) days before it is summarised as an abstract. In any case, the **PRINCIPAL INVESTIGATOR** may only use these data subject to express prior written authorisation from the **SPONSOR**.

**ELEVEN.-CORRUPT PRACTICES**

* 1. The anti-corruption policy provides that the members of the staff of ……………………………. (**SPONSOR**) and of any third party acting for the account or on behalf of the SPONSOR shall not have any personal interest or commitment that may conflict with or limit their capacity to comply in an ethically adequate manner with their respective obligations under this Agreement. Said policy provides also that any activities performed in connection with this Agreement shall comply in all respects with the ethical standards and principles above and anyapplicable laws. \_\_\_\_\_\_\_\_\_\_\_(**SPONSOR**) considers that an ethical, transparent behaviour is of the essence and applies a zero-tolerance policy to any and all corrupt practices.
  2. The members of the staff of …………………………… (**SPONSOR**) and of any third party acting on behalf of the **SPONSOR** shall not initiate any contact or authorise directly or indirectly payments of any type to any of the parties participating in the **CLINICAL TRIAL** with the aim of securing an unfair advantage or to unduly influence any decision. The term ‘Payment’ shall include payments or commitments to pay any money or anything of value, or the offer of any other good or service.
  3. **The FOUNDATION** shall keep a register of any economic transaction arising from this Agreement and shall make available to ………………… (SPONSOR), upon the latter’s request in writing, any documents required to verify due compliance with the commitments acquired within this instrument.

**TWELVE.-JURISDICTION**

* 1. To resolve any dispute arising from the application or interpretation of the provisions of this Agreement, the parties submit to the jurisdiction of the courts in the city of the Madrid Community where the Hospital is located, expressly waiving their rights to any other jurisdiction to whichthey might be subject.
  2. Should a copy of this Agreement become available in any other language, the Spanish version shall prevail.

In witness whereof and as proof of consent, the Parties sign the present document in three (3) copies to a single effect.

For the **SPONSOR**, For the **CRO**

Mr/Ms/ Mrs ………………….. Mr/Ms/Mrs ………………………

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## For theFOUNDATION FOR BIOMEDICAL RESEARCH

## OF LA PAZ UNIVERSITY HOSPITAL

Fdo.: Doña Ana Coloma Zapatero

## For LA PAZ UNIVERSITY HOSPITAL

D. Rafael Pérez-Santamarina Feijóo

For the **PRINCIPAL INVESTIGATOR**

Mr/Ms/Mrs ………………………

**SCHEDULE 2: LIST OF INVESTIGATORS**