**AGREEMENT FOR CARRYING OUT**

**RESEARCH PROJECTS**

Title: (complete title of project)

Project code: (code of project assigned by Sponsor)

In \_\_\_\_\_, on \_\_\_\_\_ of \_\_\_\_\_ 202\_,

1. **By and between**

**(Site)** For one party, **Mrs. Mª Luz Marqués González,** in his capacity as Managing Director of the **Organización Sanitaria Integrada Ezkerraldea-Enkarterri-Cruces**, **Centro Hospital Universitario Cruces**, and representing this Organization, with residence in Plaza de Cruces No 12 postcode 48903, Cruces, Barakaldo (Bizkaia) and Tax number S-5100023-J, (hereinafter Site).

For one party, **Mr.** **Jesús Larrañaga Garitano**, in his capacity as Managing Director of the **Organización Sanitaria Integrada Bilbao-Basurto, Centro Hospital Universitario Basurto,** and representing this Organization, with residence in calle Avenida Montevideo, nº 18 con C.P 48013 de Bilbao, postcode 48013 and Tax number S-5100023-J, (hereinafter Site).

For one party, **Mr. Jon Guajardo Remacha**, in his capacity as Managing Director of the **Organización Sanitaria Integrada Barrualde-Galdakao,** **Centro Hospital Universitario Galdakao-Usansolo**, and representing this Organization, with residence in Barrio Labeaga, No 46 postcode 48960, Galdakao (Bizkaia) and Tax number S5100023J, (hereinafter Site).

For one party, […],as Managing Director of the **Organización Sanitaria Integrada […] (Centro […]**) and representing this Organization, with residence in […], postcode […] and Tax number […], (hereinafter Site).

For another party, **Asociación Instituto de Investigación Sanitaria Biobizkaia** (formerly Biocruces Bizkaia) (hereinafter **Biobizkaia),** with registered address in Plaza de Cruces s/n postcode 48903, Cruces, Barakaldo (Bizkaia) and Tax number G-95756334 and registered in the general registry of Associations with number AS/B/18363/2014. **Mrs. María del Mar Mendive Bilbao with ID number 78869222Z** in her capacity as Scientific Director and on behalf of this Organization, Under the powers of attorney bestowed by public deed, granted by the specified entity and executed before the Notary of Bilbao, Mr. Juan Ignacio Bustamante Esparza, dated 24th March 2022, and with number 1.040 of his own notary protocol.

For another party **(Sponsor)** And Mr/Ms. (name of the legal representative of the Sponsor), on behalf of and in representation of (add name of company) **(hereinafter, “**Sponsor”), with company address at (add complete address) and TIN (add tax identification number) with the legal capacity to sign this Agreement.

And of the other part **(Principal Investigator)** And, (name of Principal Investigator), with National Identity Card number (add ID number) and with address for the purposes of notifications at the (add the service he/she belongs to) Service of the Site. He/She acts on his/her own behalf and in his/her own representation, as the Principal Investigator, (hereinafter, also called the “**Principal Investigator**”).

All the parties recognise each other's necessary capacity to enter into this Agreement.

1. **They Manifest and Declare**
2. That the Sponsor is interested in conducting a research project, the identification details of which are described in the heading, and whose objective and purpose are described in the following terms (add objective).
3. That to this end, the Sponsor has selected the most suitable Principal Investigator according to his/her qualifications and resources available to carry out the Project at the Site facilities, in accordance with the Agreement and the Scientific Memorandum of the Project.
4. That Biobizkaia´s foundational aims are to promote the biomedical and epidemiological investigation of public health and health services, to scientifically base the programs and policies of the health service and to preferentially enhance translational research geared to accelerating the transfer of scientific knowledge to clinical practice, following international recommendations, in the territory of Bizkaia, by virtue of the collaboration agreements with Osakidetza/SVS, in which is responsible for managing the R+D+I carried out within it. That Biobizkaia is a foundation created by the General Administration of the Autonomous Community of the Basque Country as a body designed to lead and coordinate healthcare innovation and research in the Basque Health Service or Osakidetza.
5. That the Site is willing to carry out the project under the terms and conditions agreed to by the Sponsor and Biobizkaia.

Therefore, and in compliance with the foregoing, the parties enter into this Agreement for the carrying out of a Research Project (hereinafter also called the “**Agreement**”), based on the following.

1. **Terms and Conditions**
2. **Purpose**
	1. The purpose of this Agreement is to develop, on behalf of and in the name of the Sponsor, the Research Project, identified as (complete title of project) with code (add code) **(hereinafter, the “Project**”), that shall be carried out on the premises of the Site, under the direction and responsibility of the Principal Investigator.
	2. The estimated number of patients to be included shall be (add estimated number of participants) patients at this Site.
	3. The Sponsor tasks the Principal Investigator with the recruitment procedures of the patients required for the project to be adequately conducted. The patients should be selected in accordance with the criteria and deadlines established in the Project Memorandum, without prejudice to the option of the parties extending the initially agreed period.
3. **Terms governing implementation.**
	1. Scientific Memorandum of the Project
		1. The project shall be conducted subject to the conditions and requirements of the scientific memorandum attached to this Agreement as Annexe l (hereinafter the “**Scientific Memorandum”),** respecting legislation currently in force in accordance with current legislation and GCP standards.
	2. Start and duration of Project.
		1. The start of the Project shall be determined by the favourable opinion of the Ethics Committee for Clinical Research (hereinafter, the CEI), the agreement of the Site and the signing of this Agreement by all the parties.
		2. The foreseen Project duration shall be determined in the Scientific Memorandum (indicate duration) and calculations thereof shall be made from the date of signing of this Agreement and reception of a favourable opinion from CEI.
		3. The Sponsor undertakes to issue a written annual report on the progress of the project to Biobizkaia and to give notice of the end of same within 3 months after termination.
	3. Amendments**.**
		1. Any important modification of the scientific memorandum should be agreed by Sponsor and the Principal Investigator and should receive the approval of the CEI. The parties concerned shall assess if it is necessary to make any changes to the Agreement and/or annexes of same by means of addenda.
		2. Any change of the persons participating in the project should be agreed by the parties and should receive approval from the CEI if applicable.
	4. Legal ethical Regulations.

The Project shall be conducted subject to the regulations applicable at the time of signing this Agreement and for the duration thereof, in particular the following:

* + 1. Law 41/2002, of 14 November, on the autonomy of the patient and rights and obligations with regard to clinical information and documentation.
		2. Decree 3/2005 (Basque Country), of 11 January, creating the Ethics Committee for Clinical Research of the Autonomous Community of the Basque Country.
		3. Law 14/2007, of 3 July, on biomedical research.
		4. Organic Law 3/2018, of 5 December, on Personal Data Protection and Guarantee of Digital Rights and the Regulation (EU) 2016/679 of the European Parliament and the Council of 27 April 2016, relating to the protection of individuals with regards to the treatment of their personal data and the free movement of these data.
		5. It is of mutual agreement that the project shall be conducted in accordance with the Ethical Principles contained in the Helsinki Declaration in its most recent version and in accordance with the ICH (International Conference of Harmonization) Guidelines for Good Clinical Practice (GCP).
	1. Informed consent.
		1. The Project shall be carried out with the maximum respect for patients' rights, informing them clearly and accurately of the objective of the Project and of the possible benefits and risks of participation in same. Before including any patient in the research project, informed consent shall be obtained from same, in accordance with legislation currently in force.
	2. Access.
		1. The corresponding CREC shall have access at all times to documentation about the project needed to monitor same as established in the regulatory legislation, especially informed consent of the patients that participate in same, if this is necessary.
		2. The competent Health Authority and the staff appointed by the Sponsor may have access to data for monitoring purposes and to verify the accuracy of the data facilitated by the Principal Investigator about the participants in the project and the clinical information and documentation about them that is in the Site to verify the accuracy and reliability of same.
		3. The Principal Investigator should ensure that the Sponsor's staffs respect the standards of confidentiality with regard to any information about the participants of the project.
		4. The Site shall facilitate access to said data to the CEI and the inspectors of the competent health authorities and the Sponsor's staff.
	3. Ownership and Publication of results.
		1. The industrial and intellectual property rights deriving from the data, results, discoveries and patentable or non-patentable inventions that are obtained or developed over the course of the project shall belong exclusively to the Sponsor as sole owner thereof.
		2. The Sponsor undertakes to publish the results of the project and to shall assume the responsibilities for preparing final or partial reports, and to report them to the relevant parties. To this end, the Principal Investigator shall give the Sponsor the clinical data obtained during the Project and stipulated in the **Scientific Memorandum** for preparing the final report.
		3. The Sponsor recognises the right of Biobizkaia, the Principal Investigator and the Site to publish the results, and that the Sponsor should be informed in writing within at least forty five (45) of any action taken to publish, disseminate or present the information, where any action is understood as referring to any acceptance, including but not limited to lectures, dissertations, abstracts for congresses, scientific or educational articles, or any mode of communication utilised with regard to the Project. If within said period no reply is received from the Sponsor, the proposed publication or communication shall be regarded as approved.
	4. Confidentiality and data protection
		1. The parties to this Agreement undertake to treat the documents, information, results and data relating to the project as confidential and secret, ensuring restricted circulation of said information, and shall be responsible for ensuring that said obligation is complied with by all the persons that require access to same in accordance with this Agreement. The exceptions to said undertaking of confidentiality include information that: (i) the receiving party knew at the time the disclosing party when it was received; (ii) is currently or later shall become known or generally available information and where said process is not the result of an act or omission of the receiving party; (iii) disclosure is required by law or order of a court, tribunal or the administration.
		2. The Site, the Principal Investigator and the clinical research associates and auditors appointed by the Sponsor guarantee the following: all personal data held which relates to the subjects included in the Project will be treated in accordance with the provisions of the Organic Law 3/2018, of 5 December, of Protection of Personal Data, and Guarantee of Digital Rights and the Regulation (GDPR), (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, with regard to the processing of personal data and on the free movement of such data, which supersedes the Directive 95/46/EC (Data Protection Directive), and according to the specifications stablished at Annex III to this agreement, the Law 16/2023, of December 21, of the Basque Data Protection Authority, as well as the Law 41/2002 of 14th November, which basically governs patient autonomy and the rights and obligations attached to clinical information and documentation. In particular they shall ensure that any personal data of patients communicated to the Sponsor, is previously disassociated, to ensure that the information obtained cannot be associated to an identified or identifiable individual.
1. **Participants**
	1. Sponsor

Contact details:

 Organisation: (add name of company)

 Address: (complete address of company)

Contact person: (first name and surname)

Telephone number: (telephone number)

 Electronic mail: (electronic mail address)

If any change is made with regard to the person responsible for the Project by the Sponsor, said change should be reported by the Sponsor to Biobizkaia.

* 1. Principal Investigator:

The Principal Investigator shall oversee and ensure that all the participants in the project, and especially the collaborators shall faithfully comply with this Agreement and the annexes of same, and that they have been sufficiently informed of same.

* 1. Collaborators
		1. The Principal Investigator shall be responsible for proposing the members of the research team and the support staff for the project. In this regard, the Principal Investigator has proposed the following persons as collaborative researchers:
* Mr/Ms. (Complete name of the collaborator).
* Mr/Ms. (Complete name of the collaborator).
* Mr/Ms. (Complete name of the collaborator).
	+ 1. Collaboration services:
* Mr/Ms. (Complete name of the collaborator).
	1. Other Personnel

Biobizkaia Biobizkaia, in agreement with the project requirements as detailed by the Principal Investigator, might recruit additional personnel and obtain the essential items/supplies. The hiring personnel process will be carried out by following the OTM (Open Transparent Merit) which determines the basic guidelines. The company hiring procedure complies with the HRS4R and obtained the HR Excellence in Research Award in 2017.

* 1. Biobizkaia

Biobizkaia shall be responsible for the financial and administrative management to support the Site and the Principal Investigator in the correct implementation of the project.

* 1. Research Organisation

(Optional clause) To carry out the Project, the Sponsor has contracted the services of (add company name), which is a contract research organisation with business address at (add complete address) and TIN (add tax identification number). **(hereinafter, the “CRO”),** to carry out the following functions:

* (Add function to be carried out by the CRO).
* (Add function to be carried out by the CRO).
* (Add function to be carried out by the CRO).
1. **Project Site.**
	1. The Project should be conducted at (name of Site and Service/Unit, where applicable).
	2. The Site shall make available for the purposes of conducting the project whatever human resources are used in its daily activities.
2. **Biological Samples**

In the event that the projects require the collection of biological samples, the Basque Biobank shall be the tool used to process, manage, conserve and transfer them.

In this case, an annexe is attached to this Agreement containing the Contract for transferring the samples, which includes the commitments of the Sponsor and the Principal Investigator with regard to the management of the biological samples from the Project.

1. **Supply of equipment and special material for the Project**

If special equipment or materials are required for the project, the Sponsor undertakes to facilitate them at no cost whatsoever to the Site. At the end of the Project, any surplus special equipment or materials supplied shall be returned to the Sponsor.

1. **Insurance**

If performance of the project requires any type of invasive procedure or implies a greater risk to the patient than that corresponding to habitual clinical practice, the Sponsor certifies that he has taken out a civil liability policy with the company (add name of insurance company) with number: (add policy number) that should cover all losses and damages that might be caused by their participation in the Project, as well as the responsibilities of the Sponsor, the Site, Biobizkaia and the Research Team.

1. **Financial aspects (Annex II).**

The financial aspects shall be described in the financial Report that appears in Annexe II of the Agreement, as an inseparable part thereof.

* 1. Agreement Management costs.

An amount of (add figure in accordance with table of rates) € + VAT is established, payable for management of the Agreement, and payment shall be made against the presentation of the relevant invoice, in parallel with management of the Agreement. (Table I of ANNEX II).

* 1. Costs of execution of the project.

The sum of (sum per concluded patient) €, plus tax, shall be made effective per concluded patient. (Table II of ANNEX II). All of which includes the following items

* Payment for work carried out by health professionals and other structural resources of the Site, stratified as visits made or patients with monitoring concluded.
* Direct special costs, including any expenses that were not produced from not having participated in the project.
	1. Biobizkaia shall bill the Sponsor for all the costs incurred by the project and shall distribute the funds in the following manner (Table III of Annex II)
		+ - 10% of the total of the Project shall be allocated to Biobizkaia to defray the expenses caused by managing the execution of same.
			- 25% shall be allocated to the research Site to promote the research.
			- 65% shall be allocated to the research team for reinvestment in the R+D+i activities of the Researcher or the Research Team.
			- The special costs shall be earmarked for the Site to defray the corresponding costs, as well as for Biobizkaia to defray the management expenses.
	2. Methods of payment
		1. Calculation of the level of execution of the project for the purposes of invoicing shall be reported to the Biobizkaia by the Sponsor and in parallel by the Principal Investigator, so that Biobizkaia may issue the appropriate invoices after contrasting the data.
		2. The Sponsor shall effect payment of the invoice issued by Biobizkaia within thirty (30) days dating from the date of issue of each invoice, in the account number given by the foundation.
1. **Obligations**
	1. The Sponsor shall be responsible for obtaining the necessary permits from the CEI prior to commencement of the Project.
	2. The Principal Investigator shall conduct the Project in strict compliance with the scientific memorandum, which establishes the activities and tasks that should be commenced, performed and monitored with due diligence.
	3. The Site shall facilitate provision of the work of the professionals who participate in the Project, in particular that of the Principal Investigator and other research staff.
	4. Biobizkaia shall be responsible for the financial and administrative management of the funds corresponding to the Site and, in the event that the Principal Investigator so instructs, for those corresponding to the research team.
2. **Suspension of Project**
	1. The project may be suspended in the following circumstances:
		1. As a result of a breach of the obligations borne by the Parties in accordance with this Agreement, if said breach is not amended by the breaching Party within 15 days, calculated from reception of a written notification in which the complying Party demands compliance with said obligations.
		2. If compliance with the scientific memorandum is deficient or the data is repeatedly inexact or incomplete.
		3. By mutual agreement between the contracting parties, this should be established in writing.
	2. In the event of early termination of the project, the Sponsor shall only pay the provisions made up to the date of the early termination.
3. **Applicable legal system and jurisdiction**
	1. The provisions of this Agreement shall be regulated and interpreted in accordance with applicable legislation on this type of project and in particular in accordance with the provisions of Law 14/2007 on Biomedical Research.
	2. In the event of any dispute over the interpretation or fulfilment of this Agreement, the parties, with express waiver of any other jurisdiction to which they might be entitled, submit to the courts of Vitoria-Gasteiz, offices of Osakidetza.
	3. If there is a version of this Agreement written in a different language than Spanish, the Spanish version shall prevail for all the parties.

And as approval of all the aforementioned, and in witness thereof, the Parties sign the present document.

**Biobizkaia:                                                     For the Sponsor:**

Mrs. María del Mar Mendive Bilbao (Sponsor´s legal representative)

And accepting the undertaking of the terms and conditions that appear in this Agreement:

**Site:                                                             Principal Investigator:**

 (Center managing Director)  (Name of Principal Investigator*)*

**ANNEXES**

**Annex I: Scientific Memorandum of the Project**

**Annex II: Financial Report**

**Annex III: Personal Data Protection**

**Annex I: Scientific Memorandum of the Project**

Consult in separate document

**Annex II: Financial memorandum**

**Title of Project:** (complete title of project)

**Code:** (add code assigned by Sponsor)

**Site:** (name of Site)

**No. of patients estimated for this Site:** (number of participants in the project)

**No. of participating Sites in the Autonomous Community of the Basque Country:** (number of Sites participating in the Project in the autonomous community of the Basque Country)

**Table I. Agreement Management costs**

|  |  |  |
| --- | --- | --- |
| BIOBIZKAIA | QUANTITY | euros |
|  VAT  | euros |
| **TOTAL** |  euros |

**Table II. Project Execution**

|  |  |  |  |
| --- | --- | --- | --- |
| **DESCRIPTION**  | **AMOUNT FOR VISIT €** **A** | **EXTRAORDINARY TESTS €****(B)** |  |
|   |
| Visit 1 |   |   |  |
| Visit 2 |   |   |  |
| Final Visit |   |   |  |
| Others  |   |   |  |
| **TOTAL FOR COMPLETE PATIENT** |  |  | **TOTAL\*****(A) +(B)** |
| (\*) Total execution costs per concluded patient should appear in section 8.2 of the Agreement |
| **PROJECT TOTAL** | € TOTAL (A) +(B) x No. of ESTIMATED PATIENTS |

**Table III Direct Extraordinary Costs per patient**

|  |  |  |  |
| --- | --- | --- | --- |
| **SPECIAL****TESTS (B)** | **UNITS** **(Patient)**  | **UNIT AMOUNT\*** | **TOTAL PATIENT** |
|  |   |   |  |
|  |  |  |  |
|  |  |  |  |

(\*) The price of the tests includes the percentage corresponding to Biobizkaia.

**Table IV. Breakdown of Amount per patient**

|  |
| --- |
| **BREAKDOWN OF THE AMOUNT PER VISIT****(Table II column A)** |
| A. Research Team | 65%. |  |
| B. Site | 25%. |  |
| C. Biobizkaia | 10%. |  |
| TOTAL |  |
| **BREAKDOWN OF AMOUNT FOR SPECIAL TESTS****(Table II column B)** |
| 1. Site-Cost of test
 | 90%. |  |
| B. Management costs - Biobizkaia | 10%. |  |

1. **Invoice details:**

Taxes payable in accordance with current legislation shall be applied to these amounts.

E-mail address for submit of the invoices for the procedures and visits performed is as follows:

facturacion@bio-bizkaia.eus. This address should be confirmed with the PI when the amount allocated to the research team is not managed by Biobizkaia

For the purposes of issuing invoices, the following should be recorded:

* Name of the Sponsor: (add complete name of promoting company)
* Name of the company making payment: (name of company)
* Tax address: (complete address of company)
* TIN: (tax identification code)
* Contact person: (name and surname of person responsible)
* Telephone number (telephone number)
* E-mail address:(electronic mail address)

**Annex III: Personal data protection**

The parties recognise that both the Site and the Sponsor are considered responsible for the processing of personal data managed in accordance with this Agreement as a function of their level of involvement and responsibility for the processing thereof, such that:

* The Site and/or Principal Investigator are responsible for processing of each patient’s medical record and other clinical data
* The Sponsor is responsible for the pseudonymised data from the Trial/ Study/ Project.

The parties collaborate together to ensure compliance with personal data protection legislation.

Each party shall adopt appropriate technical and organisational measures to protect against unauthorised or unlawful processing of personal data and accidental loss, destruction or damage of personal data, considering the degree of damage that could be caused to interested parties whose personal data have been subjected to unauthorised or illegal processing or loss, destruction or damage; and put in place security programmes and procedures that specifically address the nature of any special category data, as defined in Article 9 of the GDPR, comprising the aforementioned technical and organisational measures, for example, pseudonymisation and coding of personal data; development of the ability to ensure ongoing confidentiality, integrity, availability and resilience of processing systems and services; development of the ability to restore availability of and access to personal data in a timely manner in the event of a physical or technical incident; and/or establishment of a process for regularly testing, assessing and evaluating the efficacy of the technical and organisational measures taken to ensure the security of the processing.

Each party undertakes to apply the obligation of secrecy concerning personal data to individuals who have had access to data under this Agreement, even after it has served its purpose. They shall ensure the persons authorised to process personal data commit, explicitly and in writing, to respect the confidentiality of the data and adopt the necessary security measures, of which they must be duly informed. Further, they shall keep supporting documentation concerning fulfilment of the obligation established in the previous section and ensure that persons authorised to process personal data receive the necessary training in personal data protection.

If the Site and/or Principal Investigator receive an injunction, ruling or order from a court or any administrative authority obliging them to supply personal data, they shall: i) immediately notify the Sponsor; and ii) supply the corresponding data, ensuring at all times that they adopt appropriate organisational and technical measures to safeguard the confidentiality thereof.

If either of the parties becomes aware of any incident or breach of security affecting personal data, they should notify the other party of the breach, providing all the information required for documenting and reporting the incident, within 24 hours. Such notification shall not be necessary when it is unlikely that said breach of security poses a risk to the rights and freedoms of patients. In any case, it shall be the responsibility of the Sponsor to notify the relevant data protection authority of security breaches.

Patients or their legal representatives will be able to exercise their rights established by law (to access, rectification, erasure and opposition, restriction of processing, portability and not be subject to decisions based solely on automated processing), in accordance with the informed consent given, on request to the Site and/or Principal Investigator who shall inform the Sponsor, in order that appropriate action is taken. Similarly, in the event of rights being exercised through the Sponsor, it will inform the Site, again in order that appropriate action is taken.

It is the responsibility of the Sponsor to establish instructions concerning the information to be included in the information sheet and informed consent form for patients involved in the Trial/ Study/ Project. In all cases, the Sponsor shall ensure that it contains the following:

* Authorisation for data collection and processing
* Specification of the purposes of the Trial/ Study/ Project
* Establishment of responsibilities both of the Site and/or the Principal Investigator and of the Sponsor in the processing of personal data
* Details of the address patients should use to exercise their rights
* Specification of how long data related to the Trial/ Study/ Project are to be stored
* Contact details of Data Protection Officers
* Request for authorisation for the transfer of personal data to the United States of America or any other country outside the European Economic Community apart from Switzerland when such jurisdictions might not offer the same degree of legal protection as European Law.
* Statement of the right of patients to contact the relevant data protection authority.

It is the responsibility of the Principal Investigator and/or Site to obtain informed consent in accordance with the instructions laid down by the Sponsor.

The parties have appointed a data protection officer to check on compliance with data protection legislation and as a contact person for matters related to this Agreement:

* Sponsor: (specify person/email address or other contact information)
* Site and/or Principal Investigator: DBO-DPD@osakidetza.eus
* Institute: dpd@bio-bizkaia.eus

The Foundation/Institute, in accordance with this Agreement and with its functions of leading, coordination and execution of the Trial/ Study/ Project, pursuant to the data protection law, shall be responsible for processing in the event of access to personal and/or pseudonymised, and hence, shall:

* Only use personal data that that are to be processed or are collected for inclusion for purposes that are the subject matter of this Agreement.
* In the case of pseudonymised data, be able to process them for the purposes of archiving or statistical analysis in compliance with their tasks of monitoring, coordination and execution.
* Process data in accordance with the instructions laid down by the Sponsor and/or Site. If the Foundation/Institute were to consider that any instructions infringed the GDPR or any other provision of the Union or Member States in matters of data protection, it would immediately inform those responsible for the processing.
* Keep a written record of all the categories of processing activities performed in accordance with this Agreement.
* Not transfer data to third parties, except with the express authorisation of those responsible for the processing, and where legally permissible. The Foundation/Institute may transfer data to others engaged for processing by the same responsible party, in accordance with the instructions of that party. In such cases, the responsible party shall identify, in writing in advance, the entity to which data should be transferred, the data to be transferred and the security measures to be applied for conducting the transfer. If the Foundation/Institute is to transfer personal data to a third country or an international organisation, under applicable Union or Member State law, it shall inform the responsible party of any legal requirements in advance, unless said laws prohibit it for important reasons of public interest.
* Not outsource any of the services that are the subject matter of this Agreement that involve processing of personal data, except such ancillary services necessary for the normal operating of the services of the processor. Should it be necessary to outsource processing operations, the party(ies) responsible should be informed in advance in writing, indicating the processing operations to be outsourced and clearly and correctly specifying the company to which they are outsourced and its contact details. Outsourcing shall be allowed if no responsible party has raised an objection during the agreed period. The outsourced provider, who also takes on the role of processor, is similarly obliged to fulfil the obligations established in this document for the processor and the instructions laid down by the responsible party. It is the responsibility of the initial processor to manage the new relationship formed with the new processor, which is subject to the same conditions (instructions, obligations, security measures, etc.) and the same formal requirements as the original processor, regarding the proper handling of personal data and protecting of the rights of individuals involved. In the event of an outsourced processor failing to fulfil the obligations, the original processor shall remain fully responsible to the responsible party concerning their fulfilment.
* Apply the obligation of secrecy concerning personal data to which it has had access under this Agreement, even after it has served its purpose.
* Ensure that persons authorised to process personal data commit, expressly and in writing, to respect the confidentiality of the data and adopt the necessary security measures, of which they must be duly informed.
* Keep available for the responsible party supporting documentation concerning fulfilment of the obligation established in the previous section.
* Ensure that persons authorised to process personal data receive the necessary training in personal data protection.
* Help the responsible parties respond to requests to exercise rights: when individuals involved seek to exercise their rights to access, rectification, erasure and opposition, restriction of processing, portability and not be subject to decisions based solely on automated processing by contacting the Foundation/Institute, it shall inform those responsible for the processing. This should be done immediately and never later than the first working day after the request is received, together with the provision of other information, as available, that could be relevant to deal with the request.
* Adopt appropriate technical and organisational measures to protect against unauthorised or unlawful processing of personal data and accidental loss, destruction or damage of personal data, considering the degree of damage that could be caused to interested parties whose personal data have been subjected to unauthorised or illegal processing or loss, destruction or damage; and put in place security programmes and procedures that specifically address the nature of any special category data, as defined in Article 9 of the GDPR, comprising the aforementioned technical and organisational measures, for example:
	+ - * + Pseudonymisation and coding of personal data
				+ Development of the ability to ensure ongoing confidentiality, integrity, availability and resilience of processing systems and services
				+ Development of the ability to restore availability of and access to personal data in a timely manner in the event of a physical or technical incident
				+ Establishment of a process for regularly testing, assessing and evaluating the efficacy of the technical and organisational measures taken to ensure the security of the processing
				+ Notify the responsible party (ies), without unreasonable delay, and always within 24 hours, if it becomes aware of any breaches of security affecting personal data it holds, together with all the information required for documenting and reporting the incident. Such notification shall not be necessary when it is unlikely that said breach of security poses a risk to the rights and freedoms of individuals, and it shall be the responsibility of the responsible party (ies) to notify the relevant data protection authority of security breaches.
				+ In the event of personal data related to Trial/ Study/ Projects being accessed, delete all corresponding data held on the computer systems used by the Foundation/Institute. Nevertheless, the Foundation/Institute may keep a copy, with the data duly blocked, for as long as responsibilities for the execution of the Trial/ Study/ Project might arise.

The responsible parties shall aim to ensure compliance with the GDPR, in advance of and throughout the processing by the Foundation/Institute and supervise the processing, including conducting inspections and audits, as appropri