FUNDACIÓN DE INVESTIGACIÓN BIOMÉDICA
SaludMadrid Hospital Universitario de Getafe

Comunidad de Madrid

CONTRACT FOR PERFORMANCE OF OBERVATIONAL STUDY

CONTRACT No:
PROTOCOL CODE:

Getafe, on [DATE]

PARTIES

Mr./Ms. [FULL NAME], with National ID No. [ID NUMBER], acting on behalf of _____, with Tax ID no. _____ and domicile in _____, who is authorised by a power of attorney granted in [LOCATION] on [DATE], before the notary [FULL NAME OF NOTARY] with number [INSTRUMENT NUMBER], acting on behalf of _____, with Tax ID No. G-28291235, acting on behalf of _____, with Tax ID _____ (hereinafter, **SPONSOR**) by virtue of commitments signed on [DATE].

Mrs. PATRICIA RODRÍGUEZ LEGA, with National ID no. 07495515E, and Mr. **MIGUEL ÁNGEL ANDRÉS MOLINERO** with National ID no.13074648E as legal representative 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), and Tax ID no. G83727024.

Furthermore **Mr. MIGUEL ÁNGEL ANDRÉS MOLINERO**, with National ID no. 13074648E behalf and in representation of the Hospital Universitario de Getafe (hereinafter, '**HOSPITAL'**), with Tax ID no. Q2877037H and with registered address at Ctra. de Toledo, Km. 12,500, C.P. 28905, Getafe (Madrid) by virtue of the agreements between the **FOUNDATION** and the **HOSPITAL.**

Dr. _____, with National ID no. _____, and professional address at the _____ Department, Hospital Universitario de Getafe, Ctra. de Toledo, Km. 12,500, 28905 Getafe, Madrid, Tax ID no. Q-2877037H, in his/her capacity as Principal Investigator (hereinafter **INVESTIGATOR**) and representing the investigation team for the trial with Trial Code no. _____.

The parties mutually acknowledge that they have the necessary legal capacity to bind themselves by means of this Contract.

WHEREAS

1.- 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 **SERMAS**, and the **FOUNDATION**, the **FOUNDATION**'s functions include entering into agreements for clinical trials conducted at the **HOSPITAL** and monitoring such trials.

2.- In accordance with the aforementioned Agreement, it is the responsibility of the **SPONSOR** of the trial and of the Director of the **FOUNDATION** o the person in whom he/she delegates, to sign the contract setting out the economic aspects related to the observational trials conducted at Hospìtal Universitario de Getafe, which is attached to Servicio Madrileño de Salud.

3.- By virtue thereof, the **SPONSOR** expresses interest in entering into an agreement with the **FOUNDATION** to conduct the observational trial entitled: "_____" (hereinafter, the TRIAL) under the management of Researchers in the _____ Department at Hospital Universitario de Getafe, which has the necessary capabilities to undertake the Trial.

4.- The clinical and healthcare portion of the Trial will be performed in the facilities of Hospital Universitario de Getafe**,** in accordance with the protocol filed with the Oficina Técnica-Secretaría of the *Comité de Ética de la Investigación con Medicamentos* (Drug Research Ethics Committee — hereinafter **CEIm**) and with the legislation in force regarding observational post-authorisation trials studies linked to an authorisation to commercialise, subject to the ethical rules that govern them, including, but not limited to: *Real Decreto 957/2020, de 3 de noviembre, por el que se regulan los estudios observacionales con medicamentos de uso humano*, *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*; the parts of *Ley 29/2006, de 26 de Julio, de garantías y uso racional de los medicamentos y de productos sanitarios* not abolished by the aforementioned Law); *Real Decreto 577/2013, de 26 de Julio, por el que se regula la farmacovigilancia de medicamentos de uso humano*; *Real Decreto 1345/2007, de 11 de octubre, por el que se regula el procedimiento de autorización, registro y condiciones de dispensación de los medicamentos de uso humano fabricados industrialmente*; *Orden SAS/3470/2009, de 16 de diciembre, por la que se publican las directrices sobre estudios posautorización de tipo observacional para medicamentos de uso humano*; *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*; 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), and any other domestic legislation that is enacted on the subject of data protection. *Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales*. *Ley 53/1984, de 26 de diciembre, de Incompatibilidades del Personal al Servicio de las Administraciones Públicas* and *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*. In accordance with article 23 of *Ley 1/998, de 2 de marzo, de Fundaciones de la Comunidad de Madrid*, trustees may enter into agreements with the Foundation on their own behalf or on behalf of a third party subject to obtaining prior authorisation from *Protectorado de Fundaciones*.

5.- **SPONSOR** obtained clearance from the *Comité de Ensayos Clínicos con Medicamentos* of the [NAME OF HOSPITAL] on [DATE] and obtained clearance from the Management of Hospital Universitario de Getafe, attached to **SERMAS**, on [DATE].

CLAUSES

ONE.- **OBJECT OF THE CONTRACT**

1.1.- **SPONSOR** hereby engages the **FOUNDATION** to conduct the aforementioned trial, to be conducted basically in the facilities of Hospital Universitario de Getafe under the management of the **INVESTIGATOR** in accordance with the terms and conditions set out in the protocol.

1.2.- Duration

The research is expected to take **XX months** from the time the necessary authorisations are obtained and this contract is signed.

1.3.- The Trial will take place in strict compliance with its protocol and, in the event that **SPONSOR** amends this protocol, the latter undertakes to give notice of them and, if necessary, submit them for prior approval/vetting by the Hospital's *Comité de Ética de la Investigación con Medicamentos* (Drug Research Ethics Committee — **CEIm**).

1.4.- The Parties have the following obligations:
To cooperate with TRIAL monitoring visits performed by: (i) the **CEIm**, (2) monitors and auditors acting on instructions from **SPONSOR**, and (3) the competent authorities, when they perform 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. During follow-up, monitoring and audit visits, such technical or organisational measures will be taken as are required to ensure the utmost compliance with the legislation on personal data protection.
The **INVESTIGATOR**, the **SPONSOR** and the monitors and auditors must conform to the internal procedural rules of the **HOSPITAL** and the **FOUNDATION**, and also to the instructions on the performance of the TRIAL given by the CEIm responsible for monitoring it.
In any event, the Monitors will act in strict compliance with the Protocol and will only have access to the documentation and clinical history of the patients who are enrolled, provided that the Principal Investigator or a member of the research team is present to ensure that they have access strictly to the data necessary to verify proper conduct of the Trial, guaranteeing the confidentiality of the same during the performance of the Trial. If the monitor is replaced, the Sponsor will inform the Centre of the monitor appointed in their place.

1.5.- The **SPONSOR** acknowledges that they are aware of each and every one of the obligations established by law for conducting observational trials in Spain and undertakes to comply with them, and accepts all the obligations and responsibilities deriving or arising from breach of same.

1.6.- The parties undertake to collaborate and keep each other informed concerning the Trial in order to ensure its success. To this end, the **SPONSOR** is obliged to present the **FOUNDATION** with a report on a six-monthly basis outlining the number of visits made and the number of patients enrolled, as well as any incidents that arose, upon conclusion of the trial.

1.7.- Access to clinical documentation is prohibited to anyone outside the Hospital and not authorized by the Center.

Access is only allowed to personnel hired by the **HOSPITAL**, both access to clinical documentation and to HCIS. It is totally forbidden to transfer the access codes to the HCIS by the **HOSPITAL** professionals.

TWO.- **AMENDMENT OR CANCELLATION OF THE TRIAL**

2.1.- The Trial may be amended or cancelled at the request of any of the parties or by mutual agreement under the following circumstances:

- impossibility of enrolling the minimum number of patients to enable the Trial to reach a final assessment in a reasonable time scale.
- force majeure.
- if an interim analysis of the existing data makes this advisable.
- by a decision of the Spanish Agency for Medicines and Health Products (AEMPS) or the European Medicines Agency (EMA).

If the Trial is suspended, the sponsor will pay the **FOUNDATION** the amount due for the work performed, or, as appropriate, the **FOUNDATION** will reimburse the **SPONSOR** for any amount paid that has not been spent on work up to the time of suspension.

THREE.- **FINANCES**

3.1.- All details of the Trial finances must be set out in the attached trial budget (Schedule I).

3.2.- The estimated amount of the Trial (Schedule I) is _____ euro (€_____) per patient, plus the corresponding VAT, to be paid as provided in section 3.4 hereof. The trial budget will be split 78% for the RESEARCH TEAM and 22% for the FOUNDATION to cover indirect costs. That amount does not include any obligation or inducement for the **SERMAS** and/or the **INVESTIGATOR** to recommend, prescribe, buy, use or arrange the use of any of the **SPONSOR**'s products.

3.3. Furthermore the SPONSOR/CRO must be paid to the **FOUNDATION** in the payments set out below:

3.3.1 **Non – reimbursable one thousand EURO (€1.000**), VAT not included, in respect of **cost of registering and administrative processing**) before signature of Contract.

3.3.2 **Non – reimbursable seven hundred EURO (€700**), VAT not included, in respect of **cost of document management and storage upon Contract signature.**

3.3.3. In the event that the contract needed to be amended, the **FOUNDATION** will charge **three hundred and fifty EUROS (€350**), VAT not included, in respect of the cost related to amendment management.

3.4. The total contract amount (including contract-management expenses) will be € _____.

3.5.- The **SPONSOR** will pay the **FOUNDATION** all the amounts set out in the Financial Schedule by means of a bank transfer to the account that the **FOUNDATION** has at Banco Santander, C.C.C. 0049 1982 2128 1000 0070, (IBAN ES 31 0049 1982 2128 1000 0070/ SWIFT BSCHESMMXXX) within at most 60 days from presentation of the corresponding invoices issued correctly in the name of the **SPONSOR**.

3.6. All payments must be made on submission of the invoice, to which VAT will be added in accordance with the applicable law on the date it is issued on, in the name of the **SPONSOR**, or **FINANCIAL MANAGER** designated (that is to say, a legal subsidiary associated with the **SPONSOR** in Spain).

Invoices will be issued to the **SPONSOR:**
Name:
VAT number / Tax ID Number:
Domicile / Registered Address

Invoices issued to the **SPONSOR** will be paid by the following **PAYER**, whose details are:
Name:
VAT number / Tax ID Number:
Domicile / Registered Address

Invoices will be sent for processing to the following address:
Name:
Domicile / Registered Address:
Email address:

Comentado [CdS1]: Invoices will be issued to the **SPONSOR** appearing in the BY AND BETWEEN clause, unless it is expressly specified that invoices be issued to the legal subsidiary associated with the **SPONSO** in Spain, whose details must be included in this clause.
If the delegation letter sets that CRO is **just** allowed to pay, then we won´t be able to issue any invoice addressed to CRO It is NOT enough indicating that CRO can do payments. We suggest one of these terms contained in the delegation letter:
-To bill the local CRO
-The invoices must reference the local CRO
-Invoices named and addressed to the local CRO
-to issue invoices for this study in the name of the CRO

Comentado [CdS2]: Please, complete

Comentado [CdS3]: Please, complete

3.7.- The **STUDY financial budget** will be paid, at least, every six months in accordance with the Schedule I, until the total amount of the Budget has been paid. For that purpose, the **SPONSOR/CRO** and the **PRINCIPAL INVESTIGATOR** will report to the F**OUNDATION** every six months.

Comentado [CdS4]: choose as appropriate

3.8 These payments are considered to be payments on account, pending payment of the definitive total for the **CLINICAL STUDY.**

3.9.. The **INVESTIGATOR** is responsible for to propuse to the members of the research team and the support staff for the Trial; the team and staff must act independently and without any employment relationship with the **FOUNDATION** or the **SPONSOR** except with the foundation where any member of the team is a direct employee of the **FOUNDATION**.

FOUR.- **EXCLUSIVITY**

The **SPONSOR** declares that no agreements apart from this contract have been or will be entered into with the **INVESTIGATOR** and his/her co-workers that results in additional economic retribution or compensation in kind. This clause does not refer to the costs of meetings for organising the Trial or funds that the **SPONSOR** allocates in the future for disseminating the trial results in scientific meetings and publications.

FIVE.- **PROTECTION OF TRIAL SUBJECTS**

With regard to the data set out in this contract, each of the Parties is informed that the contact data of their representatives and employees will be processed by the other party for the purpose of performance, fulfilment and oversight of the research, the legal basis of the processing being the fulfilment of the contractual relationship; the data being kept for as long as the relationship subsists and thereafter until any liabilities deriving from it have expired. The Parties' data may be communicated to Public Administrations that are competent in the matter in order to comply with their respective legal obligations in accordance with the current legislation. The Parties may request access to personal data and may request that it be rectified or deleted, they may request portability or restrictions on processing, and may object to same, by giving notice to the address of the other Party at the beginning of this Contract.

Regarding the data of the subjects participating in the research, the **SPONSOR** is obliged to provide them, via the **INVESTIGATOR** with an informed consent form setting out the data that will be processed, the purpose of the processing, the third parties (public or private) that will have access to it, any international transfers, the retention periods, and the subjects' rights in the area of data protection.

In order to properly comply with the regulations, the **INVESTIGATOR** will carry out an appropriate process of dissociation of the personal data of the subjects participating in the study so that they cannot be identified or become identifiable by the **SPONSOR**, but the dissociation must be reversible for those situations in which it is necessary to re-identify any of the participating subjects. Only the monitors and/or designated representatives of the **SPONSOR**, auditors and competent authorities will have access to TRIAL subjects' personal data insofar as this is permitted by the informed consent and is for the purpose of performing their professional duties. In those cases, these purposes must be duly identified in the informed consent.

To the extent that the personal data of the Trial subjects is accessed and processed, the appropriate measures must be taken to protect such data and prevent access to it by unauthorised third parties. To this end, in conformity with the provisions of 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 and *Ley*

41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente, 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 the trial subjects, 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:

a) pseudonymisation and encryption of personal data;
b) permanent confidentiality, integrity, availability and resilience of the processing systems and services;
(c) the ability to restore availability and access to personal data quickly in the event of a physical or technical incident;
d) a regular process to verify, evaluate and assess the effectiveness of the technical and organisational measures to ensure processing is secure.

CONFIDENTIALITY AND PERSONAL DATA PROTECTION GUARANTEES.

CONFIDENTIALITY. The **PARTIES** undertake to use all available means to guarantee the confidentiality of the information provided for performance of the **STUDY** 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.

DATA PROTECTION. All the **PARTIES**, in as far as they process the personal data of the **STUDY´S** subjects, must take the necessary measures to protect them and prevent access to them by unauthorised 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 **STUDY** 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 **STUDY'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 authorisation 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 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 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 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 actions or the physical or natural environment.

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

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

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

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

7.3 SECURITY MEASURES AND SECURITY BREACHES. Taking into account the level of technology, the application costs, and the nature, scope, context and purposes of the processing, along with the variable risks

of probability and severity for the rights and freedoms of natural persons, the parties will take such technical and organisational measures as are appropriate to ensure a security level which is in line with the risk, which, as appropriate, includes, amongst others, the following:

a) personal data pseudonymisation and encoding;

b) the capacity to ensure permanent confidentiality, integrity, availability and resilience in the processing systems and services, along with rapid availability and access to the personal data en the event of a physical or technical incident.

c) a conventional verification, evaluation and assessment process of the effectiveness of the technical and organisational measures to ensure secure processing.

d) 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 to the personal data sent, stored or processed in another way, or the unauthorised 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.

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

Data protection officers' contact details for all the PARTIES:

HOSPITAL:

Contact: Comité DPD de la Consejería de Sanidad de la Comunidad de Madrid
Address: Plaza Carlos Trías Bertrán nº 7 (Edif. Sollube) Madrid 28020

FOUNDATION:

Contact: SEGURDADES S.L.
Address: C/ Castells, 6 (43800 – Valls, Tarragona)
mail: dpo@segurdades.com

SPONSOR :

Contact :_____
Address: _____

Comentado [CdS5]: Please, complete

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 authorisation from the other PARTIES affected.

SIX.- **DATA OWNERSHIP**

6.1.- The results, and the industrial property rights arising from the Trial that is the object of this contract will belong to the **SPONSOR**, without prejudice to the rights granted by law to the **INVESTIGATOR** and the **FOUNDATION**. This circumstance will not prevent the use of the results in their professional activities.

6.2.- Upon request by the **SPONSOR**, the **FOUNDATION** or the **INVESTIGATOR** must provide the evidence required to apply for and obtain patents in any country or to protect the **SPONSOR**'s interests. The latter must compensate them for the time and expenses invested in these matters.

6.3.- The **SPONSOR** undertakes to publish the results of this Trial, whether positive or negative, in media such as articles, conferences, etc., also mentioning the CEIm that approved it. Before or after such publication, the **SPONSOR** may make the results of the Trial public through the **SPONSOR**'S on-line Register of Clinical Trials or by any other means. Any personal data concerning the **INVESTIGATOR** or any member of the team involved in the Trial will be covered by the **SPONSOR**'s data protection policy.

6.4.- For the proper publication of the results of the trial, the **INVESTIGATOR** is obliged to establish a procedure for anonymising the data of the subjects participating in the Trial so as to ensure that it is impossible to identify any of them.

6.5.- Both the **INVESTIGATOR** and his/her co-workers as well as **SERMAS** and the **FOUNDATION** undertake to respect the confidential nature of all the documentation derived from the drug owned by the **SPONSOR**, in addition to that resulting from the conduct of the Trial.

This confidentiality obligation will remain in force during the performance of the Trial that is the object of this Contract, and will subsist after its conclusion unless express written authorisation is given by the **SPONSOR**, describing the scope and content in detail.

6.6.- 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:

- is in the public domain at the time it is disclosed by the **SPONSOR** to **SERMAS**, the **FOUNDATION** and/or the **INVESTIGATOR** or any person participating in the Trial.

- was already known by the **PRINCIPAL INVESTIGATOR**, by **SERMAS** and/or the **FOUNDATION** at the time of disclosure, provided that the source of the information is not directly or indirectly related to the **SPONSOR**.

- must be disclosed due to legal obligation.

- The processing of the personal data of subjects in the trial for purposes other than the investigation is strictly forbidden. The PI will establish the necessary security measures for the data, as well as its anonymisation in the publication of the results and is committed to maintaining the confidentiality of all information containing personal data of the participating subjects.

6.7.- The PI undertakes to maintain the security of the files generated relating to sensitive data of the participants in the trial in any type of format (paper, digital, electronic, etc.).

SEVEN.- **AUTHORISATION**

The SPONSOR and the PRINCIPAL INVESTIGATOR hereby confirm that the drug/medical device/diagnostic product evaluated in this observational trial will be used in an indication for which it is authorised in Spain, in the patient population for which it is authorised in Spain, under conditions of use authorised in Spain, and that its use in this trial conforms to standard clinical practice at the Hospital Universitario de Getafe.

EIGHT.- **ANTI-CORRUPTION CLAUSE**

8.1. 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.

8.2. 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 **STUDY** 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.

8.3. 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.

NINE.- **JURISDICTION**

9.1.- 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 Madrid.

9.2.- 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 in the place and on the date first written above.

XXXXXXXXXX

XXXXXXXXXXXXXXXXXXXXXX

Mr. XXXXXXXXXXXXXXXXX

PRINCIPAL INVESTIGATOR

Dr. XXXXXXXXXXXXXXXXXXXXXXXXX

FOUNDATION AND HOSPITAL

Mrs. Patricia Rodríguez Lega

Mr. Miguel Ángel Andrés Molinero

SCHEDULE II
RESEARCH TEAM