**CONTRACT FOR CONDUCTING POST-MARKETING STUDIES OF A HEALTH PRODUCT**

Title: *(complete title of study)*

Study Code: *(code of Study assigned by Sponsor)*

In \_\_\_\_\_, on \_\_\_\_\_ of \_\_\_\_\_ 201\_,

1. **By and between**

**(Centre)** Mr/Ms. *(name of the legal representative of the centre),* as the General Manager of the Healthcare Facility *(name of the centre where the study is to take place )* and in representation of said Organisation with address at *(complete address of the centre )* with Post Code *(add postcode)* in *(add the city)* and TIN *(add tax identification number)*, (hereinafter, the Centre).

**(Foundation)** And Ms. Susana Belaustegui Ituarte, Director of the R&D&I Management Area, holder of ID Number 30652282K acts on behalf and in representation of the BASQUE FOUNDATION FOR HEALTH INNOVATION AND RESEARCH (hereinafter BIOEF), the entity owning the Basque Biobank (Biobank), listed in the register of the Institute of Health Carlos III (register B.0000140), with tax identification number G-01341353 and headquarters at the BEC (Bilbao Exhibition Centre), Ronda de Azkue, nº 1, 48902 Barakaldo-Bizkaia, in accordance with the power granted by public deed on 19th July 2016 before the Notary of Mondragón, Mr. Iñigo Irache Varona, number 778

**(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 contract.

**(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 Centre. He/She acts on his/her own behalf and in his/her own representation, as the Principal Investigator, (hereinafter, also called the “**Principal Investigator**”).

*Fill in details below in the event of an organisation that acts in representation of the Sponsor.*

**(C.R.O acting in representation of the Sponsor)** Mr/Ms. *(name of legal representative of the company/organisation) as (add function presented)* of the company *(name of company)* and in representation of said Organisation with address at *(complete address of the company )* and with TIN *(Tax identification number)* hereinafter the “**CRO**”) acting in representation of *(add name of company)* (hereinafter, the “**Sponsor**”), with business address at *(add complete address )* and TIN *(add tax identification number)* in accordance with Annexe III: Powers to sign on behalf of the Sponsor.

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

1. **They Manifest and Declare**
2. That the Sponsor is interested in conducting a Clinical Trial with Health Product, the identification details of which are described in the heading, and whose objective and purpose are described in the following terms *(add objective)*, of the Product *(add the product)*.
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 Study at the centre facilities, in accordance with the contract and the Study Protocol.
4. That BIOEF 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 Centre is willing to carry out the study under the terms and conditions agreed to by the Sponsor and BIOEF.

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

1. **Terms and Conditions**
2. **Purpose**
   1. The purpose of this Contract is to develop, on behalf of and in the name of the Sponsor, the Clinical Study, identified as *(complete title of study)* with code *(add code)* (hereinafter, the “**Study**”), that shall be carried out on the premises of the Centre, 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 centre.
   3. The Sponsor tasks the Principal Investigator with the recruitment procedures of the patients required for the Study to be adequately conducted. The patients should be selected in accordance with the criteria and deadlines established in the Protocol, without prejudice to the option of the parties extending the initially agreed period.
3. **Terms governing implementation.**
   1. Protocol

The Study shall be conducted subject to the conditions and requirements of the Protocol attached to this Contract as Annexe l (hereinafter the “Protocol”), respecting legislation currently in force and the standards of BCP.

* 1. Commencement and duration of Study.
     1. Commencement of the Study shall be determined by the favourable opinion of the corresponding Ethics Committee for Clinical Research (hereinafter, the CEIC)and the agreement of the centre with the signature of this contract by all the parties.
     2. The duration of the Study shall be established in the Protocol *(add number of months)* and shall be calculated as starting from the signing of this Contract or a favourable opinion from the CEIC.
     3. The Sponsor undertakes to issue a written annual report on the progress of the study to BIOEF and to give notice of the end of same within 3 months after termination.
  2. Modifications**.**
     1. Any important modification of the Protocol should be agreed by Sponsor and the Principal Investigator and should receive the approval of the CEIC. The parties concerned shall assess if it is necessary to make any changes to the Contract and/or annexes of same by means of addenda.
     2. Any change of the persons participating in the Study should be agreed by the parties and should receive approval from the CEIC if applicable.
  3. Legal ethical standards.

The Study shall be conducted subject to the regulations applicable at the time of signing this Contract 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. Royal Decree 1720/2007, of 21 December, approving the implementing Regulations of Organic Law 15/1999, of 13 December, on Protection of Personal Data and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)
    5. [Royal Decree 1591/2009, of 16 October](http://www.aemps.gob.es/legislacion/espana/productosSanitarios/docs/Directiva_93-42-CEE/rcl_2009_2105.pdf) regulating health products
    6. [Royal Decree 1616/2009, of 26 October](http://www.aemps.gob.es/legislacion/espana/productosSanitarios/docs/Directiva_90-385-CEE/rcl_2009_2106.pdf) , regulating active implantable medical products.
    7. It is agreed that the study shall be conducted in accordance with the Ethical Principles contained in the Helsinki Declaration in its most recent version.
  1. Informed consent.

The Study shall be carried out with the maximum respect for patients' rights, informing them clearly and accurately of the objective of the Study and of the possible benefits and risks of participation in same. Before including any patient in the Study, informed consent shall be obtained from same, in accordance with legislation currently in force.

* 1. Access.
     1. The CEIC shall have access at all times to documentation about the Study 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 Trial and the clinical information and documentation about them that is in the Centre to verify the accuracy and reliability of same.
     3. The Principal Investigator should ensure that the Sponsor's staff respect the standards of confidentiality with regard to any information about the participants of the Study.
     4. The Centre shall facilitate access to said data to the CEIC and the inspectors of the competent health authorities and the Sponsor's staff.
  2. 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 study shall belong exclusively to the Sponsor as sole owner thereof.
     2. The Sponsor is obliged to publish the results of the study, whether they are negative or positive, and shall assume the responsibility for preparing final or partial reports, as well as for informing the relevant parties. To this end, the Principal Investigator shall give the Sponsor the clinical data obtained during the study and stipulated in the Protocol for preparing the final report.
     3. The Sponsor recognises the right of BIOEF, the Principal Investigator and the Centre 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 Study. If within said period no reply is received from the Sponsor, the proposed publication or communication shall be regarded as approved.
  3. Confidentiality and protection of data
     1. The parties to this Contract undertake to treat the documents, information, results and data relating to the Study 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 the agreements in this Contract. 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 parties to the contract shall undertake to ensure that the personal data of the participants in the study shall be treated in accordance with the provisions established in Law 15/1999, of 13 December, on protection of personal data and the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)and according to the specifications established in Annex IV to this contract, Law 2/2004, of 25 February, on publicly owned personal data files and on the creation of the Basque Agency of Data Protection, as well as Law 41/2002, of 14 November, on the autonomy of the patient and rights and obligations with regard to clinical information and documentation, and special care shall be taken to ensure that any personal data of the patients that is communicated to the Sponsor shall be previously disassociated in such a way that the information that is obtained from same cannot be associated with with an identified or identifiable person.

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 Study by the Sponsor, said change should be reported by the Sponsor to BIOEF.

* 1. Principal Investigator:

The Principal Investigator shall oversee and ensure that all the participants in the study, and especially the collaborators, shall faithfully comply with this contract 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 Study. In this regard, the Principal Investigator has proposed the following persons as collaborative researchers:
     + Mr/Ms. *(complete name of collaborator)*
     + Mr/Ms. *(complete name of collaborator)*
     + Mr/Ms. *(complete name of collaborator)*
     1. Pharmacy:
     + Mr/Ms. *(complete name of collaborator)*
     1. Collaboration services:
* Mr/Ms. *(complete name of collaborator)*
* Mr/Ms. *(complete name of collaborator)* 
  1. Other staff

BIOEF may contract the other professionals and material resources required to conduct the study, according to the needs indicated by the Principal Investigator, the Centre and the Sponsor.

* 1. BIOEF

BIOEF shall be responsible for the financial and administrative management to support the Centre and the Principal Investigator in the correct implementation of the study.

* 1. Research Organisation *(Optional clause)*

To carry out the Study, 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. Monitor

The Sponsor has appointed the following company staff member as monitor *(add name of company)* with TIN *(add tax identification number).* (hereinafter, the “**Monitor**”). If the monitor is changed, the Sponsor shall notify BIOEF.

1. **Place of study.**
   1. The Study should be conducted at *(name of Centre and Service/Unit, where applicable)*.
   2. The Centre shall make available for the purposes of conducting the study whatever human resources are used in its daily activities.
2. **Supply of heath product, equipment and special material for the Trial**
   1. The Sponsor shall supply the health product for the Study at no charge.
   2. If special equipment or materials are required for the Study, the Sponsor undertakes to facilitate them at no cost whatsoever to the centre. At the end of the Study, any surplus special equipment or materials supplied shall be returned to the Sponsor.
3. **Insurance**

If performance of the Study 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 Study, as well as the responsibilities of the Sponsor, the Centre, BIOEF and the Research Team.

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

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

* 1. Costs of management of the contract.

The sum of *(add figure in accordance with table of rates)* € + VAT is established, payable for management of the contract, and payment shall be made against the presentation of the relevant invoice, in parallel with management of the contract. (Table I of ANNEXE II).

* 1. Costs of execution of the study.

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

* Payment for work carried out by health professionals and other structural resources of the centre, 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 Study.
  1. BIOEF shall invoice the Sponsor for all the costs incurred from the study, except for payment of the research team (if not expressly indicated otherwise by the Principal Investigator) and the funds shall be distributed in the following manner (Table IV of Annexe II)
     + - 10% of the total of the Study shall be allocated to BIOEF to defray the expenses caused by managing the execution of same.
       - 27% shall be allocated to the research centre to promote the research.
       - 63% shall be allocated to the research team.
       - The special costs shall be earmarked for the centre to defray the corresponding costs, as well as for BIOEF to defray the management expenses.
  2. Methods of payment
     1. Calculation of the level of execution of the study for the purposes of invoicing shall be reported to the BIOEF by the Sponsor and in parallel by the Principal Investigator, so that BIOEF may issue the appropriate invoices after contrasting the data.
     2. The Sponsor shall effect payment of the invoice issued by BIOEF 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 CEIC prior to commencement of the Study.
   2. The Principal Investigator shall conduct the Study in strict compliance with the Protocol, which establishes the activities and tasks that should be commenced, performed and monitored with due diligence.
   3. The Centre shall facilitate provision of the work of the professionals who participate in the Study, in particular that of the Principal Investigator and other research staff.
   4. BIOEF shall be responsible for the financial and administrative management of the funds corresponding to the centre and, in the event that the Principal Investigator so instructs, for those corresponding to the research team.
2. **Suspension of Study** 
   1. The Study 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 contract, 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 Protocol is deficient or the data is repeatedly inexact or incomplete.
      3. By mutual agreement between the contracting parties, which should be established in writing.
   2. In the event of early termination of the Study, 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 Contract shall be regulated and interpreted in accordance with the applicable legislation on this type of study
   2. In the event of any dispute over the interpretation or fulfilment of this Contract, 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.

And in accordance with all the foregoing, in witness whereof, they enter into this contract in quadruplicate.

**BIOEF:**                                                          **the PROMOTOR:**

Ms. Susana Belaustegui Ituarte *(name of legal representative of the*  *Sponsor)*

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

**The Centre:                                                             Principal Investigator:**

*(name of the legal representative of the centre)**(name of the Principal Investigator)*

**Annexe I: Protocol**

**Consult in separate document**

**Annexe II: Financial memorandum**

**Title of study:** *(complete title of study)*

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

**Centre:** *(name of Centre)*

**No. of patients estimated for this centre:** *(number of participants in the study)*

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

**Table 1, Costs of management of the contract.**

|  |  |
| --- | --- |
| Fundación Vasca de Innovación e Investigación Sanitarias/BIO Eusko  Fundazioa |  |
| VAT |  |
| **TOTAL** |  |

**Table II. Costs of execution of the study.**

|  |  |  |  |
| --- | --- | --- | --- |
| **DESCRIPTION** | **AMOUNT FOR VISIT €**  **A** | **SPECIAL 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 7.1.2 of the contract* | | | |
| **TOTAL STUDY** | *TOTAL (A) +(B) x No. of ESTIMATED PATIENTS* | | |

**Table III Direct Special Costs per patient**

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

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **BREAKDOWN OF AMOUNT PER VISIT** **(Table II column A)** | | | | |
| A. Research Team | | 63% | |  |
| B. Centre | | 27% | |  |
| C. BIOEF | | 10% | |  |
| TOTAL | |  | | |
| **BREAKDOWN OF AMOUNT FOR SPECIAL TESTS** **(Table II column B)** | | | | |
| 1. Centre-Cost of test | | 90% | |  |
| B. Management costs - BIOEF | | 10% | |  |
|  |  |  |  | |

**Invoice details:**

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

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

* Name of promoting company: *(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)*

**Annexe III: Powers to sign on behalf of the Sponsor**

**Annexe IV: Personal data protection**

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

* The Centre and/or Principal Investigator are responsible for processing of each patient’s medical record and other clinical data
* The Promoter is responsible for the pseudoanonymized data from the trial.

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, pseudoanonymisation 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 Contract, 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 Centre 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 Promoter; 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 Promoter 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 Centre and/or Principal Investigator who shall inform the Promoter, in order that appropriate action is taken. Similarly, in the event of rights being exercised through the Promoter, it will inform the Centre, again in order that appropriate action is taken.

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

* Request for authorisation for data collection and processing
* Specification of the purposes of the trial
* Establishment of responsibilities both of the Centre and/or the Principal Investigator and of the Promoter 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 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 Centre to obtain informed consent in accordance with the instructions laid down by the Promoter.

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 Contract:

* + - * + Promoter: (specify person/email address or other contact information)
        + Centre and/or Principal Investigator: (specify person/email address or other contact information)
        + Foundation/Institute: (specify person/email address or other contact information)

*The Foundation/Institute, in accordance with this Contract and with its functions of leading, coordination and execution of the clinical trial, pursuant to the data protection law, shall be responsible for processing in the event of access to personal and/or pseudoanonymised, 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 Contract.*
* *In the case of pseudoanonymised 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 Promoter and/or Centre. 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 Contract.*
* *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 Contract 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 Contract, 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:* 
  + - * + *Pseudoanonymisation 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 clinical trials 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 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 appropriate.*