SPECIAL ADMINISTRATIVE CLAUSES AND SPECIFICATIONS
SERVICE TO CONDUCT TOXICITY STUDIES ACCORDING TO GOOD LABORATORY PRACTICE AS AN OPEN PROCEDURE

I. GENERAL PROVISIONS

1. PURPOSE OF THE CONTRACT

1.1. Needs to be met by means of the contract and factors to be taken into account:

This purpose of this contract is the delivery of toxicity studies conducted according to good practice, pursuant to the terms set out in these Specification and in the Technical Specifications (TS).

The service covers all the necessary practices and procedures to conduct a "Toxicity Study of Inhalation of a Single Dose of Sulphur Hexafluoride in Rats as per Good Laboratory Practice (GLP)", including as many pre and post activities as deemed necessary.

Therefore, pursuant to Article 28 of the Spanish Public Sector Procurement Act (LCSP) and to the documentation pertaining to this procedure, the need and appropriateness of the purpose of the proposed contract is duly justified.

The contract to be entered into is classified as a services contract, pursuant to Article 17 of the LCSP.

1.2. Division by lots:

Given that it is a specialist toxicity study service that involves direct coordinating and operating dynamics with the laboratory in order to deliver the services, the non-division of the purpose of the contract into lots is justified, as the independent delivery of the different practices and procedures included in the contract would hinder its correct fulfilment from the technical perspective.

a) 1.3. CPV [(*)]:

90715200-4 – Other pollution investigation services

[(*)] COMMISSION REGULATION (EC) No 213/2008 of 28 November 2007 amending Regulation (EC) No 2195/2002 of the European Parliament and of the Council on the Common Procurement Vocabulary (CPV).

1.4. Classification as per the purpose of the contract:

Pursuant to Article 77.1.b) of the LCSP, **the bidder is not required to be classified in order to be eligible to bid**.

1.5. Procedure No: BMG_2023-07-SERV. Toxicity studies

2. NATURE AND LEGAL SYSTEM

2.1. Tender procedure

Given the status of the Contracting Authority as Non-Public Administration Awarding Authority, the processing of the tender procedure shall be governed, in all aspects not envisaged in the specifications, by (i) the Public Sector Procurement Act 9/2017, of 8 November, transposing into the Spanish legal system the Directives of the European Parliament and of the Council 2014/23/EU and 2014/24/EU, of 26 February 2014 (LCSP), (ii) Royal Decree 817/2009, of 8 May, partially enacting the Public Sector Procurement Act 30/2007 (iii) and by the General Regulations of the Public Administrations Procurement Act, approved by Royal Decree 1098/2001, of 12 October (RGLCAP), insofar as they are not contrary to what is established in the LCSP. Additionally, the remaining provisions of administrative law that are applicable or, as relevant, those of private law, shall apply.

2.2. Effects and termination of the contract

The provisions of these specifications, the Cover Sheet and the Technical Specifications make up the content of the contract.

The Contract shall be private and shall be governed by the provisions of private law as regards its effects and termination, pursuant to Article 319.1 of the Public Sector Procurement Act 9/2017, of 8 November, transposing into the Spanish legal system the Directives of the European Parliament and of the Council 2014/23/EU and 2014/24/EU, of 26 February 2014 (LCSP), and without prejudice to the application of the precepts of the LCSP expressly envisaged in its Article 319.

3. ESTIMATED VALUE OF THE CONTRACT, MAXIMUM TENDER BUDGET AND CONTRACT PRICE

3.1. The estimated value for the full term of the contract, including any possible extensions and amendments that may be agreed, and for the deliverables in full envisaged in the technical specifications, not including VAT, is as established in Section 3 of the **Cover Sheet.**

3.2. The base or maximum tender budget, for the deliverables in full envisaged in the technical specifications, not including VAT, is as established in Section 3 of the Cover **Sheet.** Any bids that exceed the base tender budget shall be automatically excluded.

3.3. The maximum tender unit prices, not including VAT, are those established in Section 3 of the **Cover Sheet**. Those prices shall be the ceiling for the bids to be submitted by the bidders.

3.4. The price of the contract shall be the one resulting from its award, and shall include VAT as a separate item.

3.5. Those amounts shall include all the valuation factors and possible costs for the correct and full execution of the contract.

3.6. Section 4 of the **Cover Sheet** shall indicate whether or not the contract is subject to harmonised regulation.

4. CONTRACTOR PROFILE

Access to the contractor profile of the contracting authority is through the following website:

http://www.contratacion.euskadi.eus/informacion-general-perfil-contratante/w32-kpeperfi/es/

The relevant data and information pursuant to Article 63 of the LCSP shall be published in the contractor profile.

II. TENDER

5. AWARD PROCEDURE

The tender shall be processed as per the procedure established in Section 5 of the Cover **Sheet** and in accordance with the award criteria of Section 8 of the **Cover Sheet**, **pursuant** to the applicable articles of the LCSP.

6. CAPACITY AND SOLVENCY OF THE BIDDER TO CONTRACT

6.1. Standing and capacity to contract

Spanish or foreign individuals or legal entities may enter into contracts with CIC biomaGUNE, provided that they have full capacity to act, and that their purpose or activity are directly related to the purpose of the contract, in accordance with their respective articles of association or bylaws.

Furthermore, the individuals and legal entities may be considered to be awarded the contract when they tender as temporary joint ventures (hereinafter UTE); in that case each of the members of the temporary joint venture shall need to fulfil the minimum capacity and solvency requirements.

Any individual or legal entity may not tender if they fall within any of the circumstances envisaged in Article 71.1 of the LCSP, or any legal entities where it can be presumed that they are a continuation or that they result from – by means of transformation, merger or succession – other companies in which those circumstances had occurred.

6.2. Solvency to contract

Any individuals or legal entities that accredit they have the economic, financial and technical or professional (in the case of service contracts) standing specified in Section 6 of the **Cover Sheet** may take part in the tender procedure.

The bidders may count on the solvency and resources of other entities, regardless of the legal nature of their ties, provided that they will effectively have those resources at their disposal for the fulfilment of the contract.

Whether these circumstances have been met shall be accredited as envisaged in Section 6 of the **Cover Sheet**, which shall indicate the documentation required to do so.

Companies bidding in a UTE shall accredit that each meets the technical or professional, financial and economic solvency requirements.

7. CALL TO TENDER AND SUBMISSION OF BIDS

The bids shall be submitted in the form, time and place indicated in the call to tender and pursuant to Article 80 of the RGLCAP.

7.1. Call to tender

The contractor profile http://www.contratacion.euskadi.eus/w32-kpeperfi/es/v79aWar/comunJSP/v79aInicioBusqueda.do shall provide the information regarding the call to tender of this contract, including the special administrative clauses and specifications, and the technical specifications, along with the supporting documentation, as applicable.

Bidders may seek any clarifications they deem appropriate by emailing their questions to licitaciones@cicbiomagune.es.

7.2. Submitting bids electronically

Bids shall be submitted electronically using the "Electronic Bidding System" application, located on the Basque Countr's procurement platform, which will guarantee the authenticity, integrity and safekeeping of the documents submitted.

In order to carry out the formalities bidders shall need to access the common portal of the Public Administration of the Basque Autonomous Community (euskadi.eus), using the electronic bidding system:

http://www.contratacion.euskadi.eus/informacion-general-licitacion-electronica/w32-kpelicel/es/

The documentation to be submitted in the relevant envelopes shall be attached using the "Bid" option; under no circumstances may documentation be submitted using the "Submit Annexes (optional)" option.

Electronic bidding will allow the formalities performed to be consulted remotely using the aforementioned website; it shall guarantee that the bids submitted by the bidders are issued and logged in such a way so that it is impossible to know their content, except at the time and by the members of the CIC biomaGUNE contracting authority legally authorised to do so.

Therefore, the bids shall be sent encrypted and fragmented to the unit processing the tender procedure. The legal quorum of the members of the Contracting Authority's Technical Assistance Committee with their relevant recognised electronic signature certificates shall need to participate in the opening of tenders for the bids to be decrypted and recomposed.

Each bidder may only submit one bid, notwithstanding the admissibility of variants or improvements, when so envisaged. The bidder may not sign any bid as a temporary joint venture with other bidders if they have already done so individually or appear in more than one temporary joint venture. Contravening these prohibitions shall result in none of the bids signed by the bidder in question being admissible.

By submitting the bid, the bidder unconditionally accepts the SACS and TS that govern this contract.

Contravening any of the above prohibitions shall result in all of the bids signed by the bidder being inadmissible.

7.3. Deadline

The deadline shall be as established in the call to tender. Bids submitted after the deadline shall not be accepted under any circumstances.

The bid shall be deemed to have been received within the submission period, if the transmission starts within that period and is successfully completed.

7.4. Notifications and communications

Notifications and communications shall be made using the electronic bidding system.

7.5. Requirements for electronic bidding

The requirements for electronic processing by the bidder are as follows:

1. Administrative requirements:

a) To have a recognised electronic certificate, in accordance with Article 11 of the Electronic Administration Decree 21/2012, of 21 February, of the Basque Government's Ministry of Justice and Public Administration, and to use the recognised electronic signature to carry out the remote processing.

b) To be in one of the following situations:

- Be duly registered and have current certification in the Basque Classified Companies and Bidders Registry.
- Be duly registered in the temporary authorisation system.
- Should two or more economic operators tender together with the undertaking to formally set up a UTE in the case of the bid being successful: the UTE undertaking must be recorded in the temporary authorisation system.

2. Technical requirements:

The information about the technical requirements is available through following link:

http://www.contratacion.euskadi.eus/informacion-general-licitacion-electronica/w32-kpelicel/es/

8. FORM AND CONTENT OF THE BIDS

8.1. Form of submission

All the documents indicated in the application must be attached; however, only the reading and processing of documents stored with the following extensions is guaranteed: .doc, .xls, .ppt, .docx, .xlsx, .pptx, .pdf, .rtf., .sxw, .sdw, .abw, .xml, .jpg, .bmp, .tiff, .zip, y .7z.

Sending documents in .pdf, .rtf, .sxw, .jpg and .tiff formats is recommended in order to minimise the impact that the presence of viruses may have on the operating of the system.

Bids shall be sent free of viruses that make it difficult or impossible to read them; the bidder is responsible for ensuring that is the case.

8.2. Content of the bids

The bids shall be submitted electronically in **THREE (3) ENVELOPES**, which shall contain the following documentation:

8.2.1. <u>ENVELOPE 1 - "ADMINISTRATIVE DOCUMENTATION"</u> which shall include, compulsorily, the following documents:

- **Affidavit,** duly completed, by means of the European Single Procurement Document (ESPD), pursuant to Regulation (EU) no. 2016/7.

  The bidder wishing to submit a bid shall enter in https://visor.registrodelicitadores.gob.es/espd-web/filter?lang=es, as an economic operator, load the document in xml format in the "Import an ESPD" section and proceed to complete the data. Once completed, the bidder shall put it in the relevant envelope.

  *<u>Specific cases for submitting the ESPD</u>:

  - Should the bidder be a UTE, a ESPD must be submitted by each member.
  - Should the bidder resort to the capacities of other entities (Article 75 of the LCSP9, each entity to which the bidder resorts shall submit an additional ESPD containing the relevant information as per the case.
  - Should the bidder submit a bid for more than one lot, pursuant to Article 140.a.g), the bidder shall provide an ESPD for each of the lots for which they are bidding, in order to accredit the financial and economic solvency, as per the terms set out in Section 6 of the **Cover Sheet**.

- **Photocopy of the ID** of the Bidder or of the attorney-in-fact.

- Duly completed authorisation to make notifications by email (Section 1 of **Annexes to the SACS**).

- **Promoting gender equality**
  Bidders shall accredit compliance of Article 45 of the Organic Act 3/2007, of 22 March, for effective gender equality, taking into account the temporary applicability system envisaged in the Twelfth Transitory Provision, and pursuant to Legislative Royal Decree 6/2019, of 1 March, of urgent measures to guarantee equal treatment of and opportunities for women and men in employment and the workplace.

  Therefore, bidders shall complete Section 7 of **Annexes to the SACS** and attach the Equality Plan as applicable.

- **Employing workers with disability**
  Bidders shall accredit compliance of what is envisaged in Legislative Royal Decree 1/2013, of 29 November, which approved the Consolidated Text of the General Act concerning the rights of people with disability and their social inclusion.

Specifically, those bidders with 50 or more workers in their workforce shall be required to have, at least, 2 per cent of workers with disability or to adopt the legally envisaged alternative measures.

Therefore, they must provide, in any event, a certificate from the company that states both the total number of employees and the specific number of workers with disability in the workforce. Should the bidders have opted to comply with the legally envisaged alternative measures, they shall provide a copy of the declaration of exception and a statement with the specific measures applied. Furthermore, they may record in the aforementioned certificate the percentage of permanent workers with disability in the workforce, for the purposes of what is established for the cases of a tie in the clause regarding the ranking of the bids.

The aforementioned certificates shall be submitted using the model established in Section 6 of **Annexes to the SACS**.

- **Subcontracting**

  When, as per Article 11 of the **Cover Sheet** the possibility of subcontracting is envisaged, the bidders shall indicate in the bid (Section 5 of **Annexes to SACS**), pursuant to Article 215.2 a) of the LCSP, the part of the contract that they intend to subcontract, indicating its amount or percentage and the name or business profile.

Should the amount to be subcontracted be over 50%, the bidder shall submit accreditation of the technical solvency of the subcontractors that account for at least 70% of the subcontracted part.

- **Undertaking to formally set up a temporary joint venture (U.T.E.).**

  If several bidders tender as a temporary joint venture, each shall accredit their legal standing, indicating the names and circumstances of the bidders signing it, the stake of each, along with the undertaking to formally set up a temporary joint venture if awarded the contract; and the appointment of a single representative or attorney-in-fact of the venture with sufficient powers to exercise the rights and comply with the obligations arising from the contract until it is discharged.

  With respect to determining the technical and financial and economic solvency of the temporary joint venture and its effects, the accredited characteristics shall be accumulated for each its members.

  Should the contract be awarded to a temporary joint venture, the latter shall accredit its incorporation in a public deed, along with the tax number assigned to the venture prior to formalising the contract. The term of the joint venture shall be the same as that of the contract until its discharge.

- **Visit certificate** issued by CIC biomaGUNE, when a requirement established in the specifications to submit bids.

- **In the case of foreign companies**
  They shall submit:

  - **Affidavit,** duly completed, by means of the European Single Procurement Document (ESPD)
  - **Photocopy of the ID** of the Bidder or of the attorney-in-fact
  - Duly completed authorisation to make notifications by email (Section 1 of **Annexes to the SACS**)
  - Certificate issued by the bidder, accrediting that the company complies with the social obligations established in Community Law (Section 8 of **Annexes to the SACS**)

8.2.2. ENVELOPE No. 2. - "TECHNICAL DOCUMENTATION"

The technical documentation required in Section 7 of the **Cover Sheet** shall be submitted.

* Under no circumstances shall documentation on the economic bid or on the automatically assessable valuation criteria corresponding to Envelope No. 3, or any reference to them, be included in Envelope No 2; failure to comply shall be **grounds for exclusion from the procedure**.

8.2.3. ENVELOPE No. 3 - "ECONOMIC BID AND AUTOMATICALLY ASSESSABLE CRITERIA"

The documentation shall be prepared as per the model for the **economic bid and automatically assessable criteria**; any containing commissions, errors or deletions that prevent CIC biomaGUNE from clearly knowing what it deems fundamental to consider the bid shall not be accepted.

Furthermore, those bids that do not tally with the documentation examined and accepted shall be disregarded by the contracting authority; however, changing or omitting certain words of the model shall not be grounds for rejection if that does not alter its meaning.

The bid shall indicate the amount of VAT to be charged as a separate item.

The bidders shall state in the economic bid if they have taken the obligations arising from current provisions regarding job protection, working conditions and occupational health & safety, and protecting the environment into account when preparing their bids.

9. CONFIDENTIALITY OF THE BIDS

Bidders, where appropriate, shall indicate, by means of a supplementary declaration to be included in each of the envelopes, which documents and data submitted are, in their opinion,

confidential, pursuant to Article 133 of the LCSP. The declaration model is attached as Section 4 of **Annexes to SACS**.

The duty of confidentiality may not be extended to the whole content of the bid of the successful bidder.

10. RANKING OF THE BIDS, ASSESSMENT OF THE BIDS AND PROPOSED AWARD

10.1. An electronic device shall guarantee that the opening of the **bids** submitted electronically shall not occur until the end of the submission time period.

10.2. In any event, the bids shall be assessed pursuant to the award criteria established in Article 145 LCSP.

After the opening of Envelope 1, should part of the documentation required in Section 8.2.1 not have been submitted, or had not been correctly completed, the contracting authority shall ask the bidders to rectify that and allow them a period of **three (3) days**, from the day following receipt of the rectification request, to submit the corrected documentation.

Should the rectification not be made within that time, the contracting authority shall deem that the bidder has withdrawn its bid.

Envelope No. 2 - "Technical Documentation" shall then be opened; finally, Envelope No. 3 - "Economic Bid and Automatically Assessable Criteria" shall be opened; its opening can be watched on a public streaming event, on the date indicated in the call to tender, using the following links:

Url in Spanish: https://www6.euskadi.net/lizitazioa/directo_cic_biomague_es.html
Url in Basque: https://www6.euskadi.net/lizitazioa/directo_cic_biomagune_eu.html

Explanatory note: anybody wishing to attend in person the public opening of Envelope No 3 shall need to so notify by email (licitaciones@cicbiomagune.es); under no circumstances shall people be allowed to enter after the start of the opening formalities.

10.3. After examining the submitted bids and the assessments performed, pursuant to the award criteria established in Section 8 of the **Cover Sheet**, the contracting authority shall issue its award proposal in favour of the bidder whose bid has the best quality-price ratio, with the bids ranked from highest to lowest score.

A tie between several bids after applying the contract award criteria shall be settled according to the social criteria established in Article 147.2 of the LCSP.

10.4. Then, and after proceeding to the award, the contracting authority shall require the successful bidder – within a maximum of TEN (10) working days, from the day following receipt

of the request – to submit the documentation (if the successful bidder has already not done so) that is indicated below:

a) **Supporting administrative documentation** of compliance of the legal requirements to contract:

(i) List of all the documents included in the envelope.

(ii) Those that accredit the legal status of the successful bidder and, as applicable, its representation:

A. In the case of Spanish legal entities, a photocopy of the articles of association, and any statutory amendments, as applicable, entered in the Trade Registry, when so required by the applicable sector or mercantile legislation.

B. When the successful bidder is acting though a representative, documentary proof must be provided of the status of the representative and of the existence of the power of attorney and of the scope of their power to tender.

C. Tax number of the company

D. Non-EU companies must comply with the provisions of Article 68 of the LCSP.

(iii) Proof of the requirements of their technical or professional, financial and economic solvency, pursuant to Article 6 of the **Cover Sheet** or documents that accredit, as appropriate, the classification of the company.

In order to accredit solvency, the successful bidder may draw on the solvency and resources of other entities, regardless of the legal nature of their ties, provided that they shall effectively have those resources at their disposal for the fulfilment of the contract.

In any event, the contracting authority shall respect the confidential nature of the data provided by the successful bidders.

(iv) In the case of foreign company, they shall provide a statement expressly accepting to submit to the jurisdiction of all Spanish Courts and Tribunals, for any dispute that may directly or indirectly arise from the contract, and waiving, as applicable, the foreign jurisdiction to which the successful bidder may be entitled (Section 3 of **Annexes to the SACS**).

(v) Undertaking to allocate or appoint to the performance of the contract the technical, material and human resources envisaged in the technical specifications,

along with their immediate availability to implement the contract (Section 2 of **Annexes to the SACS**).

*** Accreditation by means of CERTIFICATE of the Registry of Bidders.-**

Accreditation of the circumstances listed in Sections (**ii)** and **(iii)** above (documentary proof of the successful bidder meeting the eligibility conditions as regards its standing and its capacity to act, representation, technical or professional and financial and economic solvency) may be replaced by the CERTIFICATE issued by any of the following registries:

- Official Registry of Contractors of the Basque Autonomous Community
- Official Registry of Bidders and Classified Companies of the State (as applicable)
- By means of a Community business classification

In any event, the certification shall be accompanied by an affidavit of the bidder stating that the circumstances reflected in the certificate in question have not changed.

As regards the circumstances not set out in the certificate submitted from the Registry in question, the required supporting documents must be provided, pursuant to Section 6 of the **Cover Sheet**.

b) <u>Tax and Social Security Obligations</u>:

- In the case of *national companies*:
  - Certificate of being in good standing with the tax authorities, issued by the relevant Tax Office (Provincial Government of Álava, Provincial Government of Bizkaia, Provincial Government of Gipuzkoa, Provincial Government of Navarra, Spanish Tax Office), justifying that the company is up-to-date with its tax obligations or an affidavit that it is not required to file them.
  - Certificate of being in good standing with the Social Security Territoral Treasury, justifying that the company is up-to-date with its Social Security obligations or an affidavit that it is not required to file them.

- In the case of *foreign companies*:
  - Certificate issued by the competent authority of the State to which they belong, officially translated into Spanish or Basque, accrediting that the company is in good standing regarding the payment of its tax obligations and Social Security contributions.

c) <u>Deed of formalising the temporary joint venture</u> if awarded the contract, and which shall be set up for at least the term of the contract, including any extension, until it is discharged.

d) Documentary proof of having set up, as appropriate, at the disposal of CIC biomaGUNE, the **Definitive Guarantee** required in Section 15 of the **Cover Sheet**, by any of the means indicated in that section.

e) Bank account holder certificate for the account to be used, as applicable, on the invoices to be issued as the result of this contract.

f) Actual Ownership Declaration

g) Annex IV.B: Declaration of absence of conflict of interest (DACI) for contractors and subcontractors (**Annexes to the SACS)**

h) Should the deliverable pursuant by the contract be financed by European Funds of Next Generation EU, the following documentation shall likewise be submitted:

- **Annex V:** Statement of commitment regarding the implementation of actions of the Spanish Recovery, Transformation and Resilience Plan - PRTR (**Annexes to the SACS)**

- **Annex VI:** Data assignment declaration regarding the implementation of actions of the Spanish Recovery, Transformation and Resilience Plan - PRTR (**Annexes to the SACS)**

i) Any other documentation related to the contract that is required by the contracting authority prior to the awarding of the contract.

10.5. Should the successful bidder not accredit the above points by the deadline, they shall be taken to have withdrawn their bid; in that case, the following bidder, in the order in which they bids have been ranked, shall be asked to provide the same documentation.

10.6. The outcome of the procedure and its incidents shall be duly recorded in the relevant reports.

The result of the rating, acceptance or exclusion of the bids shall be published in the contractor profile, subject to the necessary communication or notification, as applicable, to the bidders in question.

The exclusion of the bidder shall be duly notified to the latter, indicating the appropriate means of appeal against the decision.

11. AWARD

11.1. The contracting authority shall award the contract within the FIVE (5) working days following receipt of the documentation. A tender procedure may not be declared void where

there is a bid or tender that is admissible according to the criteria that appear in the specifications.

11.2. The award shall be substantiated, notified to the candidates or bidders and, simultaneously, shall be published on the contractor profile within FIFTEEN (15) days.

11.3. In any event, the notification shall contain the information required for the excluded bidder or discarded candidate to lodge, pursuant to Article 44 of the LCSP, a sufficiently well-founded appeal against the award decision. In particular, it shall include the following points:

a) As regards the discarded candidates, the summary of the reasons for which their bid has been rejected.
b) As regards the bidders excluded from the award summary, a summary of the reasons that their bid has not been accepted.
c) In any event, the name of the successful bidder or bidders, the decisive characteristics and advantages for their bids being selected over those submitted by the excluded bidder.

*** List of subcontractors.-**
For the purposes of what is established in Article 215.2 b) of the LCSP, the successful bidder shall inform CIC biomaGUNE, in writing after the awarding of the contract, of their intention of enter into the subcontracts indicated in their bid, indicating the part of the deliverable to be subcontracted, and the identity, contact details and legal representative or representatives, and sufficiently justifying the competence of the subcontractor to execute it, and accrediting that the subcontractor is not disqualified from contracting.

*** Business activity coordination.-**
Pursuant to RD 171/2004, of 30 January, enacting Article 24 of the Occupational Health & Safety Act 31/1995, of 9 November, regarding the coordination of business activities, the successful bidder shall cooperate in the application of occupational health and safety legislation, submitting, prior to signing the contract, the information required regarding the successful bidder's company in this regard.

III. PERFECTION AND FORMALISATION

12. PERFECTION AND FORMALISATION

12.1. The contract is perfected by means of its formalisation in writing.

12.2. If the contract is subject to a special appeal regarding the contracting pursuant to Article 44, the formalisation may not take place before FIFTEEN (15) working days have passed from when the award notification is sent to the bidders.

In the remaining cases, the formalisation of the contract shall take place within FIFTEEN (15) working days of the award notification being sent to the bidders, and, unless indicated otherwise

in its clauses, the contract shall be taken to be entered into in the place where the headquarters of the contracting authority is located.

The successful bidder shall then be required to formalise the contract within FIVE (5) days from the following day on which the request was received.

The formalisation of the contract shall be published in the contractor profile of the contracting authority; when it is a contract subject to harmonised regulation, it shall also be published in the Official Journal of the European Union.

The contract may be formalised as a public deed should the contractor so request, with the latter paying the costs arising from its granting. In that case the contractor shall provide CIC biomaGUNE with a certified copy and an uncertified copy of the deed within one month from its formalisation.

Should the successful bidder by a temporary joint venture, it shall accredit its incorporation in a public deed. In any event, the term of the joint venture shall be the same as that of the contract until its discharge.

12.3. When the contract has not been formalised within the above time periods for reasons attributable to CIC biomaGUNE, the contractor shall be compensated for any damages and losses that the delay may have caused.

When the contract has not been formalised within the above time period for reasons attributable to the successful bidder, CIC biomaGUNE may seek the amount of 3% of the tender base budget, excluding VAT, as a penalty, which shall be first be collected against the definitive guarantee if it has been provided.

Pursuant to Article 153.4 of the LCSP, in the above case, the contract shall be awarded to the following bidder according to the order in which the bids have been rated, after accrediting the eligibility and solvency of that bidder required to contract and other requirements established in Article 150.2 of the aforementioned legislation.

12.4. Once the contract has been formalised, the supporting documentation or material for the bids shall be made available to the interested parties. If, after it has been made available, they do not collect their documentation in the following three months, CIC biomaGUNE shall not be required to continue safeguarding it.

IV. PERFORMANCE OF THE CONTRACT

13. PERFORMANCE OF THE CONTRACT

The contract shall be executed in accordance with its clauses, with what is established herein and in the technical specifications, and according to the instruction given by CIC biomaGUNE to the contractor for its interpretation.

Specifically, the special implementation terms and conditions envisaged for that purpose in Section 16 of the **Cover Sheet** shall be fulfilled.

The contractor shall undertake to supply the deliverable established in the contract at the quoted price.

13.1. Compliance of employment obligations

The contractor shall be required to comply with current provisions regarding employment, Social Security, social integration of the disabled, and occupation health and safety, and to provide social training in that regard; subcontractors, where applicable, shall undertake to comply with current employment legislation with respect to their workers.

13.2. Material and human resources

The contractor shall undertake to provide and maintain, in order to supply the deliverable, the team and auxiliary resources necessary for the correct performance of the contract, and, in particular, those that have been included in the technical team for the implementation of the contract.

The workers of the company shall exclusively depend on the contractor. CIC biomaGUNE shall remain outside the relations of any type that exist between the contractor and the workers that the contractor uses for the performance of the contract. Under no circumstances shall the contract be taken to mean that an employment relationship exists between CIC biomaGUNE and the workers of the successful bidder.

The contractor shall be liable for any claim relating to the commercial and industrial property of the materials, procedures and equipment used for the performance of the contract, and shall compensate CIC biomaGUNE for any damages and losses that the latter may occur from claims being lodged.

13.3. Costs to be met by the contractor

The contractor shall pay for the formalities, any costs, taxes, duties, etc. and drafting and approval of the projects that have to be submitted to the relevant authorities in order to be registered and obtain the operating permit, hookups to networks and services, provisional and definitive connections, and, in general, anything necessary for the appropriate and legalised functioning of the facilities.

13.4. Risk and peril of the contractor

The performance of the contract shall be at the risk and peril of the contractor, notwithstanding the cases of force majeure of Article 239 in the case of a works contract.

13.5. Liability of the contractor for damages and losses

The contractor shall be liable for any direct or indirect damages or losses incurred by CIC biomaGUNE and third parties as the result of the operations required for the performance of this contract.

13.6. Civil liability insurance

The contractor shall have taken out the mandatory insurance, along with civil liability insurance that covers any possible liabilities arising from the performance of the contract. Specifically, the contractor shall have taken out a Professional Civil Liability policy with sufficient cover, in the opinion of CIC biomaGUNE, to meet all the possible risks arising from the performance contract and shall keep that policy in force during the term of the contract.

Should the cover of the contracted policy not be sufficient to meet any damage occurred, and should CIC biomaGUNE be furthermore ordered to compensate that damage, the contractor undertakes to repay CIC biomaGUNE the compensation paid, and the latter may deduct the amount of that compensation from any amount that CIC biomaGUNE owes the contractor for any concept.

CIC biomaGUNE may ask the contractor at any time to provide documentary proof of the contracting, payment, content and validity of the aforementioned insurance policies.

14. TERM AND EXTENSION OF THE CONTRACT

14.1. The contract shall be in force during the term established in Section 9 of the **Cover Sheet**.

The calculation of the period for the performance of the contract shall start on the day indicated or the day following its formalisation.

14.2. The contract may be extended prior to the end of its term, if so indicated in Section 9 of the **Cover Sheet**.

The extension shall be agreed by the contracting authority and shall be compulsory for the contractor unless envisaged otherwise in that section. Therefore, at least two months' notice prior to the end of the term of the contract must be given.

Should the notice period not be met, the extension shall be processed by mutual agreement. Contracts whose term is under two months are exempted from the notice obligation.

Under no circumstance may the extension happen by the tacit consent of the parties.

Should due to incidents resulting from events occurring that CIC biomaGUNE could not have foreseen during the award procedure, there are reasons of public interest not to interrupt the delivery of the service, and that a new contract guaranteeing the continuity of the deliverable to be provided by the contractor has not been formalised on expiry of the contract, the original contract may be extended until the performance of the new contract begins and, in any event, for a maximum period of NINE (9) months, without amending the remaining terms and conditions of the contract, provided that the call to tender for the new contract has been published at least THREE (3) months prior to the end date of the original contract.

15. AMENDMENT OF THE CONTRACT

15.1. Amendments envisaged in the special administrative clauses and specifications

The contract may only be amended in the cases and in the manner envisaged in Articles 203 to 207 of the LCSP.

Section 17 of the **Cover Sheet** shall indicate whether or not the contract can be amended; if that is possible, the conditions in which that can be used shall be clearly, accurately and explicitly detailed, along with the scope and limits of those amendments up to a maximum of 20% of the initial price of the contract, pursuant to Article 204 of the LCSP.

15.2. Amendments not envisaged in the special administrative clauses and specifications

Amendments not envisaged in the specifications or which, even if envisaged, are not in line with Article 204 of the LCSP, shall be governed by what is envisaged in Article 205, as well as in Article 242 of the same legal text when it is a works contract.

Any amendments to the contract that are not duly authorised by CIC biomaGUNE shall lead to liability for the contractor, even though such amendments may affect the management, inspection and oversight of the deliverable.

16. ASSIGNMENT AND SUBCONTRACTING

16.1. Assignment

Contractors must comply with the requirements established in Article 214 of the LCSP in order to be able to assign their rights and obligations to third parties.

16.2. Subcontracting

The contractor may agree with third parties for the partial supply of the deliverable subject to what is established in the specifications, except when pursuant to Section 11 of the Cover **Sheet**, the supply, or part of it, has to be directly by the former. In any event, they shall comply with the requirements established in Articles 215 to 217 of the LCSP.

Pursuant to Article 215.2 a) of the LCSP, bidders shall indicate in the bid (Section 5 of **Cover Sheet**) the part of the contract that they intend to subcontract, indicating its amount or percentage and the name or business profile.

17. PENALTIES FOR BREACH OF CONTRACTUAL OBLIGATIONS

The conduct that is classified as breach of the supply of the deliverable defined in the contract are listed in Section 10 of the **Cover Sheet.**

17.1. Penalties for breach of the implementation period

Pursuant to Article 193.3 of the LCSP, when the contractor, for reasons attributable to them, is late in compliance of the total period, CIC may opt, having regard to the circumstances of the case, to terminate the contract, retain the definitive guarantee, or to impose penalties in the proportion of EUR 0.60 for every EUR 1,000 of the contract price, excluding VAT.

Each time that the late penalties reach a multiple of 5 per cent of the price of the contract, excluding VAT, the contracting authority shall be empowered to proceed to terminate it, with retention of the definitive guarantee, or agree to it continuing to be implemented and imposing further penalties.

CIC biomaGUNE shall have the same powers as those referred to in the above sections with respect to breach by the contractor of the envisaged milestones, or when any delay in meeting them makes it reasonable to assume that it is impossible to comply with the whole timeline.

The contracting body may agree to include in Section 10 of the **Cover Sheet** of penalties other than those listed in the aforementioned Article 193.3 of the LCSP with respect to breach by the contractors of the envisaged implementation timeline.

17.2. Penalties for partial breach or defective performance

Section 10 of the **Cover Sheet** may envisage penalties for the case of defective performance of the supply of the deliverable of the contract or in the case of the undertakings that may have been established pursuant to Section 2 of Article 76 or of the special terms and conditions for the fulfilment of the contract of Section 1 of Article 202. Those penalties should be proportional to the seriousness of the breach and the amounts of each penalty may not be over 10 per cent of the price of the contract, including VAT, or their total be over 50 per cent of the price of the contract.

When the contractor, for reasons attributable to the contractor, has partially breached the supply of the deliverable defined in the contract, CIC biomaGUNE may opt, having regard to the circumstances of the case, for the termination of the contract or for imposing penalties that, for such cases, are established in Section 10 of the **Cover Sheet.**

17.3. Compensation for damages and losses

In the cases of partial breach or defective performance or of delay in the implementation where no penalty is envisaged, or should one be in place it does not cover the damages caused to CIC biomaGUNE, the latter shall seek compensation for damages and losses from the contractor.

The penalties envisaged for the causes of partial breach or defective performance or delay in the implementation shall be imposed, after completing the relevant procedure, as resolved by the contracting authority, which shall be immediately enforceable, and shall be paid by means of deducting from the amounts to be paid to the contractor as total or partial payments, or from

the guarantee, should it have been set up, when the amounts cannot be deducted from the aforementioned payments.

In the cases of compensation for losses and damages, it shall be paid from the guarantee, where applicable, without prejudice to the continued existence of the liability of the contractor as regards the amount that exceeds the seized guarantee.

V. RIGHTS AND OBLIGATIONS OF THE CONTRACTOR

18. PAYMENT OF THE PRICE

The contractor shall be entitled to the payment for the supply of the deliverable as per the terms established in the contract, pursuant to the agreed price. Section 12 of the **Cover Sheet** stipulates the terms of payment for this contract.

19. PRICE REVIEW

The price review shall be conducted as per Section 13 of the **Cover Sheet**.

20. COSTS AND TAXES PAYABLE BY THE CONTRACTOR

The contractor shall be required to pay all the costs that the company must cover for the fulfilment of the contract, such as overheads, financial, insurance, transport and travel costs, for materials, facilities, remuneration of their employees, checking and tests, duties and any other type of taxes, VAT, any tax that may be applicable for carrying out the activity, and any others that may arise from the performance of the contract during its term; however, they may not be those passed on as an independent item.

21. DUTY OF CONFIDENTIALITY AND PERSONAL DATA PROTECTION

During the period indicated in Section 14 of the **Cover Sheet,** contractors shall respect the confidential nature of the information to which they have access during the performance of the contract based on – and which is specified, as applicable – on the same action, or which for its very nature must be treated as such.

Furthermore, the contractor shall comply with the personal data protection obligations established in Section 14 of the **Cover Sheet**.

VI. CONCLUSION OF THE CONTRACT

22. REASONS FOR DISCHARGE

The contract is discharged by fulfilment or by termination.

22.1. Discharged by fulfilment of the contract

The contract shall be discharged once performed or fulfilled. The contract shall be taken to be discharged by the contractor when the whole of the purpose of the contract has been fulfilled according to the terms and conditions, and to the satisfaction of CIC biomaGUNE, at the end of its term plus any extensions, if agreed.

22.2. Discharge by termination of the contract

The termination of the contract shall be governed what is generally established in Articles 211 to 213 of the LCSP and specifically by Articles 245 and 246 for works contract, Articles 306 and 307 for supply contracts, Article 313 for service contracts, notwithstanding what is established in Articles 109 to 113 and 172 of the General Regulation of the Public Administration Procurement Act, insofar it remains applicable after the coming into force of the LCSP.

The termination of the contract shall lead to the reciprocal return of the goods and the amount of the payments, and, when that is possible or convenient for CIC biomaGUNE, the latter shall have to pay the price of the goods effectively delivered and accepted.

Grounds for terminating the contract are those that expressly appear in Section 18 of the **Cover Sheet**.

VII. APPLICABLE JURISDICTION

Pursuant to Article 26 LCSP, this contract is private. However, the contentious-administrative law courts shall be competent to settle any disputes arising from the preparation and award of this contract. The civil law courts shall settle any disputes arising from the performance, effects and discharge of the contract. The parties hereby agree to abide by the Courts and Tribunals of San Sebastián and expressly waive any other jurisdiction to which they may be entitled.

In the case of filing a special appeal with regard to contracting envisaged in Article 47 of the LCSP, in the cases in which it may take place, or in the cases of lodging an improper hierarchical appeal, they shall be heard by the Administrative Authority for Contractual Remedies of the Autonomous Community of the Basque Country, set up by Act 5/2010, of 23 December, which approved the General Budget of the Autonomous Community of the Basque Country for 2011.