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| **AGREEMENT FOR THE CONDUCT OF THE (RETROSPECTIVE/PROSPECTIVE/AMBISPECTIVE) STUDY** entitled "\_\_\_\_\_\_\_\_\_\_\_". |

In Getafe on \_\_\_ \_\_\_\_\_\_\_ 2024

**BEING ASSEMBLED**

[*Option 1 Sponsor signs*] [On the one hand, Mr. \_\_\_\_\_\_\_ *(name of the representative of the SPONSOR),* with Tax ID No. \_\_\_\_\_\_\_\_\_\_ acting on behalf of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (hereinafter **SPONSOR**), with Tax ID No. \_\_\_\_\_\_\_\_ and registered address at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(address of the Sponsor),* being empowered for this act by virtue of power of attorney No. \_\_\_\_\_\_\_\_\_\_, duly registered in the Companies Registry of \_\_\_\_\_\_\_\_, granted before the Notary of the \_\_\_\_\_\_\_\_ Notary Association Mr. \_\_\_\_\_\_\_\_\_ on \_\_\_\_\_\_\_\_\_\_\_\_ (*date*).

*[Option 2 CRO signs on behalf of the SPONSOR]* On the one hand, Mr. \_\_\_\_\_\_\_\_\_\_\_\_ *(name of the representative of the CRO),* acting as legal representative of \_\_\_\_\_\_\_\_\_\_\_\_(*name of the CRO*) and with registered office at \_\_\_\_\_\_\_\_\_\_ (*address of the CRO),* (hereinafter **CRO),** acting on behalf of *\_\_\_\_\_\_\_\_\_\_\_\_\_(name, address and VAT number of the SPONSOR)*, (hereinafter **SPONSOR),** authorized for this purpose, according to the powers issued at \_\_\_\_\_\_\_\_\_\_\_\_, dated \_\_\_\_\_\_\_\_\_\_\_, before the Notary Mr. \_\_\_\_\_\_\_\_ . This is without prejudice of the SPONSOR’s liability under RD 1090/2015, of December 4, regulating clinical trials with medicinal products, the Committee on the Ethics of Medicinal Products Research and the Spanish Registry of Clinical Studies, and Royal Decree 957/2020, of November 3, regulating observational studies with medicinal products for human use [Please attach powers of attorney before a Notary by which the CRO may sign on behalf of the SPONSOR].

**Of another part:**

**Mrs. PATRICIA RODRÍGUEZ LEGA**, with National ID no. 07495515E, as Director of the FOUNDATION, and **Mrs. ZITA QUINTELA GONZÁLEZ** with with National ID no. 11815128M, in accordance with the powers of attorney granted, resolutions passed by public deed no. 1985, dated 6 November 2024, , acting for and on behalf of the **FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL UNIVERSITARIO DE GETAFE** (hereinafter **FOUNDATION**), with registered address at Ctra. de Toledo, Km. 12,500, 28905, Getafe (Madrid), Spain, and Tax ID no. G83727024.

Furthermore ,**Mrs. ZITA QUINTELA GONZÁLEZ** with with National ID no. 11815128M, in her capacity as manager of the University Hospital of Getafe (hereinafter, **HOSPITAL),** in use of the powers attributed in article 7 of Decree 246/2023, of October 4 (BOCM of October 5, 2023), and in accordance with the resolutions of the meeting of July 5, 2024 of the Board of Directors of the Madrid Health Service, acts in the name and representation of the **HOSPITAL,** with registered office at Ctra. de Toledo, Km. 12,500, 28905 Getafe, Madrid, Spain, and CIF nº Q2877037H, by virtue of and in accordance with the agreements between the **FOUNDATION** and the **HOSPITAL.**

**And on the other hand**, Mr/Ms. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(name of the Researcher)* with TAX ID No. \_\_\_\_\_\_\_\_\_\_\_\_\_\_, acting in his/her own name and right (hereinafter, **LEAD RESEARCHER**), with address for notification purposes at the Medical Service of \_\_\_\_\_\_\_\_\_\_\_\_\_ of the HOSPITAL.

The Parties acknowledge that they have the mutual capacity to execute this Agreement (hereinafter, the Parties),

**WHEREAS**

The SPONSOR is interested in carrying out the Observational Study described in the first clause of the Agreement.

The CRO, as representative of the SPONSOR, may make payments on behalf of the SPONSOR. [Adjust according to specific situation].

The FOUNDATION, in accordance with the provisions of its Statutes, is attributed, among other functions, the development of research, inspired by the principle of legality, ethical principles and professional deontology, of which the management of the research activity carried out at the HOSPITAL is a part.

On the other hand, the FOUNDATION, in accordance with the provisions of the current General Collaboration Agreement, dated XX of XX of 2020, signed between the MADRID AUTONOMOUS COMMUNITY, through the DEPARTMENT OF HEALTH and the MADRID HEALTH SERVICE and the FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA DEL HOSPITAL XXXXX, has, among other functions, the contracting and monitoring of the clinical studies carried out at the HOSPITAL.

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

**CLAUSES**

1. **FIRST. PURPOSE OF THE AGREEMENT**

1.1 The purpose of the present Agreement is to carry out the STUDY whose title is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (hereinafter, the STUDY), with Protocol code \_\_\_ (hereinafter, the PROTOCOL), which will be carried out on the premises of the HOSPITAL, under the direction and responsibility of its LEAD RESEARCHER. The STUDY will be carried out in accordance with the contents specified in the PROTOCOL, the version and date of which coincide with those stated in the updated favourable opinion of the Committee on the Ethics of Medicinal Products Research (hereinafter, CEIm).

1.2 The Parties agree to include in this HOSPITAL an estimated total of \_\_\_\_\_\_\_subjects and/or Study data (use whichever is applicable), assessable according to the criteria indicated in the PROTOCOL.

1.3 In the event that the SPONSOR submits one or more amendments to the STUDY Protocol, this shall be carried out in accordance with the provisions thereof, provided that they have the favourable opinion of the reference CEIm and the authorization of the Community of Madrid (if applicable).

**2. SECOND. LEGAL NATURE. APPLICABLE LAW.**

2.1 This Agreement shall be governed, by way of example but not limitation, mainly by the following rules:

2.1.1 Royal Decree 577/2013 of July 26 regulating pharmacovigilance of medicinal products for human use.

2.1.2 Royal Decree 957/2020, of November 3, regulating observational studies with medicinal products for human use.

2.1.3 Act 14/2007, of July 3, 2007, on biomedical research and Royal Decree 1716/2011, of November 18, 2011, which establishes the basic requirements for the authorization and operation of biobanks for biomedical research purposes and for the treatment of biological samples of human origin, and regulates the operation and organization of the National Register of Biobanks for biomedical research, for biological samples of human origin, and of the treatment of biological samples of human origin, which have been obtained as a consequence of the STUDY directly or indirectly and especially whenever they are going to be used for biomedical research purposes once the STUDY is completed.

2.1.4 Act 41/2002, of November 14, basic regulatory act on patient autonomy, and Regulation 2016/679, of April 27, on the protection of natural persons with regard to the processing of personal data and the free movement of such data and repealing Directive 95/46/EC (GDPR) and Organic Act 3/2018 of December 5, on the Protection of Personal Data and guarantee of digital rights, as well as the rest of the regulations in force on the protection of personal data that may be applicable.

2.1.5 Act 53/1984, of December 26, 1984, and Royal Decree 598/1985, of April 30, 1985 on incompatibilities of personnel in the service of the Public Administrations.

2.1.6 Principles contained in the Declaration of Helsinki, the ICH (International Conference of Harmonization Guideline) standards for Good Clinical Practice (GCP), as well as the deontological standards and national and international anti-corruption legislation contained in the OECD Convention adopted on November 21, 1997, also contained in the Foreign Corrupt Practices Act (FCPA) that may be applicable to any or all of the Parties to this agreement.

2.1.7 Order 730/2004, of June 30, 2004, of the Department of Health and Consumer Affairs, which establishes the requirements for the performance of observational post-authorization studies with medicinal products for human use in the Autonomous Community of Madrid*.*

Notwithstanding the foregoing, the Parties undertake at all times to respect and comply with the applicable legislation in force during the term of this Agreement. If, during its validity, such legislation is modified, it shall be understood to be automatically applied to this Agreement, unless the corresponding regulation or its modification establishes a transitory regime to that effect.

**3. THIRD. START DATE. DURATION OF THE STUDY.**

3.1 The Parties are aware and accept that the Study may only commence when a favourable opinion has been obtained from an accredited CEIm, and in the case of observational studies with prospective follow-up medicinal products in which the absence of commercial intent is not accredited, once the authorization of the Community of Madrid has also been obtained as indicated in clause 5.2.10.

3.2 The anticipated duration of the STUDY is \_\_\_ months, as established in the PROTOCOL.

**4. FOURTH. ENTRY INTO FORCE OF THE AGREEMENT**

The present Agreement shall enter into force on the date of its execution by the Parties and shall remain in force until the completion of the STUDY. For these purposes, the STUDY shall not be deemed to have been completed until the Parties have fulfilled all their obligations thereunder.

**5. FIFTH. OBLIGATIONS AND RESPONSIBILITIES OF THE PARTIES.**

5.1. The obligations of the Parties are those contained in RD 957/2020, as well as the complete provision of the services foreseen in the present Agreement and in the Study Protocol.

5.2. In addition, the Parties have the following obligations:

5.2.1. To collaborate in the follow-up visits of the STUDY carried out by: (1) CEIm, (2) monitors and auditors acting at the request of the SPONSOR, and (3) the competent authorities when carrying out inspection activities. These visits, except for inspection visits, shall be notified at least one week in advance, unless the Parties expressly agree on a different term. During such follow-up visits, monitoring and audits, technical or organizational measures shall be taken to ensure compliance with the regulations on personal data protection.

5.2.2. To comply with the internal rules of the HOSPITAL and of the FOUNDATION, as well as the indications on the development of the STUDY given by the CEIm responsible for its follow-up.

5.2.3. The Parties, in relation to the performance of the STUDY, may not enter into agreements or terms among themselves or with third parties outside of this Agreement that contravene or prevent the fulfillment of the respective obligations assumed by them or that imply the assumption of other different obligations that violate the applicable regulations or the terms of the Agreement itself. To this effect, both Parties expressly declare that as of the date of this Agreement, they are not party to any agreement or pact that violates or prevents the fulfillment of any of the terms and conditions set forth herein. In particular, the Parties expressly accept the obligation not to agree or pay considerations of any kind other than those provided for in the economic report of this Agreement. The expenses for meetings held for the purpose of organizing and supervising the conduct of the STUDY, as well as for analyzing or publicizing the results of the STUDY (presentations or scientific publications) are excluded from this prohibition.

5.2.4 The HOSPITAL and the SPONSOR, prior to accessing the personal data necessary for the performance of the STUDY, will mutually agree on who will be responsible for carrying out the data anonymization or pseudonymization process provided for in the PROTOCOL. In the event that the Parties agree that such process shall be carried out by a third party external to the present contractual relationship, they shall require the signature of a contract under the terms set forth in Article 28 of the GDPR, which shall be made available for consultation.

5.2.5. The SPONSOR has the obligation to provide continuous support to the RESEARCHER and to provide him/her and CEIm with any new relevant information arising from the STUDY, the medicinal product or the medicinal product being the subject of the research.

5.2.6. The FOUNDATION is responsible for the financial management of this STUDY, receiving the payments made on behalf of the SPONSOR/CRO (choose as appropriate) and distributing them in accordance with the provisions of Annex I.

5.2.7 It is the LEAD RESEARCHER'S obligation to provide the information to the subjects participating in the STUDY and to secure their consent, when required, in accordance with the PROTOCOL and with the provisions of the CEIm's report.

5.2.8. The LEAD RESEARCHER undertakes to keep custody of the identification codes of the subjects included in the STUDY. The SPONSOR, the LEAD RESEARCHER and the HOSPITAL, according to their responsibilities, undertake to keep the essential documents of the STUDY for the time and under the conditions established by the legislation in force.

5.2.9. The selection of the members of the research team and of the support personnel for the STUDY is also the LEAD RESEARCHER’s responsibility. A detailed list of the members of the research team at the time of signing this Agreement is attached as Annex II.

5.2.10. Observational studies with prospective follow-up medicinal products not accredited by the SPONSOR that it is a non-commercial research, in addition to having the favourable opinion of an CEIm, must have, prior to their initiation, the authorization of the competent body of the Community of Madrid, in accordance with the provisions of article 4.2 of RD 957/2020, of November 3.

5.2.11. Where, in accordance with the provisions of clause 7, or in application of current data protection regulations, or in view of the characteristics of the study, and without prejudice to the provisions of clause 5.2.4, it should be necessary for any of the parties to enter into a data processor contract with any third parties or with any of the other signatories to this Agreement, it shall inform the other parties as soon as possible of its date of execution, effects and validity, as well as of any other circumstance that may be relevant for the execution of both the agreement and the study.

**6. SIXTH. FINANCIAL REGIME.**

6.1. The STUDY has been initially budgeted at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Euros ( \_\_\_\_\_\_\_\_.-€), which will be distributed as reflected in the table of the financial report attached as Annex I. Said amount does not include in any case an obligation or liability of the HOSPITAL, the FOUNDATION and/or the LEAD RESEARCHER to recommend, prescribe, purchase, use or arrange the use of any of the SPONSOR's products.

6.2 The trial budget will be split 75% for the RESEARCH TEAM and 25% for the FOUNDATION to cover indirect costs. Furthermore , the SPONSOR/CRO must be paid to the **FOUNDATION** in the payments set out below

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

6.2.2. **Non – reimbursable five hundred EURO (€500**), VAT not included, in respect of **cost of document management and storage upon Contract signature.**

6.2.3. 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.

The total contract amount (including contract-management expenses) will be € \_\_\_\_\_\_\_\_\_\_\_.

6.3 The economic-financial management of the STUDY shall be carried out through the FOUNDATION, at least once every six months, until full payment is made. The SPONSOR shall pay the FOUNDATION the amounts corresponding to the costs incurred by the STUDY upon submission of the corresponding invoice. The payment shall include the PROTOCOL number and the SPONSOR of the PROTOCOL

6.4 The final amount to be paid by the SPONSOR/CRO (choose as appropriate) for the completion of the STUDY shall be determined by the activity actually carried out.

6.4.1 Within three (3) months of the completion of the STUDY at the HOSPITAL, the SPONSOR/CRO (choose as appropriate) and the LEAD RESEARCHER will notify in writing to the FOUNDATION the total number of: (1) subjects recruited and evaluated, (2) visits actually made and/or records finally obtained, and (3) incidents observed.

6.4.2 All payments shall be made within a maximum period of 30 days from submission of the invoice, to which VAT shall be applied in accordance with the regulations applicable on the date of issue of the invoice and in the name of the SPONSOR, with the following details:

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:**

*(NOTE: Where it is necessary to include a purchase order number on invoices, this must be indicated, as well as the procedure for requesting it from the Foundation).*

Invoicing proposals will be sent for processing to the following address: XXXXXXXXXXXXXXXXXXXXXXXXXX

6.4.3 The financial expenses generated by the completion of the STUDY shall be borne by the SPONSOR.

6.4.4 Payments shall be made by bank transfer, upon submission of the corresponding invoices to the following address:

**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**

6.5. The PARTIES agree that, where the HOSPITAL lacks the necessary equipment to adequately carry out the STUDY, the SPONSOR will provide it to the HOSPITAL free of charge by assigning its use, either directly or through a third party. Likewise, the SPONSOR will assume the cost and will be responsible for the supply, installation, maintenance, calibration and removal of the equipment, and for the training of the personnel for its use, if necessary. Under no circumstances will the HOSPITAL, the FOUNDATION, or the LEAD RESEARCHER be responsible for its maintenance, nor for its possible loss.

The team shall consist of the following components:

The Equipment will always be the property of the SPONSOR or a third party and will bear the corresponding identification to that effect. The Equipment shall only be used to carry out the STUDY, and at the end of the STUDY it shall be returned to the SPONSOR or to a third party at no cost to the HOSPITAL or the FOUNDATION.

Upon receipt of a request for return, the LEAD RESEARCHER shall make the Equipment available to the SPONSOR or the third party designated by the SPONSOR for collection.

At the end of the STUDY, the SPONSOR may transfer the Equipment to the HOSPITAL or to the FOUNDATION free of charge, for which purpose the necessary documents will be formalized.

Where additional equipment needs are detected during the performance of the STUDY and after the signature of this Agreement, the PARTIES shall sign an addendum that includes the equipment made available respecting the conditions and terms indicated in the previous paragraphs.

**7. SEVENTH. CONFIDENTIALITY. DATA PROTECTION**

7.1. CONFIDENTIALITY. The Parties undertake to use all the means available to guarantee the confidentiality of the information provided for the conduct of the STUDY and obtained during its performance, as well as the personal data of the subjects recruited for the STUDY, in order to comply with all the requirements established in the regulations in force. Exceptions to this confidentiality obligation are the information which: (i) is in the public domain, (ii) was previously known by the Parties at the time of disclosure, or (iii) is required to be disclosed by law.

7.2. DATA PROTECTION. All Parties, to the extent that they process personal data of the subjects of the STUDY, shall take appropriate measures to protect them and prevent access by unauthorized third parties. The Parties are bound to the strictest observance of the provisions of the GDPR and the Organic Act 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights. Likewise, said legislation shall be applicable to the personal data contained in this Agreement. If necessary, the Parties shall formalize the required agreements to ensure compliance with such legal obligations.

The HOSPITAL, the LEAD RESEARCHER and the FOUNDATION will appropriately treat the personal data of the subjects participating in the STUDY in such a way that they cannot be identified by the SPONSOR/CRO (as appropriate). Only monitors and/or representatives designated by the SPONSOR/CRO (as appropriate), auditors and competent authorities shall have access to personal data of the STUDY subjects, in which they are identified, to the extent permitted by informed consent and in the exercise of their professional duties.

The PARTIES to this Agreement mutually bind themselves:

* To access to personal data only when it is essential for the proper performance of the STUDY.
* To process the data for the sole purpose of fulfilling the purpose of the contract.
* If any of the parties considers that another party is in breach of the GDPR, Organic Act 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights, or any other data protection provisions of the Union or member states, it shall immediately inform the others, in order to proceed to their prompt remedy.
* To assume the corresponding responsibility in the event that they use the data for purposes other than the fulfillment of the object of this Agreement, communicate them or use them in breach of the stipulations of the regulations in force, being liable for the breaches in which they may have personally incurred.
* Not to allow access to personal data to any employee under its responsibility who does not have a need to know them for the performance of this STUDY or any of the obligations contained in this Agreement.
* Not to disclose, transfer, assign or otherwise communicate any personal data, whether verbally or in writing, by electronic means, on paper or by computer access, even for storage purposes, to any third party, unless there is prior authorization or instruction to do so.
* They shall keep a record of all categories of processing activities carried out in compliance with this Agreement, containing the information required by Article 30.2 of the GDPR and 31 of Organic Act 3/2018, of December 5, on the Protection of Personal Data and Guarantee of Digital Rights.
* To ensure the necessary training in personal data protection of the staff authorized to process personal data.
* To support each other in conducting data protection impact assessments, where appropriate.
* To support each other in carrying out prior consultations with the Control Authority, when appropriate.
* To make available to the other party all the information necessary to prove compliance with its obligations, as well as for the performance of audits or inspections carried out by the other party in order to verify the proper performance of this Agreement.
* To adopt and implement the security measures stipulated in this Agreement, in accordance with the provisions of Article 32 of the GDPR, and the National Security Scheme applicable where appropriate, to ensure the security of personal data and to prevent its alteration, loss, unauthorized access or processing, taking into account the state of technology, the nature of the data stored and the risks to which they are exposed, whether from human action or the physical or natural environment.
* To designate a data protection delegate, when legally required, and to communicate his/her identity and contact details to the other party, as well as to comply with all the provisions of Articles 37, 38 and 39 of the GDPR, and 35 to 37 of the Organic Act 3/2018 of December 5, on the Protection of Personal Data and guarantee of digital rights.
* In the event that either party is required by applicable Union or Member State law to transfer or allow access to personal data under the responsibility of the other party to a third party, it shall inform the other party of this legal requirement in advance, unless prohibited for reasons of public interest.
* In the event that the processing includes the collection of personal data, the procedures corresponding to the collection of the data will be established, especially with regard to the reliable identification of users, the duty of information and, where appropriate, obtaining the consent of those affected, ensuring that these instructions comply with all legal and regulatory requirements required by current legislation on data protection.
* To supervise the processing and compliance with data protection regulations by the other party.

7.3 SECURITY MEASURES AND SECURITY BREACHES. Taking into account the state of the art, the costs of implementation, and the nature, scope, context and purposes of the processing, as well as risks of varying likelihood and severity to the rights and freedoms of natural persons, the parties shall implement appropriate technical and organizational measures to ensure a level of security appropriate to the risk, including, where appropriate, among others:

a) pseudonymization and encryption of personal data;

b) the ability to ensure the continued confidentiality, integrity, availability and resilience of the processing systems and services, as well as the availability of and access to personal data in a timely manner in the event of a physical or technical incident.

c) a process of regular verification, evaluation and assessment of the effectiveness of technical and organizational measures to ensure the security of the processing.

d) a list of security measures recognized in information security regulations or standards.

In assessing the adequacy of the level of security, the Parties shall take into account the risks posed by the data processing, in particular as a result of accidental or unlawful destruction, loss or alteration of personal data transmitted, stored or otherwise processed, or unauthorized disclosure of or access to such data.

The Parties shall allow and contribute to audits, including inspections, of all other parties.

Also, in case of modification of the current regulations on data protection or other related regulations applicable to the processing object of the present Agreement, the Parties guarantee the implementation and maintenance of any other security measures that may be required, without this implying a modification of the terms of the present contract.

In the event of a breach of security of personal data in the information systems used by the Parties for the development of the STUDY, they shall notify each other, without undue delay, and in any case before the maximum period of 24 working hours, of such security incidents, together with all relevant information for the documentation and communication of the incident in accordance with the provisions of Article 33.3 of the GDPR.

In such case, each party, to the extent that it is entitled to do so under the data protection regulations, shall notify the security breaches to the Spanish Data Protection Agency and/or to the data subjects in accordance with the provisions of the regulations in force.

7.4 RIGHT OF INFORMATION. Each of the Parties is informed that the contact details of a professional nature will be processed by the other party for the purpose of managing the present Agreement, the basis of the processing being the execution thereof. The details will be kept for the duration of the contractual relationship and until the expiration of any liability arising therefrom. In addition, the Parties will not transfer the data to third parties, except where they are legally obliged. The Parties may at any time exercise their right of access, rectification, limitation, suppression, opposition and portability, with respect to their personal data, by contacting the corresponding data protection delegates and the LEAD RESEARCHER when applicable.

Contact details of the data protection officers (DPD) of the parties:

(Please include contact details of the Parties' data protection officers)

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

If any of the Parties would like to make a transfer of Personal Data of the signatories outside the European Economic Area (EEA) or Switzerland, it will be made only when authorised by the applicable legislation in the EEA, on the occasion of the performance of the STUDY and based on the legal mechanisms of transfer and prior authorization of the rest of the Parties concerned.

**8. EIGHTH. MODIFICATION OF THE AGREEMENT**

Any modification to the provisions of this Agreement shall be made in writing and shall be signed by the Parties as an addendum to this Agreement. In any case, the modification shall comply with the provisions of Royal Decree 957/2020.

**9. NINTH. SUSPENSION OF THE AGREEMENT**

9.1. The Agreement may be suspended in either of the following cases:

9.1.1. By mutual agreement of the Parties, expressed in writing.

9.1.2. For breach of the applicable legislation or of any of the obligations assumed by the Parties, where such breach cannot be remedied within three months.

 In such cases, the contract shall resume its effects at the end of such suspension.

**10. TENTH. TERMINATION OF THE AGREEMENT**

10.1. The Agreement may be terminated in either of the following cases:

10.1.1. By mutual agreement of the Parties, expressed in writing.

10.1.2. For breach of the applicable legislation, provided that it is not a cause for suspension.

10.1.3 If the conditions of the authorization of the STUDY are altered.

10.1.4. If the ethical principles contained in Royal Decree 577/2013 of 26 July are not complied with.

10.1.5. For breach of the obligations assumed by the Parties, provided that this is not a cause for suspension and that such breach is not remedied within fifteen (15) days from the written request of either of the Parties.

**11. ELEVENTH. RESULTS. PUBLICATIONS**

11.1. All information, data, results and methods obtained or developed during the STUDY by the researchers or any person involved in the STUDY shall be the exclusive property of the SPONSOR.

11.2. The researcher may present the data related to the study in any scientific media, prior express written authorization from the SPONSOR. The SPONSOR shall receive a copy of the text proposed by the researcher for publication and/or dissemination for review, in accordance with the PROTOCOL. For this purpose, the material shall be sent to the SPONSOR at least forty-five (45) days prior to the date of submission to the scientific journal and at least twenty (20) days prior to the date of submission to the scientific journal where the material is an abstract.

11.3. Patient confidentiality shall be guaranteed.

11.4. The SPONSOR undertakes to publish, once the STUDY has been completed, the results obtained, regardless of them being positive or negative. This publication shall be made in scientific media, preferably open access, mainly in scientific journals.

11.5 If the final results of the STUDY have not been submitted for publication by the SPONSOR within twenty-four (24) months after having received the final report of the STUDY results, the RESEARCHER may disclose said data for professional purposes, and in scientific journals and publications, mentioning at least the SPONSOR. In this case, the SPONSOR shall receive for his/her information a copy of the text proposed for publication and/or dissemination, at least forty-five (45) days before the date of submission to the scientific journal, and at least twenty (20) days before in the case of an abstract.

11.6. Mention should be made of the HOSPITAL as the facilities where the STUDY was carried out. However, neither the SPONSOR nor the researcher may make use of the corporate image of the HOSPITAL, and shall mention only the degree of participation of said HOSPITAL in the STUDY.

**12. TWELFTH**. **ANTI-CORRUPTION CLAUSE**

12.1. Anti-corruption policies establish that none of the employees of the Parties and of any third party acting for them, or on their behalf, shall have any interest or commitment that conflicts with or prevents them from performing their obligations under this Agreement in an ethical and proper manner. The Parties consider it essential to behave with integrity and transparency, as well as the application of a zero-tolerance policy for any corrupt practices.

12.2. The employees of the Parties and any third party acting on their behalf shall not, under any circumstances, directly or indirectly, make contacts or authorize payments of any kind to any of the parties participating in the STUDY for the purpose of obtaining an advantage or unduly influencing any decision-making. The concept of "payments" includes any payments or promises to pay, in kind and/or in cash, as well as any other offer of goods or services.

12.3. The FOUNDATION shall reliably record all monetary transactions derived from this Agreement and shall make available to the SPONSOR, when requested in writing, the corresponding documentation that allows verification of compliance with the commitments contained in this document.

**13. THIRTEEN**. **JURISDICTION**

13.1. To resolve any discrepancy that may arise in the application or interpretation of the provisions of this Agreement, the parties submit to the jurisdiction of the Courts and Tribunals of the city of Madrid, expressly waiving any other jurisdiction that may correspond to them.

13.2. Where a copy of this Agreement is available in another language, the Spanish version shall prevail.

And for the record, and in proof of conformity, the Parties execute this document in three/four (adapt as appropriate) copies, and to a single effect.

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| SD.: Mr./Ms. \_\_\_\_\_\_\_\_\_\_  SPONSOR | SD.: Dr. D. \_\_\_\_\_\_\_\_\_\_  l  Lead Researcher\_. |
| SD.: Ms. Patricia Rodríguez Lega  Director Biomedical Research Foundation  Hospital | SD.: Ms. Zita Quintela González  Managing Director  Hospital |

**ANNEX I**

**FINANCIAL SCHEDULE**

**ANNEX II**

**LIST OF MEMBERS OF THE RESEARCH TEAM**

The research team is composed of the following members:

Lead Researcher:

Dr. XXXXXXXX

ID No. XXXXXX

XXXXXXX Service

Collaborating Researchers:

Dr. XXXXXXXX

ID No. XXXXX

XXXXXXX Service

Dr. XXXXXXXX

ID No. XXXXXXX

XXXXXXX Service

Nurse:

Ms. XXXXX

ID No. XXXXXX

XXXXXXXX Service