**CONTRACT FOR OBSERVATIONAL STUDIES WITH MEDICINES FOR HUMAN USE**

**CONTRACT BETWEEN (name of the enterprise/organization/private the Sponsor of the observational study)*,* AND THE INSTITUT CATALÀ D'ONCOLOGIA (I.C.O) FOR THE CONDUCT OF THE STUDY: (title) WITH PROTOCOL CODE (protocol code / sponsor code)**

In Girona, (detail agreement date),

**GATHERED**

The party of Mrs. Candela Calle Rodríguez, General Director on behalf of INSTITUT CATALÀ D'ONCOLOGIA

And the party of Ms. name of Sponsor's legal representative acting on behalf of name of the enterprise/organization/private the Sponsor of the observational study.

**BETWEEN**

First, on behalf of the public company **Institut Català d’Oncologia-Girona (ICO GIRONA)** (hereinafter referred to as the “**Study Site**” or “**ICO Girona**”), with registered office  in Av. Gran Via, 199-203 08908 of Hospitalet de Llobregat (Barcelona)  and CIF number ESQ5856383D with sufficient powers to sign all agreements and contracts related to clinical trials according to the competencies delegated in agreement with the Administrative Council of this public company with protocol number 1416 authorized by Mr. Carlos Masià Martí of the Illustrious Notary Association of Catalonia  with residence in Barcelona awarded on 29th October 2021.

Second, Mr/Ms. (name of Sponsor's legal representative) for and on behalf of (name of the enterprise/organization/private the Sponsor of the observational study) **(hereafter referred to as the “Sponsor”)**, with registered office at (Sponsor's full address) (town) (postcode) and with Tax Id. No: (tax identification number), who guarantees and declares having sufficient valid powers for the signature of this document.

Both parties mutually recognise necessary and sufficient capacity to bind themselves by this contract.

Likewise, acting as a management company of the Study, Dr. Margarita Nadal Sánchez, Director of the **Institut d’ Investigació Biomèdica de Girona** **Dr. Josep Trueta** (hereinafter **“IDIBGI” or “Foundation”)**, on behalf of that Institution, TIN ESG17432592, and address Doctor Castany, s/n - Edifici M2, Parc Hospitalari Martí i Julià, 17190 – Salt (Girona) Spain. Intervenes in her capacity as Director and in exercise of the powers conferred by virtue of the deed of empowerment dated March 11, 2021, granted before the Notary of Barcelona, Mr. Jaime Agustín Justribó, with number 465 of his protocol, signs the present contract in proof of conformity with the content of the same.

**THEY DECLARE**

That the Sponsor is interested in a **Observational Study (Study)** entitled “**xxxxxxxxxxxxxxxx”**, with protocol code **xxxx** (referred to as the “Protocol”), in the Study Site and under the direction of **Dr. xxxxxxx** (referred to as the “Principal Researcher”) of the **xxxx Department**. The Observational Study shall be conducted according to the Study Protocol enclosed to this Contract (Appendix 1), although it constitutes part of itself, and all the parties know of it and thus accept it. The said Protocol is deposited in the Ethics Committee for investigation with medicinal (ECim) of the xxxxxxxxxx (RECm of reference – Research Ethic Committee of Medicaments)

*(If applicable) That Sponsor has entered into a separate agreement with xxxxxxxxxxxx (hereinafter referred to as “CRO”) so that CRO may, acting as an independent contractor under the authority of Sponsor, handle the site contracting for the Trial, execute this Contract and make payments on Sponsor’s behalf. However, the Sponsor is not absolved of the responsibility that corresponds according to the applicable law.*

The Site, having legal personality, aims to provide health services and, among its units makes available the xxxxxxx Department.

That the Study Site has delegated to the IDIBGI all financial aspects arising from all kinds of investigation carried out in the Study Site.

**THEY AGREE**

1. The study Site undertakes to see that **Dr. xxxxxxxxx,** as Principal Researcher, carries out the Study referred to above in accordance with the conditions specified in the protocol, having the Study Site’s consent.

This Contract will come into force on the day of its signature and will be valid until the finalization of the Study, without prejudice to what is set out in Agreement. For these purposes, the Study will not be understood as finalised until the parties have complied with all their obligations arising from this Contract. The estimated duration of the Study is **xxxxxxx months** from the date of the Contract or until all the subjects included have completed their participation in the Study as stipulated in the Study protocol.

1. The Study Site undertakes to see that the Researcher complies with the international standards relating to the undertaking of observational studies, set out in the International Guidelines for Ethical Review of Epidemiological Studies (Council for the International Organizations of Medical Sciences-CIOMS-Geneva, 1991) and in particular, as an example but not limiting, Royal Decree Legislative 1/2015, of 24 July, which approved the redrafted text of the Act on guarantees and the rational use of medicines and health products, Royal Decree 577/2013, of 26 July, which regulates the pharmacovigilance of medicines for human use, **Royal Decree 957/2020, of November 3, which regulates observational studies with medicines for human use**, Provisions of the Helsinki Declaration, ICH (International Conference of Harmonization Guidelines) standards for Good Clinical Practices (GCP), the autonomous legislation applicable in each case, Organic Law 3/2018, of December 5 on Personal Data Protection and Royal Decree 1720/2007, of 21 December; and to collaborate in the making of monitoring visits by the study monitor, audits by the auditors appointed by the Sponsor and inspections by the competent health authorities.
2. The Sponsor undertakes not to start any activity in the Study Site related with recruiting subjects for the Study until having the essential favourable report from the corresponding E.C.I.M and the contract has been signed.
3. The Sponsor, the Study Site, The Foundation and the Principal Researcher are obliged to carry out the services envisaged in this contract in full, in accordance with what is provided in it and in the Protocol. The Parties will comply with their own obligations in accordance with the tenor of the regulations set out in Agreement 2 of this document. The obligations, duties and functions envisaged in **Royal Decree 957/2020, of November 3, which regulates observational studies with medicines for human use** constitute for each of the Parties, for all purposes, the content of obligations in this Contract, so that failure to observe them will be taken as non-compliance with this Contract.
4. The Study the subject of this Contract is envisaged to include **xxx patients** in this Study Site. This Study will be carried out for a total of xxx patients at national level, the recruitment for the Study being not competitive and multicentre. This fact can affect the number of patients intended to be included in the study Site, their number being able to be varied.

1. The estimated direct and indirect cost for conducting this Study in the Study Site amount to a total of **xxxxx Euros**. This amount corresponds to the sum of **xxxx Euros per evaluable patient** in accordance with the terms of the financial memorandum attached to this Contract as Appendix 1.

The Sponsor/CRO undertakes to pay the IDIBGI, the sum of xxxxx euro per evaluable patient, equal to 20% of the budgeted direct costs per patient. The overhead is included in the total amount per patient indicated above.

The Fundació Institut d'Investigació Biomèdica de Girona Josep Trueta (IDIBGI), the entity which takes charge of the financial management of the Study will invoice 100% of the services supplied to the Sponsor and charge the appropriate taxes.

The Sponsor will make all payments quarterly (starting from the date of inclusion of the first patient) to Fundació Institut d'Investigació Biomèdica de Girona Josep Trueta (IDIBGI) according to visits made by the evaluable patients in accordance with the detail of visits attached in the Financial Memorandum (appendix 1), by bank transfer at 30 days from invoice date, against receipt of the corresponding invoices (with VAT itemised).

All the payments must be made on presentation of an invoice, in which VAT will be charged in accordance with the regulation applicable on its date of issue, in the name of the Sponsor (tax details):

|  |  |  |  |
| --- | --- | --- | --- |
| **FISCAL DATA OF THE ENTITY** | | | |
| **Fiscal Name:** |  | | |
| **Fiscal number** |  | | |
| **Direction:** |  | | |
| **Postal Code:** |  | | |
| **Population:** |  | | |
| **Country:** |  | | |
| **E-mail:** |  | | |
|  |  |  |  |
| **DATA FOR SENDING THE INVOICE** | | | |
| **(Fill in if the shipment data differs from the entity's data)** | | | |
| **Name:** |  | | |
| **Direction:** |  | | |
| **Population:** |  | | |
| **Postal Code:** |  | | |
| **Country:** |  | | |
| **E-mail:** |  | | |

All payments will be made by transfer to the IDIBGI bank account:

|  |  |
| --- | --- |
| **Beneficiary Name** | INSTITUT D'INVESTIGACIO BIOMEDICA DE GIRONA (IDIBGI) |
| **TAX Number** | ESG17432592 |
| **Address of beneficiary** | C/ DR CASTANY S/N PARC HOSPITALARI MARTI I JULIA EDIFICI M2 - 17190 SALT (GIRONA) |
| **Name of the bank** | CAIXABANK, SA |
| **Bank Address** | CENTRE INSTITUCIONS CATALUNYA Pl. de la Ciencia s/n 08242 - MANRESA |
| **Bank account** | 2100 0002 5002 0139 6544 |
| **IBAN** | ES9521000002500201396544 |
| **SWIFT** | CAIXESBBXXX |
| **Payment reference** | *Invoice number issued, advance payments without invoice are not accepted.* |
| **Payment contact address** | aacc@idibgi.org |

*In any case, the Sponsor will be ultimately responsible for the obligations of payment arising from this Contract, IDIBGI being able to approach the Sponsor directly should the CRO fail in any of the payments arising from this Contract.*

It is ESSENTIAL to indicate the invoice number on all payments.

In the case of early termination of the Study, whatever may be the cause, the sum to be paid will be modified in proportion to the number of patients included and their time of remaining in it.

In the even that an evaluable patient leaves the Trial before its termination for any reason, only the visits taking place until that time will be paid for.

1. The Sponsor sets on record that, in relation with carrying out this Study in the Trial Site, no agreements have been established nor will be established outside this Contract with the Principal Researcher or collaborating researchers in the study Site, which could result in additional financial compensation or of any other type. Excluded from this clause are the expenses of meetings for the organization of the Study, in the even that it is multitrial Site, and the facilities which the Sponsor may make available in the future for dissemination of the results obtained in the Study in meetings and scientific publications.
2. In accordance with article 5 of Royal Decree 957/2020, the Parties undertake to process the personal data of participants in a trial in accordance with the national and European regulations in force in this area and, specifically, in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (hereinafter "Regulation (EU) 2016/679").

Likewise, the Parties undertake and assume responsibility to ensure compliance with said regulations and their duty of confidentiality to their employees and to those third parties that subcontract and participate in any way in the processing of information of subjects participating in a Study.

The patient data communicated to the Sponsor will be previously dissociated by means of a double coding system so that the information obtained cannot be linked in any way to a person identified or identifiable by the Sponsor. The Sponsor or its legal representatives must always comply with current regulations on the protection of personal data.

Any treatment of the data outside the object of the Study that legitimizes access is prohibited and no personal data of the subjects of the Study will be transferred, except in those circumstances were permitted by law.

The study Site is responsible for processing the personal data of the subjects participating in a Study, in accordance with the provisions of Regulation (EU) 2016/679. The Sponsor will only have access to information regarding the subjects participating in a Study prior to its codification unless a rule with the rank of law or a judicial authority so permits. The Sponsor shall be responsible for the correct processing of the data entered in the Study database.

The study Site expressly authorizes the Principal Researcher of a Study to have access to the clinical history of the subjects included in said Study for its development.

The monitors and/or auditors appointed by the Sponsor may have access to the information and clinical documentation on the subjects included in a Study that are in the Study Site, in order to verify the accuracy and reliability of the data provided by the Principal Researcher, but they may not collect under any circumstances and in any form of documentary or other support, the personal identification data of the Study subjects. The Study Site shall also provide access to these data to the inspectors of the competent health authorities, when required to do so by the regulations in force.

The processing of personal data of the subjects participating in a Study by monitors, auditors and other third parties designated by the Sponsor may only be carried out after signing a contract for processing between the Centre and these third parties, in the terms established in Regulation (EU) 2016/679.

For the purposes of the provisions of Regulation (EU) 2016/679 and the corresponding implementing regulations, the Parties hereby state that the personal data contained in the present Contract, in its Exhibits or in the previous preparatory documents thereof, shall be of exclusive use for the purposes of the reciprocal relations between the Parties, shall not be assigned and shall be kept for the duration of this Contract and its Exhibits.

The parties may exercise their rights of access, rectification, deletion, opposition, limitation of the processing and/or portability of the data by writing to the following addresses:

* IDIBGI: [transparencia@idibgi.org](mailto:transparencia@idibgi.org)
* Sponsor: XXXXXXX
* Study Site: [lopd@iconcologia.net](mailto:lopd@iconcologia.net)

The parties may communicate with the Data Protection Officer (DPO) of the other party regarding the processing of their personal data. The parties may exercise their rights by writing to the following addresses:

* IDIBGI: Fundación TIC Salud Social | Parque TecnoCampus Mataró Maresme - Torre TCM3, Av. Ernest Lluch, 32, 6ª planta | 08302 Mataró or at the following e-mail address: [dpd@ticsalutsocial.cat](mailto:dpd@ticsalutsocial.cat)
* Sponsor: XXXXXXXXXX
* Study Site: [lopd@iconcologia.net](mailto:lopd@iconcologia.net)

In the event that one of the Parties detects an incidence in the management of the data related to the data of the patients of the Study, the other Party shall immediately be informed.

1. The results of the Study, all the works and reports prepared and all the industrial property rights arising from this Study are the Sponsor's exclusive property.
2. When the Study is finished, the Sponsor undertakes to disseminate the results obtained, whether negative or positive, in media for public access.

Publication of the results in scientific magazines or books by the Principal Researcher of the Study Site must take place by common accord between both parties; a copy of the manuscript or the original must be delivered to the Sponsor so that its content can be known, and the appropriate checks carried out. The Sponsor, within a maximum of 45 calendar days, must communicate to the Principal Investigator whether it agrees with the content. This term having passed without the Sponsor having responded, it will be considered to have been agreed and the Principal Investigator can proceed to the publication.

The Sponsor must apply to the Study Site and the Principal Researcher for relevant express authorizations to be able to use their names in scientific publications or in any media of dissemination for commercial ends or circulation.

1. The Observational studies are exempted from the obligation of signing third party liability insurance.
2. The undertaking of the Study in the Study Site can be cancelled at the instance of one of the parties or by mutual agreement, in the following circumstances:
3. Impossibility of including a minimum number of subjects to enable the final evaluation of the Study in a reasonable time, in accordance with the study characteristics.
4. If from an intermediate analysis of the data or other information available, it is inferred that it is not safe or is not justified to continue administering the medicine under investigation to the subjects of the Study.
5. For non-compliance with the obligations accepted in this Contract by any of the contracting parties.
6. By mutual agreement between the parties, set out in writing.
7. By the wish of one of the parties, set out in writing and with at least one month's notice.

In the event of suspension of the Study, the Sponsor/CRO must pay the IDIBGI the sum corresponding to the work carried out, in accordance with the financial memorandum attached as appendix 1 to this contract.

The finalization of the Study involves the necessary discussion and coordination between the contracting parties, in order to guarantee the safety of the subject, evaluate the continuity of the treatment and ensure compliance with the legal regulations in force in the matter.

1. In case of notifications to be done, the following addresses are designated:

* To IDIBGI, dealing with administrative tasks or financial aspects: [aacc@idibgi.org](mailto:aacc@idibgi.org)
* To the Study Site, dealing with scientific tasks: Dr. Begoña Martín, [bmartin@iconcologia.net](mailto:bmartin@iconcologia.net)
* To the Sponsor: xxxxxxxxxxx

1. Any alteration of what is provided in this Contract must be made in writing and signed by the parties as an addendum to it.
2. The anticorruption policy establishes that none of the Sponsor's employees nor any third party acting for it, or in its name, may have any interest or commitment which comes into conflict with or prevents them from carrying out their obligations under this Contract in an ethical and proper manner, to ensure that all the activities are carried out respecting and complying strictly with ethical standards and the legislation applicable. The Sponsor considers integrity and transparent behaviour essential and applies a policy of zero tolerance of any corrupt practice.

The Sponsor's employees and any third party acting in its name may make any contacts or authorize, for any reason, directly or indirectly, payments of any kind, to any of the participants in the Study with the purpose of obtaining an improper advantage or an undue influence in the taking of any decision. The concept of “payments” includes payments or promises of payment, in kind and/or cash, and any other offer of goods or service.

The Foundation, as financial manager of this Contract, will formally record all the financial transactions taking place in connection with this Contract and will make available to the Sponsor, when the latter so requests in writing, all the relevant documentation which allows verification of compliance with the undertakings set out in this document.

1. To settle any dispute which may arise in the application or interpretation of what is set out in this Contract, the two parties submit themselves, with express waiver of the forum which could correspond to them, to the jurisdiction of the courts and tribunals of the registered office of the study Site.

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In witness whereof, the parties sign this Contract electronically, having the same legal force and effect as the handwritten exchange of signatures, and and for one sole purpose, in the place and on the date given in the heading of this document.

For the Sponsor/ For the Study Site

By CRO on behalf of the Sponsor

**Mr/Mrs. xxxxxxxxxxxxxxxxxxxx Dr. Candela Calle Rodríguez**

General Director ICO

IDIBGI signs this agreement also, in compliance with the obligations taken on as trial managing in the Study Site

**Dr. Margarita Nadal Sánchez**

Director IDIBGI

This Contract is also signed, in evidence of acceptance and agreement with the obligations accepted, as Principal Investigator of the Study in the Study Site, by:

**Dr. XXXXXXXXX**

XXXXX Department

I.C.O Girona

**Appendix 1.** Financial memorandum of the contract between Sponsor entity, and the I.C.O. GIRONA , for the conduct of Observational Study **: “xxxxxxxxxxxxxxxxxxxxxxx” Protocol code xxxxxx**

**Dr. xxxxxx**

**Sponsor xxxxx**

**Patients: xxxxxx**

## TOTAL AMOUNT PER ELIGIBLE PATIENT:

## Research Fund (20%) 00.00 EURO

## Clinical Research Personnel 00.00 EURO

**NET TOTAL 1,2 00. 00 EURO**

All payments must be made on presentation of invoice, plus VAT where applicable, at the percentage in force on the date of issue of each invoice.

**1Tables of cost breakdown per visit per evaluable patient completed (in EURO)**

2 **There is and additional budget for invoiceable items and costs:**

**PAYMENT FORM**

The Sponsor will make all payments quarterly (starting from the date of inclusion of the first patient) to Fundació Institut d'Investigació Biomèdica de Girona Josep Trueta (IDIBGI) according to visits made by the evaluable patients in accordance with the detail of visits attached in the Financial Memorandum (appendix 1), by bank transfer at 30 days from invoice date, against receipt of the corresponding invoices (with VAT itemised).

All payments will be made by transfer to the IDIBGI bank account:

|  |  |
| --- | --- |
| **Beneficiary Name** | INSTITUT D'INVESTIGACIO BIOMEDICA DE GIRONA (IDIBGI) |
| **TAX Number** | ESG17432592 |
| **Address of beneficiary** | C/ DR CASTANY S/N PARC HOSPITALARI MARTI I JULIA EDIFICI M2 - 17190 SALT (GIRONA) |
| **Name of the bank** | CAIXABANK, SA |
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| **Bank account** | 2100 0002 5002 0139 6544 |
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| **SWIFT** | CAIXESBBXXX |
| **Payment reference** | *Invoice number issued, advance payments without invoice are not accepted.* |
| **Payment contact address** | aacc@idibgi.org |

All payments hereunder will reference the invoice number, Principal Investigator's name and protocol code.

* Original invoices should be issued to:

xxxxxxxxx

* And shall be sent for processing to:

xxxxxxxx