**CONTRACT FOR PERFORMANCE OF CLINICAL TRIALS \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (PROTOCOL CODE)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (FOUNDATION CODE)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (EUDRACT no.)

In Getafe, on [DATE]

# PARTIES

***[Complete as appropriate]***

Mr./Ms. [FULL NAME] and Mr./Ms. [FULL NAME], respectively acting in the name and on behalf of [FULL NAME OF SPONSOR] (hereinafter, the **SPONSOR**), with registered office at [ADDRESS OF SPONSOR REGISTERED OFFICE], who are empowered for this act by means of a power of attorney no. \_\_\_\_\_\_\_\_\_\_\_\_\_, duly registered at the Companies Registry of [CITY], executed before the Notary of [CITY], Mr/Ms. [FULL NAME OF NOTARY] and dated [DATE OF POWER OF ATTORNEY].

Mr./Ms. [FULL NAME OF CRO's REPRESENTATIVE], as legal representative of [NAME OF CRO] with registered office in [FULL ADDRESS OF CRO'S REGISTERED OFFICE], acting for and on behalf of the **SPONSOR.**

[FULL NAME, ADDRESS AND TAX ID OF SPONSOR — pharmaceutical company, scientific society, legal person) (hereinafter *SPONSOR*), who is authorised for these purposes by means of a power of attorney granted in [CITY] on [DATE] before the Notary Mr./Ms. [NOTARY]. There is no exemption from the **SPONSOR**'s liability under *Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos* (hereinafter, RD 1090/2015).

Mr. **MIGUEL ÁNGEL ANDRÉS MOLINERO**, as President of Patronato of the **FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO DE GETAFE** (hereinafter **FOUNDATION**), acting for and on behalf of the latter, which has its with registered address at Ctra. de Toledo, Km. 12,500, 28905, Getafe (Madrid), as duly empowered [DETAILS OF POWERS].

**Mr. MIGUEL ÁNGEL ANDRÉS MOLINERO**, for and on behalf of the **SERVICIO MADRILEÑO DE SALUD** (hereinafter **HOSPITAL**), with registered office at Ctra. de Toledo, Km. 12,500, C.P. 28905, Getafe (Madrid), by virtue of his appointment as authorised signatory by virtue of *Resolución 385/2020, de 11 de junio, de la Viceconsejera de Asistencia Sanitaria, de Delegación de Competencias en materia de contratación y gestión económico-presupuestaria*, published in the BOCAM, dated June 15, 2020.

Dr. [FULL NAME OF PRINCIPAL INVESTIGATOR]*,* [DEPARTMENT], [LOCATION] (hereinafter **PRINCIPAL INVESTIGATOR**).

The **PARTIES** mutually acknowledge that they have the necessary legal capacity to enter into this Contract (hereinafter, the **PARTIES**)

# WHEREAS

The ***SPONSOR*** is interested in carrying out the **CLINICAL TRIAL** described in the first clause of the Contract*.*

***[Modify as appropriate]***

The **CRO** may, as representative of the **SPONSOR**, make payments on its behalf.

In accordance with the provisions of its Articles, the **FOUNDATION** has the object of engaging in research, innovation and knowledge management, inspired by the principles of legality and ethics and by professional deontology, which are applicable to the management of the clinical trials carried out at the **HOSPITAL**. Moreover, in accordance with the provisions of the current *Convenio General de Colaboración*, dated April 19, 2020, between the MADRID REGIONAL GOVERNMENT, through the CONSEJERÍA DE SANIDAD and the SERVICIO MADRILEÑO DE SALUD, and FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO DE GETAFE, the **FOUNDATION**'s functions include entering into agreements for clinical trials conducted at the **HOSPITAL** and monitoring such trials.

Based on the foregoing recitals, the **PARTIES** hereby enter into this Contract in accordance with the following:

# CLAUSES

**ONE.- OBJECT**

*1.1.* The object of this Contract is to carry out the **TRIAL** entitled [FULL NAME OF TRIAL] (hereinafter **TRIAL**) with protocol code [PROTOCOL CODE] (hereinafter **PROTOCOL**), which will be carried out in the premises of the **HOSPITAL**, without prejudice to the possibility that, for organisational reasons, some techniques or visits may be carried out in third-party premises, identified in Schedule I of this contract, under the direction and responsibility of the **PRINCIPAL INVESTIGATOR**. The **TRIAL** will be carried out in accordance with the content specified in the **PROTOCOL** whose version number and date match those set out in the updated favourable opinion issued by the *Comité de Ética de la Investigación con Medicamentos* (Drug Research Ethics Committee — hereinafter **CEIm**).

# TWO. ENTRY INTO FORCE AND TERM

* 1. This Contract will come into force on the day it is signed and it will remain in force until conclusion of the **TRIAL**, without prejudice to the provisions of Clause Nine. For these purposes, the **TRIAL** will not be deemed to have concluded until the **PARTIES** have fulfilled all their obligations arising under this Contract.
  2. In no event may the **TRIAL** commence until the **CEIm** has issued a favourable report in this connection and the obligatory authorisation of the Spanish Agency of Medicines and Medical Devices (hereinafter **AEMPS**), in the terms provided in Royal Decree 1090/2015, and any other authorisation that may be necessary under the applicable legislation have been obtained. The entry into force of this contract is conditional upon the obtainment of the aforementioned authorisations.
  3. The planned term of the **TRIAL** is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ months, as established in the **PROTOCOL.**

# THREE.- APPLICABLE LEGISLATION

* 1. Legislation governing clinical trials:
     1. *Ley 10/2013, de 24 de julio, por la que se incorporan al ordenamiento jurídico español las Directivas 2010/84/UE del Parlamento Europeo y del Consejo, de 15 de diciembre de 2010, sobre farmacovigilancia, y 2011/62/UE del parlamento Europeo y del Consejo, de 8 de junio de 2011, sobre prevención de la entrada de medicamentos falsificados en la cadena de suministro legal, y se modifica la Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios*.
     2. *Real Decreto Legislativo 01/2015, de 24 de julio, por el que se aprueba el texto refundido de la Ley de garantías y uso racional de los medicamentos y productos sanitarios*.
     3. *Real Decreto 1090/2015 de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités Ética de la Investigación con Medicamentos y el Registro Español de Estudios Clínicos (hereinafter RD 1090/2015).*
     4. *Real Decreto 1015/2009, de 19 de junio, por el que se regula la disponibilidad de medicamentos en situaciones especiales*.
     5. *Decreto 39/1994, de 28 de abril, por el que se regulan las competencias de la Comunidad de Madrid en materia de ensayos clínicos con medicamentos*.
  2. 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, and repealing Directive 95/46/EC (General Data Protection Regulation) (hereinafter, **GDPR**) and *Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales* (hereinafter, **LOPDGDD**), as well as any other current legislation on personal data protection that may be applicable.
  3. *Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica*.
  4. *Ley 14/2007, de 3 de julio, de investigación biomédica and Real Decreto 1716/2011, de 18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica*, for biological samples of human origin, and the treatment of biological samples of human origin obtained directly or indirectly as a result of the TRIAL, particularly where they are to be used for biomedical research once the TRIAL has concluded.
  5. *Ley 1/1998, de 2 de marzo, de Fundaciones de la Comunidad de Madrid*. In accordance with article 23, sponsors may enter into contracts with the Foundation, on their own behalf or on behalf of a third party, subject to first obtaining authorisation from the Protectorado de Fundaciones
  6. *Ley 53/1984, de 26 de diciembre, de incompatibilidades del personal al servicio de las Administraciones Públicas y Real Decreto 598/1985, de 30 de abril, sobre incompatibilidades del personal al servicio de la Administración del Estado, de la Seguridad Social y de los Entes, Organismos y Empresas dependientes*.
  7. The guidelines for Good Clinical Practice (GCP) issued by the International Council for Harmonisation (ICH): GCP E6(R2).
  8. The basic principles of ethics established in internationally accepted recommendations, including the current version of the Declaration of Helsinki.
  9. Domestic and international rules of ethics and anticorruption legislation as set out in the OECD Convention adopted on 21 November 1997 and also in the Foreign Corrupt Practices Act (FCPA) that are applicable to any or all of the **PARTIES**.
  10. Nevertheless, the **PARTIES** undertake, at all times, to respect and comply with the legislation that is applicable on the date of signature of this Contract and during its term. If, during its performance, the relevant regulations are amended, they will be understood to apply automatically to the Contract except where any such regulation provides for a transitory regime with a different application.

# FOUR.- OBLIGATIONS OF THE PARTIES

* 1. The **PARTIES** are obliged to perform fully as provided for in this Contract, in accordance with its content and that of the **PROTOCOL**
  2. Additionally, the **PARTIES** have the following obligations:
     1. Cooperate with **TRIAL** monitoring visits performed by: (1) the **CEIm**, (2) monitors and auditors acting on instructions from the **SPONSOR**, and (3) the competent authorities, when they perform inspections. Apart from inspections, at least one week's advance notice will be given of such visits except where a different time frame has been agreed by the **PARTIES**. When such follow-up, monitoring and audit visits are paid, such technical or organisational measures will be taken as are required to ensure the utmost compliance with the legislation on personal data protection.
     2. The **PRINCIPAL INVESTIGATOR**, the **SPONSOR** and the monitors and auditors must conform to the internal procedural rules of the **HOSPITAL** and the **FOUNDATION**, which will be provided by those parties, and also the instructions on the performance of the **TRIAL** given by the **CEIm** responsible for monitoring it.
     3. Among themselves or with third parties unrelated to this document, the **PARTIES** may not enter into agreements or terms in connection with the performance of the **TRIAL** that might obstruct, qualify, except, contravene or prevent performance of the respective obligations or which involve other undertakings which are contrary to the applicable regulations. For these purposes, each of the **PARTIES** declares that, at the date of this Contract, it is not a party to any agreement or pact of the type referred to above. In particular, by virtue of this Clause, the **PARTIES** accept that they may not agree upon or pay consideration of any kind other than as provided for in the Contract. This prohibition does not apply to the costs of the meetings held to organise and supervise performance of the **TRIAL**, and the cost of analysing or publishing their results (presentations or scientific publications).
  3. In addition to those set out in the applicable legislation, the **SPONSOR**'s obligations are to provide ongoing support to the **PRINCIPAL INVESTIGATOR** and to provide the latter and the **CEIm** with any new information of relevance that arises about the investigational drug.
  4. The obligation of the **FOUNDATION** is to manage the finances of the **TRIAL**, to receive payments made for the account of the **SPONSOR/CRO** (delete as applicable) and distribute them in accordance with the provisions of Annex I.
  5. The **PRINCIPAL INVESTIGATOR** undertakes to safeguard the subjects' identification codes. In the scope of their respective responsibilities, the **SPONSOR**, the **PRINCIPAL INVESTIGATOR** and the **HOSPITAL** undertake to safeguard the essential documents for the TRIALS for the time and under the conditions provided for in current legislation.
  6. The **PRINCIPAL INVESTIGATOR** is also responsible for selecting the members of the research team and support staff for the **TRIAL**, which may be made up of natural persons and/or trading companies or any other kind of entity with the appropriate material and human resources for conducting it. The attached Schedule II sets out a list of the members of the research team at the time this contract is signed. Any change to the research team must be notified to the **CEIm** in accordance with current regulations.

# FIVE.- FINANCIAL ASPECTS

* 1. The cost of this **TRIAL** has been initially budgeted at [COST OF TRIAL] EURO, not including VAT, (€\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) (hereinafter, the **TRIAL Budget**), in accordance with the provisions of the **TRIAL** Financial Memorandum (Schedule I), which specifies all financial aspects of same. In any event, that amount does not include any obligation or inducement for the **HOSPITAL**, the **FOUNDATION**, and/or the **PRINCIPAL INVESTIGATOR** to recommend, prescribe, buy, use or arrange the use of any of the **SPONSOR**’s products.

Additionally, on signature of this contract, the **SPONSOR** will make a one-off, non-refundable payment in the amount of [AMOUNT OF ONE-OFF PAYMENT] euro to cover administration and contract management expenses. (*Adapt as appropriate).*

* 1. The amount to be paid by the **SPONSOR/CRO** (delete as applicable) during performance of the **TRIAL** will be calculated by applying Schedule I and must be paid to the **FOUNDATION** according to the schedule detailed below:
     1. The **TRIAL** budget will be paid at least once every six months as detailed in the table of amounts per visit and enrolled subject set out in Schedule I, until the total amount of the Budget has been paid. For these purposes, the **SPONSOR/CRO** (delete as applicable) and the **PRINCIPAL INVESTIGATOR** will report to the **FOUNDATION** every six months.
     2. These payments are considered to be payments on account, pending payment of the total final amount of the **TRIAL**.
  2. The total final amount to be paid by the **SPONSOR/CRO** (delete as applicable) for performing the **TRIAL** will be calculated based on the work actually carried out to conduct the **TRIAL** (hereinafter, the **Total Final Amount**). The Total Final Amount Total will be calculated as follows:
     1. Within at most three (3) months from completion of the **TRIAL** at the **HOSPITAL**, the **SPONSOR/CRO** (delete as appropriate) and the **PRINCIPAL INVESTIGATOR** will notify the **FOUNDATION** in writing of the total number of: (1) subjects enrolled and assessed, (2) visits actually made, (3) incidents that occurred, and (4) any test, analysis, exploration, appointment or hospital stay of an extraordinary nature that arose, whether or not they are reflected in the Financial Memorandum (Schedule I).
     2. As soon as possible after the information referred to in the preceding paragraph has been submitted, the **FOUNDATION** will calculate, issue and notify to the **SPONSOR/CRO** (delete as appropriate) the settlement of the final amount, in the form of a final invoice for the trial, and will claim any amounts outstanding, which must be paid within one (1) month, without the need for a subsequent request. Once the final payment has made, the **SPONSOR's financial obligations will be deemed to have been discharged.**
  3. All payments must be made against invoices, to which will be added Value Added Tax in accordance with the law that is applicable on the date it is issued, in the name of the **SPONSOR** or the designated PAYMENT ENTITY (i.e. a duly incorporated and legally bound subsidiary of the **SPONSOR** in Spain).

Invoices will be issued to the **SPONSOR** with the following particulars: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(NOTE: Invoices will be issued to the **SPONSOR** designated in the PARTIES section above unless it is expressly specified that the invoices are to be issued to the duly incorporated and legally bound subsidiary of the **SPONSOR** in Spain, whose details must be set out in this clause).

Invoices issued to the **SPONSOR** will be paid by the following payer, whose details are as follows: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(NOTE: If it is necessary to quote a purchase order number on invoices, it should be stated as well as the procedure by which the Foundation can request it).

Invoices must be sent for processing to the following address:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* 1. Payments to the **FOUNDATION** will be made by bank transfer (expenses for the account of the sender), to:

Account holder: Fundación para la Investigación Biomédica del Hospital Universitario de Getafe

Bank: Banco Santander

IBAN/SWIFT number: ES31 0049 1982 21 2810000070

VAT number: ESG83727024

* 1. Payments made by the **SPONSOR/CRO** (delete as applicable) to the **FOUNDATION** will fully relieve the former of liability, and the **FOUNDATION** will be liable for paying any amounts due to the investigators in the **TRIAL**.
  2. The **PARTIES** agree that, if the **HOSPITAL** lacks the necessary equipment to conduct the **TRIAL** properly, the **SPONSOR** will provide it to the **HOSPITAL**, free of charge, either directly or via a third party. The **SPONSOR** will also bear the cost and arrange for the supply, installation, maintenance, calibration and removal of the equipment, and any training required for the personnel to operate it. In no event will the **HOSPITAL**, the **FOUNDATION** or the **PRINCIPAL INVESTIGATOR** be liable for its maintenance or for any loss.

The equipment will consist of the following:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

The Equipment will remain the property of the **SPONSOR**, or of a third party, and will be labelled accordingly. The Equipment may only be used to conduct the **TRIAL** and, once it has concluded, it must be returned to the **SPONSOR** or a third party at no cost to the **HOSPITAL** or the **FOUNDATION.**

Upon receipt of a request for return, the **PRINCIPAL INVESTIGATOR** will place the Equipment at the disposal of the **SPONSOR** or the third party designated by the latter to collect it.

Upon conclusion of the **TRIAL**, the **SPONSOR** may assign the Equipment to the **HOSPITAL** or the **FOUNDATION** free of charge, to which end any necessary documents will be signed.

If the need for additional equipment arises during performance of the **TRIAL** subsequent to the signature of this contract, the **PARTIES** must sign an addendum setting out the equipment made available while conforming to the terms and conditions set out in the preceding paragraphs.

# SIX.- INSURANCE AND LIABILITY

The **SPONSOR** has arranged a third-party liability insurance policy which complies with the provisions of **RD 1090/2015** in all respects. The policy, no. [INSURANCE POLICY NUMBER], was arranged with [INSURANCE COMPANY] and is current since the **SPONSOR** is up-to-date with the premiums. The policy also explicitly covers the **PRINCIPAL INVESTIGATOR**, his/her co-workers, the **HOSPITAL** and the **FOUNDATION** (a copy of the policy or certificate of insurance is attached).

# SEVEN.- GUARANTEES OF CONFIDENTIALITY AND PERSONAL DATA PROTECTION.

* 1. CONFIDENTIALITY. The **PARTIES** undertake to use all means at their disposal to guarantee the confidentiality of the information provided for performing the **TRIAL** and obtained during its performance, and of the personal data of the subjects enrolled for same, in order to comply with all the requirements of the current regulations. This confidentiality undertaking does not apply to information that: (i) is in the public domain, (ii) was already known to the **PARTIES** at the time it was disclosed, or (iii) must be disclosed due to legal obligation.
  2. DATA PROTECTION. To the extent that they process **TRIAL** subject data, all the **PARTIES** must take the appropriate measures to protect such data and prevent access to it by unauthorised third parties. The **PARTIES** are bound to comply strictly with the provisions of the **GDPR** and the **LOPDGDD**. That legislation will also apply to the personal data set out in this contract. The **PARTIES** will enter into such agreements as may be necessary to ensure compliance with those legal obligations.

The **HOSPITAL**, the **PRINCIPAL INVESTIGATOR** and the **FOUNDATION** will process the personal data of the **TRIAL** subjects in such a way that they cannot be identified by the **SPONSOR** and **CRO** (as appropriate). Only the monitors and/or designated representatives of the **SPONSOR**, **CRO**, auditors and competent authorities will have access to **TRIAL** subjects personal data by which they may be identified insofar as this is permitted by the informed consent and is for the purpose of performing their professional duties.

The PARTIES to this contract undertake:

* + - To access the personal data solely where absolutely necessary for the implementation of the project.
* To process the data solely for the purpose of performing the contract
  + To immediately notify the other parties if they consider that any other party is in breach of the **GDPR**, the **LOPDGDD** or any other data protection legislation of the Union or the member states, so that the matter can be remedied without delay.
  + To bear the appropriate liability in the event that the data is used for a purpose other than the performance of this contract, or is disclosed or used in breach of the provisions of the current regulations, and take responsibility for any breaches that they commit on a personal basis.
  + Not allow access to personal data by any employee under their responsibility who does not need such access in order to perform their duties.
  + Not disclose, transfer, assign or otherwise disclose the personal data, whether verbally or in writing, by electronic means, on paper or by computer access, to any third party, not even for storage purposes, unless there is prior authorisation or instruction to do so.
  + Keep a record of all the categories of processing activities carried out in performing this contract, which must contain 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 authorised to process personal data.
  + Give mutual support in carrying out impact assessments relating to data protection, when appropriate.
  + Give mutual support in carrying out consultations with the Supervisory Authority, as appropriate.
  + Make available to the other party all the information needed to demonstrate compliance with its obligations, and for the performance of audits and inspections by the other party for the purpose of verifying proper performance of this contract.
  + Adopt 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 unauthorised 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 action 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 any of the parties must transfer or allow access to personal data which are the responsibility of the other to a third party under the applicable law of the European Union or of the Member state, it will give advance notice of this legal requirement to the other party unless this is prohibited on grounds of public interest.
* In the event that the processing involves gathering personal data, appropriate procedures will be established for data gathering, particularly in relation to properly identifying trial subjects, disclosure requirements and any consent obtained from the data subjects, while ensuring that such instructions conform to all the applicable requirements of data protection law and regulations.
  + 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 probability and severity of the risks to the rights and liberties of natural persons, the parties will take such technical and organisational measures as are appropriate to ensure a security level which is commensurate with the risk, including, as appropriate, the following:
     1. pseudonymisation and encryption of personal data;
     2. the capacity to ensure 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 regular process to verify, evaluate and assess the effectiveness of the technical and organisational measures to ensure processing is secure.
     4. a catalogue of security measures recognised 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 of the personal data that is sent, stored or otherwise processed, or unauthorised disclosure of, or access to, such data. The parties will allow, and contribute to, audits and inspections by the other party.

Furthermore, in the event of amendment of the current regulations on data protection, or other related regulations which are applicable to the processing which is the object of this contract, the parties undertake 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 must notify each other, without undue delay, and within at most 24 working hours in any event, of the breaches of the security in connection with the personal data held by them that they are aware of, together with all the relevant information in order to document and give notice of the incident in accordance with the provisions of article 33.3 of the **GDPR**.

In that event, each party, to the extent that it relates to them, must notify data security breaches to the Data Protection Authority and/or the data subjects in accordance with the provisions of the current regulations.

* 1. RIGHT TO INFORMATION. Each of the PARTIES is hereby informed that the professional contact details will be processed by the other party for the purpose of managing this contract, the legal grounds being the performance of this contract. The data will be stored while the contractual relationship persists and until any liabilities arising from it have lapsed. Furthermore, the PARTIES may 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, deletion, objection and portability with respect to their personal data, by writing to the PARTIES’ data protection officers:

Data Protection Officer (DPO) of FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO DE GETAFE:

Data Protection Officer (DPO) particulars:

Alaro Avant, S.L.

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

dpo.fibgetafe@alaroavant.com

(Insert contact details of the data protection officers of all the PARTIES, including the PRINCIPAL INVESTIGATOR).

The PARTIES are also entitled to complain to the Spanish Data Protection Agency.

If any 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 and subject to prior authorisation from the other PARTIES affected.

# EIGHT.- INVESTIGATIONAL DRUGS

* 1. The **SPONSOR** will supply the investigational drugs free of charge, including those for comparison and placebos, in the terms provided for in **RD 1090/2015**.
  2. The investigational drug will be supplied via the **HOSPITAL**’s Pharmacy Unit and dispensed on a controlled basis in accordance with the guidelines in the **PROTOCOL**.
  3. The investigational drug will not be made available to the **HOSPITAL** or the **PRINCIPAL INVESTIGATOR** until the **CEIm** has cleared the trial and it has obtained the mandatory authorisation from the **AEMPS**.

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

**AMENDMENT**

* 1. Any amendment to the provisions of the Contract must be made in writing and be signed by the **PARTIES** as an addendum to it. In any event, the amendment must conform to the provisions of article 26 of **RD 1090/2015**.

# CANCELLATION OR SUSPENSION

* 1. The **TRIAL** may be cancelled or suspended by any of the **PARTIES** in any of the situations provided for in article 27 of **RD 1090/2015**, and also in the following cases:
     1. In the event of breach by any of the PARTIES of the essential obligations undertaken by them.
     2. In the event of breach or deficient performance of the other obligations by any of the other PARTIES, unless such breach is remedied within fifteen (15) days from notice being given by the other Party requiring such performance.
     3. By mutual agreement of the **PARTIES**, set out in writing.

# TERMINATION OF THE CONTRACT

* 1. The discontinuation or suspension of performance of the **TRIAL** will entitle the Party not in breach of its contractual obligations to terminate the Contract.
  2. The **PARTIES** will guarantee the safety of the subject at the end of the **TRIAL**, as well as the continuity of the treatment; accordingly, they will continue to provide the treatment under the trial to the subjects in compliance with the provisions of Real Decreto 1015/2009, de 19 de junio, por el que se regula la disponibilidad de medicamentos en situaciones especiales. If the CEIm requests continuation of the treatment, the **PARTIES** must agree on the supply taking into account the feasibility of production and the data on the efficacy and safety of the investigational drug/trial treatment.

# TEN. RESULTS AND PUBLICATIONS

* 1. All of the data, the results of the **TRIAL**, and all of the work and industrial and intellectual property rights arising from it are the property of the **SPONSOR**, and the PARTIES are bound by the provisions of the applicable legislation.

This circumstance will not prevent the **PRINCIPAL INVESTIGATOR** or the **FOUNDATION** from using the results in their non-commercial professional research and teaching activities, while safeguarding the **SPONSOR**’s industrial and intellectual property rights and conforming to the provisions of the **PROTOCOL**.

* 1. In accordance with the provisions of **RD 1090/2015**, the **SPONSOR** undertakes to publish the results, whether positive or negative, once the **TRIAL** has concluded. Such publication will be in publicly accessible scientific media, preferably in scientific journals.
  2. If the final results of the **TRIAL** are not submitted for publication by the **SPONSOR**, the **PRINCIPAL INVESTIGATOR** may publish those data, discoveries or inventions for professional purposes in scientific journals and publications while mentioning at least the **SPONSOR**, in accordance with the following criteria: Trials with products not on the market: in the first year after their authorisation and marketing in any country; Trials performed after commercialisation: in the year following the end of the **TRIAL**, unless this compromises publication in a peer-reviewed medical journal or contravenes domestic law. The **SPONSOR** must be provided with a copy of the text proposed for publication and/or dissemination for review, in accordance with the provisions of the **PROTOCOL**; where the PROTOCOL is silent, then at least forty-five (45) days before the date of submission to the scientific journal or, in the case of a summary, at least, twenty (20) days before the event, unless provided otherwise. In any event, the **PRINCIPAL INVESTIGATOR** may only use the data with prior express written authorisation from the **SPONSOR**.
  3. The **PARTIES** agree that the consideration provided for: (i) is, in their experience, a fair consideration for the services provided; (ii) is not an incentive for, or in exchange for, past, present or future prescriptions, purchases, recommendations, use, obtainment of preferential formulaic status or waivers of any of the **SPONSOR**’s products, or, in any way, conditional on any other similar activity; and (iii) does not impair the judgment of the **PRINCIPAL INVESTIGATOR** or the **HOSPITAL** in relation to advising and caring for each one of the subjects.

# ELEVEN. ANTI-CORRUPTION CLAUSE

* 1. The anti-corruption policy provides that no employee of the **PARTIES** or of any third party acting for them or on their behalf may have any interest or commitment that clashes with their obligations under this Contract or prevents them from performing them. All work must be carried out in strict compliance with the applicable ethical standards and legislation. The **PARTIES** consider integrity and transparency to be essential, and have a policy of zero tolerance for corrupt practices.
  2. The employees of the **PARTIES** or of any third party acting on their behalf may not make payments of any kind, under any heading, either directly or indirectly, to any of the **PARTIES** participating in the **TRIAL** in order to obtain an improper advantage or exert undue influence on any decision. This refers to payments or promises of payment, in kind and/or in cash, and any other offer of goods or services.
  3. The **FOUNDATION** must keep accurate records of all financial transactions arising from this Contract and will, when requested to do so in writing, make the relevant documentation available to the **SPONSOR** for verification of compliance with the commitments set out in this document.

# TWELVE.- JURISDICTION

* 1. The **PARTIES** expressly waive any other venue to which they might be entitled and agree that any dispute about the application or interpretation of the provisions of this Contract be submitted to the jurisdiction of the courts and tribunals of the municipality in the Madrid Autonomous Region where **HOSPITAL** is located.
  2. Where a copy of this Contract is available in another language or tongue, the Spanish version will prevail.

In witness whereof, the PARTIES sign this document in [NUMBER OF COUNTERPARTS] counterparts, each an original.

|  |  |  |
| --- | --- | --- |
| For the **SPONSOR** |  | The **CRO** *(only if acting in the name and on behalf of the sponsor)* |
| Mr./Ms. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | Mr./Ms. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  |
| For **FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL** |  | **SERVICIO MADRILEÑO DE SALUD\*** |
| Mr. Miguel Ángel Andrés Molinero |  | Mr. Miguel Ángel Andrés Molinero |
| **\*as president of Patronato of the Foundation, (acuerdos de la Fundación elevados a escritura pública, con fecha 13 de junio de 2019).** |  | **\* Resolución 385/2020, de 11 de junio, de la Viceconsejera de Asistencia Sanitaria, de Delegación de Competencias en materia de contratación y gestión económico-presupuestaria, published in BOCAM on 15 June 2020** |
| PRINCIPAL INVESTIGATOR |  |  |
| Mr./Ms. Dr. |  |  |

# SCHEDULE I (Centre’s specific form)

**MINIMUM DISCLOSURES REQUIRED IN THE ECONOMIC REPORT**

|  |  |  |
| --- | --- | --- |
| **SPONSOR:PRINCIPAL INVESTIGATOR: DEPARTMENT/UNIT: PROTOCOL CODE** |  | |
|  | **PROJECTED NUMBER OF SUBJECTS:** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **DESCRIPTION** | **No. of VISITS** | **AMOUNT OF VISITS €** | **TOTAL €** | **EXTRAORDINARY DIRECT COSTS €** |
| Selection visits |  |  |  |  |
| Baseline visit |  |  |  |  |
| Treatment visits |  |  |  |  |
| Follow-up visits |  |  |  |  |
| Final visit |  |  |  |  |
| Screening failure/Other |  |  |  |  |
| **TOTAL PER FULL SUBJECT** |  |  |  |  |
| **TRIAL TOTAL** |  |  |  |  |
|  | | | | **TOTAL €** |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| **EXTRAORDINARY DIRECT COSTS** | **UNITS** | **AMOUNT** | **TOTAL €** |
| **A.** |  |  |  |
| **B.** |  |  |  |
| **C.** |  |  |  |

**Include indirect costs, patient reimbursements, medicine supplied and additional payments**

**SPONSOR/CRO, PRINCIPAL INVESTIGATOR, FOUNDATION, SERVICIO MADRILEÑO DE SALUD**

# SCHEDULE II

**LIST OF MEMBERS OF THE RESEARCH TEAM**

The research team is made up of the following members:

**Principal Investigator:**

Mr./Ms. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

National ID no. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mr./Ms. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

National ID no. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Mr./Ms. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

National ID no. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_