**CONTRACT FOR THE IMPLEMENTATION OF CLINICAL RESEARCH PROJECTS TITLED:** “     ”

PROTOCOL CODE:

FOUNDATION CODE No.:

In Madrid, on

**BY AND BETWEEN**

Of the one part, Mr./Ms. ………………………………………………… and ………………………………………………… Respectively acting in the name and on behalf of ………………………..………. (hereinafter, the SPONSOR), with registered office at ………………………..………., 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), as legal representative of (CRO name) and with registered office at (CRO’s full address) in (town and post code), (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) authorized for this purpose under powers of attorney issued in …………… on …………… (date), before the Notary, Mr./Ms. ……………

And Carmen Martínez de Pancorbo González, with Nat'l ID 30562827-J, acting on behalf of the **FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO 12 DE OCTUBRE** (FOUNDATION FOR BIOMEDICAL RESEARCH OF THE UNIVERSITY HOSPITAL 12 DE OCTUBRE) (hereinafter, **FOUNDATION**), with business address at Av. de Córdoba, s/n, Edifício: Centro de Actividades Ambulatorias (CAA), 6ª planta, Bloque D, Madrid, CP-28041, Spain, with fiscal ID No. G 83727016, authorised as per power of attorney issued in Madrid, Spain, dated 19 December 2011, and notarised by Mr. José Amérigo Cruz, of Madrid, Spain.

Dr. Carmen Martínez de Pancorbo González also acting on behalf of **HOSPITAL UNIVERSITARIO 12 DE OCTUBRE** (hereinafter, **HOSPITAL**).

And       , with Nat'l ID No.       acting on their own behalf (hereinafter, ***PRINCIPAL INVESTIGATOR***), with address at, for notification purposes, in the ***HOSPITAL***, located at Avda. de Córdoba, s/n – 28041, Madrid, Spain.

The Parties, acknowledging that they have the required capacity to bind themselves by the present Agreement (hereinafter, **the Parties**),

**THEY STATE**

Whereas the ***SPONSOR*** is interested in conducting the Clinical Research Project described in the first clause of the Agreement.

Whereas the***FOUNDATION*** andResearch and Studies of the Community of Madrid, signed, on the 20th of April 2020, a General Agreement for the Management and Coordination of Biomedical Research conducted in the ***HOSPITAL***, and is empowered to establish contracts, agreements or any other type of document that provides them support.

Based on the foregoing, the Parties decide to formalise this Agreement, according to the following:

**CLAUSES**

**ONE.- PURPOSE**

* 1. The purpose of this Agreement is to conduct the **Clinical Research Project** titled “     ” (hereinafter, **PROJECT**), protocol code “     ” (hereinafter, **PROTOCOL**), to be mainly conducted at the **HOSPITAL** facilities identified in the Recital of the present Agreement, under the management and responsibility of Dr.        who will act as its **PRINCIPAL** **INVESTIGATOR**. The **PROJECT** shall be conducted according to the content specified in the **PROTOCOL**, with the same version and date as those included in the CEIm's updated favorable opinion.

**TWO.- COMMENCEMENT AND TERM**

* 1. The **PROJECT** will not start under any circumstances until the **PROTOCOL** has been presented together with the favorable opinion of an EC accredited in Spain. This opinion will be unique, binding and recognized throughout the national territory and must comply with the requirements of each Autonomous Community where it has been requested, if they are required by law. The Parties undertake to ensure that the **PROJECT** is carried out in accordance with the provisions of the **PROTOCOL**.
  2. The estimated duration of the **PROJECT** is       months, starting from the date the EC approval has been granted.

**THREE.- APPLICABLE REGULATIONS**

* 1. The Parties agree, at all times, to respect and comply with current legislation applicable at the time of signature of this Agreement and during its term, as well as to expressly comply with the principles and ethical norms, particularly, the following:
     1. 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.
     2. Law 14/2007 of July 3 on biomedical research.
     3. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (hereafter “GDPR” and repealing Directive 95/46/EC (General Data Protection Regulation), Organic Law 3/2018 of 5 December on the Protection of Personal Data and guarantees of digital rights and Basic Law 41/2002, of 14 November regulating patient autonomy.

**FOUR.- PARTIES' OBLIGATIONS**

* 1. The Parties are bound to fully execute all services set forth in this Agreement, in accordance with that set forth in the Agreement and the **PROTOCOL.** Each party shall comply with its obligations, as per the regulations indicated in the Clause 3. For each party, the obligations, duties and functions set forth in the aforementioned legislation are considered, for all effects, binding content in the current Agreement, so that any violation shall be considered noncompliance of the current Agreement.
  2. The duties of the Parties are:
     1. To collaborate in the **PROJECT’S** follow-up visits conducted by (i) the EC, (ii) the monitors and auditors acting on behalf of the **SPONSOR**, and (iii) the competent authorities when conducting inspections. These visits shall be reported at least one week in advance unless otherwise agreed upon among the Parties. Technical and organisational measures will be taken during these follow-up, monitoring and audit visits to ensure maximum compliance with legislation on personal data protection.
     2. Comply with internal **HOSPITAL** regulations on the part of the **INVESTIGATOR**, **SPONSOR**, monitors and auditors, as well to comply with the indications on the conduct of the **PROJECT** established by the EC responsible for its supervision.
     3. No agreements or pacts shall be made related to the performance of the **PROJECT**, or any that might result in exceptions or contradictions with the content of this Agreement. Therefore, each Party states that, as of this agreement date, they are not part of any agreement or pact that might contradict its content. Specifically, by virtue of this Clause, the Parties accept that no agreement can be made nor can any compensation of any kind be given to the **PRINCIPAL INVESTIGATOR** or any of the collaborators other than those stated in this Agreement. Expenditures for meetings held to organise and supervise the implementation of the **PROJECT** are excluded from this prohibition, as well as those to analyse or disseminate the results of the **PROJECT** (scientific presentations or publications).
  3. In addition to the obligations stated in the applicable norms, the **SPONSOR** is bound to provide continuing support to the **PRINCIPAL INVESTIGATOR** and to provide him/her and the EC with any new relevant information related to the **PROJECT**.
  4. The **FOUNDATION** is bound to the financial management of the present **PROJECT**. The **FOUNDATION** shall receive the payments from the **SPONSOR**, and shall distribute them according to the provisions of Annex 1.
  5. The **PRINCIPAL INVESTIGATOR** agrees to safeguard the patients’ identification codes. The **SPONSOR** and **PRINCIPAL INVESTIGATOR** agree to maintain the essential documents of the **PROJECT** during the time period and according to the conditions set forth by current legislation.
  6. It is the **PRINCIPAL INVESTIGATOR’S** responsibility to select the members of the research team and the support staff for the **PROJECT**. They can either be individuals, trading entities or organisations of a different nature with adequate material and human resources for its implementation.

**FIVE.- FINANCIAL ASPECTS**

* 1. The cost of this **STUDY** has been initially budgeted at     EUROS (€   ) (hereinafter, **Study Budget**). This cost has been determined by applying a cost of     EUROS (€   ) per evaluable subject, as established by the Payment Schedule of the **STUDY** (Annex I), which specifies all its economic aspects.
  2. The amount to be paid by the **SPONSOR/CRO (choose as appropriate)** during the execution of the **STUDY** will be determined by application of Annex I and shall be paid to the **FOUNDATION**.
     1. The **SPONSOR/CRO (choose as appropriate)** and the **PRINCIPAL INVESTIGATOR** shall inform the **FOUNDATION**, at least every six months, of the number of patients included and visits carried out, as detailed in Annex I, on the basis of which the **FOUNDATION** shall issue the corresponding invoices until the full amount constituting the Budget has been paid.
     2. These payments are considered as payments on account, dependent on the settlement of the final amount of the **STUDY**.
  3. The final amount to be paid by the **SPONSOR/CRO (choose as appropriate)** for the execution of the **STUDY** shall be determined on the basis of the activity actually carried out for the execution of the **STUDY** (hereinafter, the **Final Amount**). The Final Amount shall be calculated as follows:
     1. Within a maximum of (3) three months from the completion of the **STUDY** at the **HOSPITAL** the **SPONSOR/CRO (choose as appropriate)** and the **PRINCIPAL INVESTIGATOR** shall communicate in writing to the **FOUNDATION** the total number of: (i) subjects recruited and evaluated, (ii) visits actually carried out, (iii) incidents that have occurred, as well as (iv) of any test, analysis, examination, consultation or hospital stay, of an extraordinary nature that has occurred, whether or not they are reflected in the Economic Report (Annex I).
  4. All payments must be made within 30 days against presentation of the invoice, to which VAT tax will be applied in accordance with the regulations applicable on the date of issue of the invoice and in the name of the **SPONSOR** or **ECONOMIC RESPONSIBLE** established.

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| **INVOICES WILL BE ISSUED TO** | |
| **NAME** |  |
| **CIF/VAT NUMBER/ ID** |  |
| **DOMICILE** | **ADDRESS** |
| **COUNTRY** |
| **INVOICES WILL BE SENT TO** | |
| **NAME** |  |
| **e-mail** |  |

The **SPONSOR/CRO** must communicate by e-mail to the **FOUNDATION** the total amount to be invoiced, detailing the breakdown of the visits and procedures that have been carried out. For this, must send an e-mail to [facturacion.hdoc@salud.madrid.org](mailto:facturacion.hdoc@salud.madrid.org)

Payment shall be made by bank transfer, at the payer's expense, to:

**Holder/Beneficiary:** Fundación para la Investigación Biomédica del Hospital Universitario 12 de Octubre

**Bank:** Caixabank, S.A.

**Address:** Paseo de la Castellana, 51 3º 28046-Madrid

**Account Nº/IBAN:** ES20 2100 5478 7102 0002 5607

**SWIFT CODE:** CAIXE SBBxxx

**VAT number /Tax ID CODE:** G-83727016

The payments made by the **SPONSOR/CRO (choose as appropriate)** shall be performed through the **FOUNDATION** in 30 days, which shall fully clear the debt of the former. It shall be the FOUNDATION’Sresponsibility to distribute the corresponding amounts to the Investigators or study subjects, as applicable.

Furthermore, upon signature of this contract, the **SPONSOR/CRO (choose as appropriate)** pay the amount of 2,500/2,000 Euros, in a one-time, non-refundable payment, as administrative and contractual management costs. This payment includes expenses for CEIm's evaluation, relevant amendments, administrative formalities for the management of the contract and addendum/s to the contract. / This payment includes administrative costs for the management of the contract and addendum/s to the contract.

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| **INVOICES WILL BE ISSUED TO** | |
| **NAME** |  |
| **CIF/VAT NUMBER/ ID** |  |
| **DOMICILE** | **ADDRESS** |
| **COUNTRY** |
| **INVOICES WILL BE SENT TO** | |
| **NAME** |  |
| **e-mail** |  |

**SIX.- 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 **PROJECT,** 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 **PROJECT**’ 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. If required, the **PARTIES** will enter into such agreements as are necessary to ensure compliance with the aforementioned legal obligations.

The **HOSPITAL**, the **PRINCIPAL INVESTIGATOR** and the **FOUNDATION** will suitably process the personal data of the subjects taking part in the **PROJECTS** 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 **PROJECT S’** 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.
  1. 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 in 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:

**FOUNDATION:** [dpo.fib12octubre@alaroavant.com](mailto:dpo.fib12octubre@alaroavant.com)

**HOSPITAL:** protecciondedatos.sanidad@madrid.org

**PRINCIPAL INVESTIGATOR:** [protecciondedatos.sanidad@madrid.org](mailto:protecciondedatos.sanidad@madrid.org)

**SPONSOR:**

**CRO:**

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.

**SEVEN.- AGREEMENT MODIFICATION, TERMINATION, OR SUSPENSION**

* 1. Any modification to the provisions of this Agreement shall be done in writing, signed by all Parties and attached as an addendum.
  2. The **PROJECT** can be terminated or suspended by any of the Parties under any of the following conditions:
     1. Noncompliance of essential obligations undertaken by any of the Parties.
     2. Noncompliance or defective compliance of the remaining obligations undertaken by any of the Parties, as long as such non-compliance is not rectified within fifteen (15) days after giving written notification by the other Party.
     3. By mutual written agreement among the Parties.
  3. Termination or suspension of the **PROJECT** shall allow the dissolution of the Agreement by the Party that has not breached the obligations of the Agreement.
  4. The Parties shall ensure the participants' safety at the end of the **PROJECT** and compliance with current applicable legislation.

**EIGHT.- RESULTS AND PUBLICATIONS**

* 1. All of the data and results from the **PROJECT**, as well as all its resulting work and industry rights are the **SPONSOR’S** property, and the Parties are bound to comply with relevant legislation on this matter. This circumstance will not prevent the **PRINCIPAL INVESTIGATOR** and the **FOUNDATION** from using the results in their professional activities.
  2. The **SPONSOR** agrees to disseminate the results of the **PROJECT** (once the **PROJECT** has been completed), whether negative or positive, in publicly accessible scientific media.
  3. If the **SPONSOR** has not submitted the final results of the **PROJECT** for publication, after having received the final report of the **PROJECT’S** results in the space of 24 months, the **PRINCIPAL INVESTIGATOR** can disseminate the data, discoveries or inventions through journals or scientific publications with professional purposes, with reference at least to the **SPONSOR**. In this case, The **SPONSOR** shall receive for its review a copy of the text proposed for publication and/or dissemination at least forty-five (45) days before it is sent to a scientific journal, and at least twenty (20) days before if it is an abstract. In any case, the **PRINCIPAL INVESTIGATOR** can only use these data after receiving express written authorisation from the **SPONSOR**.

**NINE.- 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 **PROJECTS** 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 **FOUNDATION** 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.

**TEN.- 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 and for a single purpose

**SPONSOR/CRO ON BEHALF OF THE SPONSOR (choose as appropriate),**

Mr./Ms.

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**THE PRINCIPAL INVESTIGATOR,**

Dr.

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**HOSPITAL/FOUNDATION**,

Dr. Carmen Martínez de Pancorbo González

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**WITH THE SIGNATURE OF THIS DOCUMENT, THE SIGNATURE PROCESS ANNEX I WILL BE FORMALIZED**