



***Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR)***

RECORD No.: 2022-028 CRO SERVICES FOR (MuCCUA study / CRESCER Project)

**SPECIFIC ADMINISTRATIVE BIDDING CONDITIONS  
NOT HARMONISED CONTRACTING – OPEN PROCEEDINGS**

**SERVICE FOR HIRING A CRO SPECIALIZED IN THE MANAGEMENT OF PHASE I-IV CLINICAL TRIALS WHO IS IN CHARGE OF DATA MANAGEMENT, MEDICAL WRITING AND BIOSTATISCAL SERVICESFOR THE “MOTHER AND CHILD INTERVENTIONS FOR CHRONIC UNDERNUTRITION IN ANGOLA. A COMMUNITY CLUSTER AND COST-EFFECTIVENESS TRIAL” (MUCCUA STUDY) AS PART OF THE PROJECT “OPERATIVE RESEARCH AGAINST CHRONIC CHILD MALNUTRITION IN ANGOLA” (CRESCER PROJECT)-FED/2020/418-106 FROM FUNDACIÓ HOSPITAL UNIVERSITARI VALL HEBRON - INSTITUT DE RECERCA (VHIR).**



**Funded by  
the European Union**



## **BIDDING PROCEDURE SUMMARY CHART**

### SPECIFIC ADMINISTRATIVE BIDDING CONDITIONS

#### **A. - DESCRIPTION OF THE PURPOSE OF THE TENDER:**

The purpose of this call for tenders is to set the contracting of the service of a CRO specialized in the management of phase I-IV clinical trials, research training, capacity building and clinical trial auditing. for the data management, medical writing and biostatistical services for the study “Mother and Child interventions for Chronic Undernutrition in Angola. A community cluster and cost-effectiveness trial” (MuCCUA study) as part of the **project “Operative Research Against Chronic Child Malnutrition in Angola” (CRESCER project)**- of the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR).

#### **B. - ESTIMATED VALUE OF THE CONTRACT:**

ONE HUNDRED EIGHT THOUSAND EUROS (€ 108.000,00) without VAT.

<b>Concept</b>	<b>Price (VAT not included)</b>
Maximum budget	90.000,00 Euros
Possible modifications	18.000,00 Euros
Possible extensions	00,00 Euros
<b>Total</b>	<b>108.000,00 Euros</b>

#### **B.1. BASE BUDGET FOR TENDER.**

ONE HUNDRED EIGHT THOUSAND NINE HUNDRED EUROS (€ 108.900,00), with VAT.

<b>Item</b>	<b>Value (without VAT)</b>	<b>VAT</b>	<b>Total value (with VAT)</b>
Base budget for tender	90.000,00 Euros	18.900,00 Euros	<b>108.900,00 Euros</b>

#### **C. - DURATION OF THE CONTRACT:**

The duration of the service object of this tender will coincide with the validity of the aforementioned project, which is until **February 14 of 2025**, the completion date of the project's “Operative Research Against Chronic Child Malnutrition in Angola” (CRESCER project),

The start date of the contract will be the one stated during its formalization.



**D. - EXTENSIONS:**

No. However, if this project were to be found, for any of the reasons that are not now can foresee, subject to the request of a possible extension, the end date will be susceptible to being extended, at most to the one that is finally authorized.

**E. - PLACE OF EXECUTION:**

This tender will be carried out according to the following premises:

- The contractor will provide online services free of charge during business hours.
- Business hours are from 9:00 to 18:00, South Africa time. (the supervision of working hours will be carried out by the group responsible for the CRESCER project).
- Travels can be performed upon the request of the investigational team.

**F. - LOTS:** No.

**G. - PROVISIONAL SECURITY:**

Not applicable.

**H. - DEFINITIVE SECURITY:**

5% of the award amount, excluding VAT.

**I. - WARRANTY PERIOD:**

See Clause 21 of these Conditions.

**J. - VARIANTS AND IMPROVEMENTS ACCEPTABLE:**

Yes. Variants and improvements in the bids submitted by participating bidders are acceptable.

**K. - CONDITIONS FOR CAPACITY:**

See Clause 6 of these Conditions.

**L. - SOLVENCY:**

See Clause 6 of these Conditions.

**M. - SUBMISSION OF BIDS:**

**Format and place for presentation:**

Using the Digital Envelope electronic bidding tool, which is integrated into the Public Contracting Services Platform of the Catalan Regional Government?

**Closing date:** May 13<sup>th</sup> of 2022

**Closing hour:** until 11:00 am.

**Format and place of submission:** Using three digital envelopes entitled "Envelope 1, 2 and 3", which must be submitted using the Digital Envelope electronic bidding tool, which is integrated into the Public Contracting Services Platform of the Catalan Regional Government. (See the "Main points on the DIGITAL ENVELOPE" document). The documents and bid summary will be duly encrypted.



## **N.- OPENING OF ENVELOPES NUMBER 2 AND NUMBER 3.**

All envelopes that do not contain administrative information must have a keyword defined for the company, which will encrypt the files in the browser before sending them. It is essential that you keep these keywords, as once the deadline for submission has expired, they will be required by the contracting organism. It is important that you keep this into account as, once the time comes to open the envelopes, if a given company has not provided the previously required keywords, its bid will be discarded outright from the tender in question.

### **OPENING OF ENVELOPE NUMBER 2, CONTAINING THE PROPOSAL TO BE ASSESSED THROUGH THE APPLICATION OF VALUE JUDGMENTS:**

**Date:** May 20<sup>th</sup> of 2022 at 12:00 pm.

**Place:** VHIR, using the Digital Envelope tool. The opening of envelope No. 2 will not be carried out publicly pursuant to the Report of the Directorate-General of Public Contracting of the Catalan Regional Government of 12 April 2019.

### **OPENING OF ENVELOPE NUMBER 3, WHICH CONTAINS THE PROPOSAL TO BE ASSESSED THROUGH THE APPLICATION OF CRITERIA THAT CAN BE QUANTIFIED THROUGH THE APPLICATION OF AUTOMATIC FORMULAE:**

**Date:** June 1<sup>st</sup> of 2022 at 09:30 am.

**Place:** Sala d'Actes, Planta 2a, Edifici Mediterrània (VHIR), through the Digital Envelope tool. Public opening.

[https://teams.microsoft.com/dl/launcher/launcher.html?url=%2F\\_%23%2F%2Fmeetup-join%2F19%3Ameeting\\_ZmZjZjIwZGEtZjk2OS00ZGE0LTk2MGMtYWU2ZGRINWEzZTY1%40thread.v2%2F0%3Fcontext%3D%257b%2522Tid%2522%253a%2522f7db6655-27bc-4cb5-9419-2b135ddaf536%2522%252c%2522Oid%2522%253a%25226b813aaf-759e-430e-8032-0df1d99aaaa5%2522%257d%26anon%3Dtrue&type=meetup-join&deeplinkId=f94a7134-0bcc-43d7-9507-5662d9521720&directDI=true&msLaunch=true&enableMobilePage=true&suppressPrompt=true](https://teams.microsoft.com/dl/launcher/launcher.html?url=%2F_%23%2F%2Fmeetup-join%2F19%3Ameeting_ZmZjZjIwZGEtZjk2OS00ZGE0LTk2MGMtYWU2ZGRINWEzZTY1%40thread.v2%2F0%3Fcontext%3D%257b%2522Tid%2522%253a%2522f7db6655-27bc-4cb5-9419-2b135ddaf536%2522%252c%2522Oid%2522%253a%25226b813aaf-759e-430e-8032-0df1d99aaaa5%2522%257d%26anon%3Dtrue&type=meetup-join&deeplinkId=f94a7134-0bcc-43d7-9507-5662d9521720&directDI=true&msLaunch=true&enableMobilePage=true&suppressPrompt=true)

**In case the link does not work, please copy and paste the link in your default browser.**

## **O. - CRITERIA FOR THE AWARDING OF THE CONTRACT:**

As per **Appendix number 2** of these Conditions.

## **P. - MODEL FOR BIDS CONCERNING THE CRITERIA TO BE ASSESSED THROUGH FORMULAS:**

As per **Appendix number 1** of these Conditions.

## **Q. - MODIFICATION OF THE CONTRACT:**

Specific clauses on modifications to the contract have been established.

## **R. - ASSIGNATION OF THE CONTRACT:**

See clause 22 of these Conditions.



**S. - PROCESSING:**

Ordinary, through the open procedures established in articles 156 to 158 of the Public Sector Contracting Law.

**T. - PUBLICATION:**

Contracting profile:

Available on the website of the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR):

[http://www.vhir.org/portal1/article\\_menu\\_llistat\\_licitacions.asp?s=institut&contentid=1348](http://www.vhir.org/portal1/article_menu_llistat_licitacions.asp?s=institut&contentid=1348)

As well as in the public contracting section of the Catalan Regional Government:

<https://contractaciopublica.gencat.cat>

**U. - INFORMATION AND TROUBLESHOOTING SERVICE AVAILABLE TO BIDDERS:**

Any doubts, questions and/or requests for information must be sent in writing to the following email address: [contractacio.publica@vhir.org](mailto:contractacio.publica@vhir.org), 5 days before the end of the closing date for the submission of bids at the latest. The subject of the message must contain the code/record No.

Likewise, interested parties are hereby notified that the information concerning the processing state of these proceedings shall be published on the contracting profile, including any relevant clarifications and statements as appropriate. Interested parties are advised to regularly check the Contracting Profile to remain up-to-date on the situation of contracting procedures.



### SPECIFIC ADMINISTRATIVE BIDDING CONDITIONS

SERVICE CONTRACT  
PROCESSING: Ordinary  
PROCEDURE: Open  
REGULATION: Not Harmonized

code	Contract	2022-028 CRO SERVICES FOR (MuCCUA study / CRESCER Project)
	Contract description	SERVICE FOR HIRING A CRO SPECIALIZED IN THE MANAGEMENT OF PHASE I-IV CLINICAL TRIALS WHO IS IN CHARGE OF DATA MANAGEMENT, MEDICAL WRITING AND BIOSTATISCAL SERVICESFOR THE "MOTHER AND CHILD INTERVENTIONS FOR CHRONIC UNDERNUTRITION IN ANGOLA. A COMMUNITY CLUSTER AND COST-EFFECTIVENESS TRIAL" (MUCCUA STUDY) AS PART OF THE PROJECT "OPERATIVE RESEARCH AGAINST CHRONIC CHILD MALNUTRITION IN ANGOLA" (CRESCER PROJECT)-FED/2020/418-106 FROM FUNDACIÓ HOSPITAL UNIVERSITARI VALL HEBRON - INSTITUT DE RECERCA (VHIR).
	CPV Code	73200000-4

## I. GENERAL PROVISIONS

### CLAUSE 1.- PURPOSE AND LEGAL FRAMEWORK OF THE CONTRACT

1.1 The purpose of these Specific Administrative Bidding Conditions is to lay down the conditions that will govern the awarding by the Fundació Hospital Universitari Vall Hebron – Institut de Recerca (hereinafter, "VHIR" or "the contracting entity"), the services object whereof is described in **section A** of the Summary Chart. The aforementioned conditions are defined in this document and its appendices.

The indication on the non-division into lots of the contract appears in section F of the Table Summary of Features.

1.2 The contracting entity is subject to the provisions of Law 9/2017, of 8 November, of Public Sector Contracts, by which they are transferred to the Spanish Legal Directives of the European Parliament and of the Council 2014/23 / EU and 2014/24 / EU, of February 26, 2014 (hereinafter, "LCSP"), relating to contracting not harmonized than as a contracting authority that does not have the character of Administration Public are applicable.



In relation to the eventual contractual modifications that may occur, it will be application of the regime provided for in subsection 4 of Section 3 of Chapter I of the Title I of the LCSP.

1.3. The contract is considered a private contract and is subject, in terms of its effects and termination, to private law, governed by this Specification, by the contract and documentation attached, and in everything not provided for, by civil and commercial legislation applicable.

In the preparation and award of this contract, the provisions in Title I of the Third Book of the LCSP.

1.4. To resolve any discrepancies that may arise from the preparation, adjudication and contractual modifications, when the latter are based on non-compliance of what is established in articles 204 and 205 of the LCSP, when it is understood that said modification should have been the subject of a new award, the parties shall submit to the contentious-administrative jurisdictional order.

To resolve any discrepancy that may arise in relation to the effects and termination of this contract, the parties will submit to civil jurisdiction.

1.5. This List of particular administrative clauses, its annexes and the List of Particular technical requirements will be of a contractual nature. The contract will be adjusted to the content of this Specification, whose clauses will be considered an integral part of the respective contract.

1.6. The presentation of proposals implies the unconditional acceptance by the bidders of the content of this Specification and of all the documentation that makes up this tender, without any exception, condition or reservation.

1.7. The interpretation of the contract and the discrepancies on its application will be made taking into account taking into account, in the first place, the Specifications of particular administrative clauses and the technical prescriptions, which will prevail over any other standard.

Ignorance of the contract in any of its terms and of the other documents contractual of all kinds that may have application in the execution of the agreement, not exempt the successful bidder from the obligation to comply with them.

1.8. In the event that this Specification is translated into other languages, in the event of discrepancy, the version in Spanish will prevail.

## **CLAUSE 2.- ESTIMATED CONTRACT VALUE, BASE BUDGET FOR TENDER AND CONTRACT VALUE**

2.1. The estimated contract value for the purpose of establishing awarding procedures, publication and the competence of the contracting organism is that which is stated in **section B** of the summary chart, and it does not include Value-Added Tax.



This estimated value has been calculated in conformity with the contents of article 101 of the LCSP. This value is the sum of the base budget for tender with any possible modifications and, when applicable, extensions or other options, in the terms established in these Conditions.

2.2. The base budget for tender of this contract is the figure stated in **section B.1** of the summary chart.

The breakdown of the base budget for tender is stated in **Appendix No. 5** of these Conditions.

This base budget includes all assessment factors and any expenses which shall be borne by the successful bidder pursuant to the contractual documents and currently applicable legislation, as well as taxes of any nature, including Value-Added Tax.

Any bids for an amount greater than the base budget for tender or the prices per unit in which it is broken down shall be discarded outright.

2.3. The contract value shall be the value for which the tender is awarded plus the appropriate Value-Added Tax, which shall be stated under a separate heading.

The contract value shall be deemed to include all other taxes, levies and royalties of any nature that may be applicable, as well as any expenses to be borne by the successful bidder pursuant to the attached contract model a, the Specific Administrative Bidding Conditions and attached documents.

The award value shall under no circumstances exceed the base budget for tender. In the event that the bidder should exceed this or any other value, he or she shall be excluded from the procedure outright.

The VHIR shall not be bound to spend the entirety of the budget for tender, but rather, only those services that are effectively provided based on the prices offered shall be billed.

2.4. The value of the contract shall not be subject to review.

2.5. It is hereby stated that sufficient credit is available to fulfil the financial obligations arising from fulfilment of the contract that is the object of this document by the contracting entity until its conclusion.

### **CLAUSE 3.- DURATION OF THE CONTRACT**

The duration of the contract is the period stated in **section C** of the summary chart or, as appropriate, the one stated by the bidder, whichever is shorter.

The duration of the contract shall begin at the date established for the underwriting thereof.





#### **Possibility of project extension. No**

However, if this project were to be found, for any of the reasons that are not now can foresee, subject to the request of a possible extension, the end date will be susceptible to being extended, at most to the one that is finally authorized.

In this case, the extension will be agreed by the contracting body and will be mandatory for the successful bidder, in accordance with the provisions of article 29 of the LCSP.

#### **CLAUSE 4.- INVITATION TO TENDER, CONTRACT AWARDING PROCEDURE AND DOCUMENTS TO BE PROVIDED TO BIDDERS**

1. Contracting of the aforementioned service shall be awarded through the open procedures established in articles 156 to 158 of the LCSP.

The contract will be awarded to the submission with the best overall value to money according to the award criteria stated in **Appendix No. 2** of these Conditions.

2. **NEED AND SUITABILITY OF THE CONTRACT:** The needs to be satisfied by the contracting entity through this contract are those stated in the agreement on need.

3. **DOCUMENTS TO BE PROVIDED TO BIDDERS:** From the date of the publication of the invitation to tender onwards, interested companies may obtain the necessary documents to submit their proposals through the Contracting Profile through the websites stated in **section T** of the Summary Chart. Said documents include the following:

- These Specific Administrative Bidding Conditions (PCAP).
- Appendix 1 (PCAP).
- Technical Specifications.
- Main points on the Digital Envelope.
- European Single Procurement Document (ESPD)
- Instruction on filling in the ESPD.

All of the above documents shall be of a contractual nature. Likewise, it is hereby stated that the model contract attached as an Appendix hereto governs the obligations of the contractor, including but not limited to means of payment, conditions for execution, contracting, payments to subcontractors and providers, penalties, termination of the contract, etc., which must therefore be taken into account by prospective bidders.

Pursuant to article 138.3 of the LCSP, the contracting organism shall provide all interested parties with additional information concerning the Conditions and other complimentary documentation they may request 6 days prior to the expiry of the term to submit bids



whenever they have been requested at least 5 days prior to the closing date for the submission of bids.

4. Contract manager: A contract manager shall be appointed by the contracting entity, and his or her identity shall be disclosed to the successful bidder once the contract has been awarded. The aforementioned manager shall be in charge of supervising the execution thereof and adopting any decisions and issuing any instructions that may be required to ensure the proper execution of the contracted provision within the scope of the powers vested unto him or her.

5. CONTRACTING ORGANISM: The contracting organism for this contract, in view of the value thereof, is the Director of the VHIR.

## **CLAUSE 5.- PUBLICATION OF THE INVITATION TO TENDER**

This invitation to tender shall be published through an announcement on the Contracting Profile, which may be accessed in the manner stated in **section T** of the Summary Chart through the website of the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR):

[http://www.vhir.org/portal1/article\\_menu\\_llistat\\_licitacions.asp?s=institut&contentid=1348](http://www.vhir.org/portal1/article_menu_llistat_licitacions.asp?s=institut&contentid=1348)

As well as through the public contracting section of the Catalan Regional Government:

<https://contractaciopublica.gencat.cat>

## **II. BIDDING PROCEDURES**

### **CLAUSE 6- CONDITIONS ON THE CAPACITY AND SOLVENCY OF BIDDERS**

1. Any Spanish or foreign individual or corporation with full capacity to act pursuant to article 65 of the LCSP, who do not incur in any of the grounds for exclusion from contracting stated in article 71 of the aforementioned Law and who can certify the level of solvency required herein and who are endowed with the professional or corporate certification that may be required to carry out the activity or service provision that is the object of this contract, may contract with the contracting entity.

The requirements for capacity, solvency and absence of grounds for exclusion from contracting must be fulfilled at the time of the submission of the bid and must be maintained until the moment of the awarding and underwriting of the contract.

2. Pursuant to article 75 of the LCSP, solvency may be certified based on the solvency and means of other entities, regardless of the legal nature of extant bonds, whenever it is certified that the aforementioned means will be available for the execution of the contract. Moreover, in what concerns academic or professional diplomas or professional experience, the capacity of other entities may only be invoked whenever they are to execute the part of



the object of the contract for which said qualifications are required. The aforementioned third parties shall have to certify their capability, suitability and solvency as required in these conditions.

Should the bidding company invoke the capacity of other companies to certify its financial and/or technical solvency pursuant to the provisions of article 75 of the LCSP, or should it intend to subcontract, it must clearly state this in the ESPD as per section 9.1.1 of these Conditions and submit another ESPD for each of the companies the capacity whereof it invokes or which it intends to subcontract, duly signed.

In the event that the economic and financial solvency of other entities is invoked, the bidder and the entities with which it cooperates for the performance of this contract shall be jointly responsible for the execution thereof.

3. Bidding companies must fulfil the criteria for solvency below. Notwithstanding this, only the company or companies proposed as awardees shall have to submit documents to certify fulfilment of these requirements. Notwithstanding the above, the contracting party may request certification of these facts from bidders at any time prior to the proposal for award.

#### **A) Financial and economic solvency:**

- Statement on overall turnover and, if appropriate, on turnover in activities corresponding to the purpose of the contract during, at the latest the last three years available based on the date of creation and/or beginning of the activities of the company, insofar as figures for turnover are available. Overall yearly turnover must amount to at least 1,5 times the tender value of the service for which they are bidding.

In the event that a company could not provide the requested references for justified reasons, it may certify its economic and financial solvency through any other means deemed sufficient by the contracting entity.

#### **B) Technical or professional competence:**

- A statement of the main services of an equal or like nature to that of the object of the contract that have been carried out over the course of the last three years, including the values, dates and public or private recipients thereof. The aforementioned works or services must be certified through certificates issued by the competent organism in the event that the recipient was a public sector entity or, when the recipient was a private company, through the issuance of a certificate by the same. In the absence of certificates, the provision of services may be certified through a statement by the entrepreneur.

(\*) Entrepreneurs must certify to have executed a minimum value of 135.000,00 Euros over the course of the aforementioned period, excluding taxes.



4. Foreign non-EU companies must likewise fulfil the requirements established in article 68 of the LCSP.

5. The contracting entity may contract with joint ventures that may be incorporated for this purpose on a temporary basis. This participation shall be implemented during the bidding phase through the submission of a private deed stating the will to submit a bid jointly, specifying the names and information of those constituting said union, the share held by each of them and appointing a single representative or agent with sufficient powers to exert the rights and fulfil the obligations derived from the contract until the termination thereof, notwithstanding the existence of joint and several powers in other aspects, and undertaken the commitment to formally constitute themselves as such in the event that they are awarded the bid. It shall not be necessary to formalize it in a public deed until the bid has been awarded to them.

The aforementioned contractors shall be jointly liable before the contracting entity.

The formalization of the aforementioned joint venture in a public deed shall not be required until the contract has been awarded to it.

6. The contracting organism shall adopt any measures that may be required to ensure that the participation of companies that have participated in the drafting of the technical specifications or the preparatory documents for the contract, or that may have provided counselling to the contracting organism during the drafting of the contracting procedure, does not distort competition. In any event, the rules laid down in article LCSP shall be observed.

In the event that a bidding company or a company related thereto may have participated in the drafting of the technical specifications or of preparatory documents for the contract, this fact must be stated expressly, specifying the nature of its participation and submitting the appropriate affidavit in Envelope No. 1.

7. Companies may only be awarded contracts the performance whereof is featured among the corporate purposes, object or field of activity stated in their articles of incorporation or founding rules.

8. Bidders with fifty or more permanent employees shall have to feature at least two percent of employees with disabilities with regard to the entirety of their staff or to fulfil the alternative measures established in Royal Decree 364/2005, of 8 April, or any law that may replace it.

## **CLAUSE 7.- BIDDERS' PROPOSALS: GENERAL RULES**

1. Bids must be submitted within the maximum deadline established in **section M** of the Summary Chart and the Invitation to tender. Submissions submitted after the due date shall not be accepted under any circumstances.



All bidders must provide an address, telephone number, fax number, e-mail address and contact person for any communications and liaisons that may arise from these proceedings or that may affect the bidder in any way at the time of the submission of their bids.

2. Bids must be valid for four months from the date of the opening of the submissions. After this period, bidders may choose to maintain or withdraw their proposals, upon which the parties will hold each other harmless and shall not be entitled to request any manner of indemnities or compensation. Bids that have not been withdrawn shall be deemed to be valid and binding to bidders for all intents and purposes according to these Conditions.

No bidder may underwrite a bid jointly with other bidders if they have already done so individually or participate in more than one such grouping. Any breach of the prohibition established in this paragraph shall lead to the refusal of all submissions made by said bidder.

4. Simultaneous submissions from related companies shall imply the effects established herein concerning the application of the regime for submissions with abnormal or disproportional values.

5. Should the bid be for a contract the purpose whereof is the surveillance, supervision, monitoring, control or direction of any contract, as well as coordination in matters of health and safety, said contract may not be awarded to the same company to which the corresponding contract has been awarded nor to a company related thereto.

## **CLAUSE 8.- FORMAT FOR THE SUBMISSION OF BIDS AND DIGITAL MEANS OF COMMUNICATION: GENERAL RULES**

### *Electronic submission.*

1. Bids must feature three (3) envelopes upon which the tender is stated. The contents of each envelope must likewise be stated thereon, broken down into a numerical list.

Envelope number 1 must contain the documents certifying the prior requirements stated in article 140 of the LCSP. Envelope number 2 must contain documents to be assessed in conformity with the criteria to be graded based on value judgments, and Envelope number 3 must contain the financial offer or aspects the assessment whereof depends on automatic formulae, which must be drafted according to the model attached hereto as **Appendix No. 1**.

The documents contained in envelope No. 2 may not contain any information that would disclose the contents of envelope No. 3 with regard to the financial submission and technical documentation on criteria to be assessed automatically. Failure to comply with this obligation will imply exclusion from the tender.

Bidders may state which information of their proposal is of a confidential nature. The financial submission may under no circumstances be declared confidential. The contracting organism will guarantee the confidentiality of any information expressly classified as such within the boundaries of the law and whenever it does not affect the right to information of



the rest of bidders in conformity with the provisions of applicable legislation on the subject of access to public information.

2. Bidding companies must submit documentation confirming their offers within the deadline stated in the invitation to tender using the Digital Envelope tool, which can be accessed by following the link below: <https://contractaciopublica.gencat.cat>  
**(See the "Main points on the Digital Envelope" document).**

Once they have accessed the Digital Envelope web tool through the link above, bidding companies shall have to fill in a form to register an account in the tool, after which they will be sent a message to the email address stated on the registration form for the activation of the submission<sup>1</sup>.

**Bidding companies must keep the email address used to activate the submission due to the fact that the link contained in the activation message is their exclusive means of access to file their submissions using the Digital Envelope tool.**

Once they have accessed the website for the submission of bids through the link thus provided, bidding companies must prepare all required documents and attach them in digital format to the appropriate envelopes. Bidding companies may prepare and send these documents in stages before submitting their bid.

3. In order to begin processing the documents, the tool will prompt bidding companies to enter a **keyword** for each envelope with encrypted information that is a part of the bid (no keyword shall be required for envelope A, as its contents are not encrypted). This keyword shall be used to encrypt the documents when the bids are sent.

Likewise, the decrypting of submitted documents shall be carried out using the same keyword, which must be kept by bidding companies. It is necessary to keep in mind the importance of properly storing this or these keywords (they may be the same for all envelopes or a different one for each) as only bidding companies shall have them (the Digital Envelope tool does not store or save passwords) and they are essential to decrypt submissions and, therefore, to access their contents.

4. The Contract awarding committee shall request bidding companies to access the Digital Envelope web tool to enter their keywords at the appropriate time by sending them an email to the email address stated in the registration form for the Digital Envelope tool.

Once the bidding companies have entered their keywords, the decryption process will begin for the documents, which will be stored in a secure virtual space that guarantees the inaccessibility of the documents before the constitution of the contract awarding committee, as appropriate, and the opening of the envelopes at the stated date and time.

**Bidding companies shall be requested to enter the keyword 24 hours after the deadline for the submission of bids has expired and, in all cases, they shall have to enter it prior to the opening of the first encrypted envelope, namely envelope No. 2.**

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<sup>1</sup> Email addresses provided by bidding companies in the registration form for the Digital Envelope Tool, which shall be the ones used to send email messages concerning the use of the Digital Envelope Tool, must be the same as those stated in the DEUC to receive the appropriate notices and notifications.



**As it is established in the document "Main points on the Digital Envelope", if the Contract awarding committee has not received the keywords that have been duly requested from bidding companies at the date of the opening of Envelope No. 2, said company shall be automatically excluded from the proceedings.**

5. Once all of the documents for the submission have been filled in and the documents that make it up have been attached, the submission of the bid per se may be carried out. From this point onwards, any documents that have been provided will no longer be modifiable.

In the event that any of the documents submitted by bidding companies is damaged, blank, illegible or infected by a virus, the contract awarding committee will consider the legal consequences concerning the participation of said company in the proceedings that would arise from the inability to access any of the documents in the submission based on which documents have been affected. If the documents in question are essential to know or assess the submission, the committee may decide to exclude said company.

Bidding companies may submit a backup copy of submitted digital documents in physical digital format, which will be requested from bidding companies as required in order to access the contents of documents that have been damaged. In this respect it is necessary to keep in mind that it is important not to manipulate these files in order not to alter their digital footprint, which will be checked to ensure the concordance of the documents with the backup copies that have been sent in physical digital format and those that have been sent in the submission through the Digital Envelope tool.

6. The following formats will be accepted for digital documents:

**- PDF.**

7. Submissions from parties that incur in any of the circumstances stated in article 71 of the LCSP on exclusions from contracting shall not be accepted under any circumstances. Any submissions that are incomplete, anomalous, or that contain omissions, mistakes or statements that do not allow for a correct understanding of their terms and, ultimately, do not allow for a clear knowledge of the conditions to assess the submission or may lead to error, will likewise be excluded from the procedure.

8. Pursuant to additional disposition fifteen of the LCSP, the processing of this Invitation to tender implies the sending of notices and notifications as appropriate exclusively through electronic means.

Notwithstanding the above, spoken communication may be use for any notifications other than those concerning essential elements, that is, the conditions and submissions, duly documenting the contents of the aforementioned spoken communication, for instance, through written or recorded records of the main elements of communication.

Periods of time after notifications will be computed from the date on which said notifications were sent should the object of the notification have been published on the same day on the profile of the contracting organism's contracting profile. Failing that, time will be counted from receipt of the notifications thus sent by the recipient company. Notwithstanding this, the terms of notifications that have been carried out concerning special appeal procedures before the Catalan Contracts Court shall be counted from the date on which the notification warning was sent.



9. Moreover, in order to receive any information concerning this tender, companies that wish so and, in all cases, bidding companies must be recorded as interested parties in this tender through the update subscription service of the virtual bidding space made available to them for this purpose on the contracting profile of the contracting organism and which can be accessed on the Public Contracting Services Platform of the Catalan Regional Government: <https://contractaciopublica.gencat.cat>

This subscription will allow for notifications on any news, publications or warnings to be sent immediately to the email addresses of subscribers.

Likewise, certain notifications to be carried out as a consequence of the bidding and awarding procedures for this contract shall be made on the notice board associated to the virtual bidding space for this tender on the Public Contracting Services Platform. This digital notice board, which contains faithful information on the authenticity, integrity, date and time of publication of published information, will also contain information concerning the tender and the contract.

10. Digital certificates. Pursuant to the first additional disposition of DL 3/2016, the use of an advanced electronic signature based on a quality certificate or an acknowledgment of electronic signatures under the terms established in Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC, will be sufficient. Therefore, this is the minimum required safety level of the electronic signature certificate that will be accepted for the signing of the ESPD and the submission.

With regard to foreign EU certificates, certificates from any country in the European Union will be accepted pursuant to the aforementioned Regulation (EU) No 910/2014 on electronic identification and trust services, which states that “a qualified electronic signature based on a qualified certificate issued in one Member State shall be recognized as a qualified electronic signature in all other Member States”.

## **CLAUSE 9.- SUBMISSIONS BY BIDDERS: DOCUMENTS**

### **9.1. Documents to certify compliance with prior requirements**

#### **ENVELOPE 1**

**Title:** Documents certifying compliance with prior requirements.

#### **CONTENTS:**

“Envelope 1” must contain the document(s) stated below:

##### **9.1.1. European Single Procurement Document (ESPD).**

The contracting organism will accept a European Single Procurement Document (ESPD) that has been duly filled in and updated as preliminary evidence of the fulfilment of the





legally established provisions to contract with the public sector as well as of the requirements for capacity and solvency established herein.

Therefore, bidding companies must submit the ESPD through which they declare their capacity and economic, financial and technical solvency in conformity with the minimum requirements stated in these conditions; that they do not incur any of the grounds for exclusion from contracting or, if so, that they have adopted measures to demonstrate their trustworthiness in all legally appropriate cases; that they are up to date in the payment of their tax and social security obligations, and they comply with all other requirements stated herein.

Bidding companies may fill in the ESPD form through the online service of the European Commission through which it is possible to import the ESPD model for this tender, fill it in, download it and print it out for submission. The model for this document can be downloaded from the following link:

<https://visor.registrodelicitadores.gob.es/espd-web/filter?lang=es>

Moreover, the specific instructions on filling in the ESPD are also available as an additional document in the file for this tender. These may be accessed at the following link:

[https://ec.europa.eu/isa2/solutions/european-single-procurement-document-espd\\_es](https://ec.europa.eu/isa2/solutions/european-single-procurement-document-espd_es)

Special aspects concerning temporary joint ventures:

- a. Each entrepreneur in the joint venture must submit the appropriate ESPD or affidavit.
- b. It is necessary to submit a document certifying the appointment of a single representative of attorney endowed with sufficient powers to exercise the rights and fulfil the obligations arising from the contract until the termination thereof, as well as a statement of the names and information of the entrepreneurs underwriting it, the share held by each one of them, and their commitment to formally constitute a joint venture in the event that the contract is awarded to them.
- c. The temporary Tax Identity Number assigned by the competent administration may also be attached. It shall not be necessary to formalize it in a public deed until the bid has been awarded to the joint venture.

Other special aspects:

- Whenever an entrepreneur invokes the solvency and means of other entities, each one of them shall have to submit a duly filled in ESPD form.

**The contracting organism will prompt the company to which the contract will be awarded so that it may certify compliance with the requirements for personality, capacity and solvency by submitting the documents stated in clauses 6 and 12 of these Conditions prior to the awarding of the contract.**

In any event, the contracting organism may request that bidders submit documents certifying compliance with the conditions established to be awarded the contract laid down in the aforementioned clauses 6 and 12 of these Conditions at any time prior to the adoption of the proposal for award.

**9.1.2. Should a company wish to invoke the capacity of other entities, it will have to submit the written commitment of the aforementioned entities pursuant to the provisions of article 75.2 of the LCSP.**



**9.1.3. Document certifying the constitution of the provisional security whenever it is required pursuant to section G of the Summary Chart.**

This security shall guarantee the maintenance of offers until the conclusion of the contract, and it may be provided in some of the ways established in section 1 of article 108.

The provisional security shall be automatically terminated and returned to bidders after the conclusion of the contract.

**9.1.4. In the event that several entrepreneurs should participate together in a joint venture, a commitment to constitute said joint venture must be provided in accordance with the provisions of article 69.3 of the LCSP.**

**9.1.5. In the event that the contract is executed in Spain, foreign companies must submit a statement whereby they submit to the jurisdiction of the courts and tribunals of Spain of any order for all matters directly or indirectly arising from the contract, expressly waiving any foreign jurisdictions that might apply to them.**

**9.1.6. Affidavit concerning the part or parts of work that will be subcontracted and, if this information is available, the names of the contractors.**

**ENVELOPE 2**

**Title:** Technical submission and/or references the assessment whereof is based on judgment values.

**CONTENTS:**

**9.2.** Technical submission and/or references the assessment whereof is based on judgment values

Bidders must include all technical aspects of the bid being submitted in this envelope. Said information must be clearly stated and the contents of the envelope must be indexed in numerical order, and the contents and requirements stated in the Technical Specifications must be presented in accordance with the contents.

Based on the principles of equality and non-discrimination, accepted bidders may be invited to complete and make more explicit the certificates and documents in envelope No. 2 whenever it is deemed necessary for better knowledge of the submission in question.

This proposal will be assessed based on the award criteria established in **Appendix No. 2** of these Conditions.

**ENVELOPE 3**

**Title:** Financial submission and other references that can be assessed automatically.

**CONTENTS:**

"Envelope 3" must contain the document(s) stated below:



**9.3.** The financial offer and other references that can be assessed automatically must be formulated according to the model attached hereto as **Appendix No. 1**.

With regard to the financial offer, all manner of necessary expenses, arbitrations or fees arising from the Contract and its proper execution shall be deemed to be included in the offered price.

Moreover, the submitted price must contain a separate heading for the currently-applicable Value-Added Tax. Any changes in VAT rates shall be applicable from the date of their validity onwards.

Failure to follow the submission model established in **Appendix No. 1** shall imply the exclusion of the submitting company.

Any submissions for an amount greater than the base budget for tender or per unit prices in which it is broken down will be excluded outright.

#### **CLAUSE 10.- CRITERIA FOR THE AWARDING OF THE CONTRACT.**

1. Submitted and accepted bids will be analyzed, assessed and analyzed based on the criteria contained in **Appendix No. 2** hereof.

The submission of a submission/bid by a bidder implies that the same has been made in accordance with the law and that it can be executed under the terms stated. This responsibility shall in no way be affected or reduced by the fact that the bid may have been assessed or accepted by the parties in charge of the contracting entity.

2. The contract will be awarded to the bid displaying the best value for money, which will be that which obtains the best score among all bids accepted in the tender that match or surpass the minimum score established herein. Should none of the bids achieve the minimum required score to be awarded the contract based on the criteria for award, all offers will be turned down and this invitation to tender will be declared null and void.

The award decision shall be justified and, unless it contradicts the offer made by the contract awarding committee or it is based on different considerations, it shall be understood to adopt the reasons contained in the proposal of the aforementioned Contract Awarding committee.

3. Allegedly abnormal or disproportionate submissions will be examined in accordance with the provisions of **Appendix No. 2**.

Should a submission be identified as allegedly abnormal or disproportionate based on the application of these criteria, the contracting organism will request from affected bidders any information and justifications it deems fit concerning the different components of the



submission in writing from the affected bidders. This procedure must be carried out within a maximum period of three working days.

Once the requested information and justifications have been received, the contracting organism will request a technical report from the technical services of the entity to assess the justifications provided by bidders incurring in an alleged abnormal or disproportionate submission.

The relationship between the financial offer made by the bidder and the other elements offered will be taken into account for the analysis of the justification of submissions that may be deemed abnormal or disproportionate.

Based on the justification of the bidder and the technical report, the contracting organism will assess whether or not the submission may be fulfilled by the bidder as a consequence of the inclusion of abnormal or disproportionate values. Should the submission be deemed to be abnormal or disproportionate, the contracting organism shall exclude it from the tender procedures.

Should an abnormally low offer reveal that the per unit prices of salaries for the employees involved in the submission are below the values established in the applicable collective agreement, a complementary technical report may be requested from a labor union or trade union in order to verify the suitability of the offer in relation to wage prices.

Likewise, submissions will be excluded in the event that, during the hearing proceedings for a bidding company that has submitted a bid that has been deemed to be abnormally low, it is revealed that the per unit prices of salaries for the employees who will execute the contract are below those established in their collective agreement.

4. In the event of a tie between the scores obtained by bids from bidding companies, the following shall be given priority for the awarding of the contract:

- The bid submitted by those companies with over 2% of employees with disabilities in their staff at the time of the certification of their technical solvency, whenever their submissions match the most advantageous one in terms of the criteria used as the basis for the award.
- Bidding companies with the highest number of permanent employees with disabilities in their staff will be given preference for the award.
- Bids submitted by entities acknowledged as Fair Trade Organizations shall be given preference for the award of contracts the object whereof is products for which there are fair trade alternatives.
- Propositions submitted by companies which include measures of a social and labor nature promoting equal opportunities between men and women by the closing date of the period for the submission of bids.



Should the tie persist once the additional award criteria have been applied, the contract will be awarded through a draw that will be carried out in public after having published a call on the Contracting Profile.

#### **CLAUSE 11. - CONTRACT AWARDING COMMITTEE**

The Contract Awarding Committee is made up from the following members:

President: Mr. Xavier Bros Marín, VHIR Finance Coordinator.

Member: Ms. María de Valles Silvosa, Director of the HR and Legal Unit of the VHIR.

Member: Ms. Esperanza Esteban Serna, International Project Manager PROSICS (Programa de Salud Internacional del Instituto Catalán de Salud)

Secretary: Ms. Mireia Casamajor Castañeira, Head of the VHIR Tenders and Procurement Unit.

During the constitution of the Contract Awarding Committee, its members will issue statement on the existence or inexistence of any prior incompatibilities of a general nature according to the LCSP. In the event that an incompatibility should exist, the member of the Committee affected by the same shall have to leave said committee and, in this case, the substitute member would occupy his or her place or another member who would fulfil any requirements for experience and suitability would be appointed to replace the member incurring in the aforementioned incompatibility.

#### **CLAUSE 12.- OPENING AND EXAMINATION OF THE SUBMISSIONS**

1. Once the term established in the call for the submission of bids has expired, "Envelope 1" will be opened in order to verify that it contains the documents established in clause 9.1 hereof and to qualify the validity thereof.

The Contract Awarding Committee may request from bidders that they submit the entirety or part of the documents certifying their suitability, capacity and solvency for the purpose of verifying any one of the points in the statement on the fulfilment of prior requirements whenever it deems there to be reasonable doubts on the validity or trustworthiness of the statement, or whenever it is required to ensure the good development thereof. The deadline to contribute the required documentation shall be five days from the receipt of the aforementioned request.

2. Following that, if appropriate, bidders will be notified of the existence of any amendable defects or omissions and a deadline will be set for the bidders to submit their statements. This deadline shall under no circumstances be greater than three calendar days from the date of the aforementioned notification.

Defects that involve failure to fulfil requirements shall be deemed to be unamendable, and those that refer to a mere lack of certification thereof shall be deemed to be amendable. The decisive moment to assess compliance with the requirements for capacity in order to enter into the contract shall be the end of the delay for the submission of bids.



Any bidders who display unamendable defects or who have failed to amend any defects within the period of time granted shall not be accepted and excluded forthwith.

Moreover, the Contract Awarding Committee may request clarifications from bidders concerning the certificates and documents that have been submitted or to request that they submit additional documents or certificates.

3. Failure to submit any of the documents required in Envelope 1 shall be grounds for exclusion from the tender procedure unless the Contract Awarding Committee deems it to be amendable and it is amended within the allotted period of time.

Submissions from entrepreneurs who have been excluded from the tender shall be excluded from the awarding procedures and the envelopes that contain them shall not be opened.

4. In a period no longer than twenty days counting from the closing date for the submission of bids, at the date, time and place stated in the invitation to tender or through the information published on the Contracting Profile, the Contract Awarding Committee shall open envelope number 2, disclosing the information concerning the opening of envelope number 1.

The technical services of the entity will assess the submissions contained in Envelope 2 in accordance with award criteria that can be analyzed based on value judgments established in **Appendix No. 2** hereof and shall submit said assessment to the Contract Awarding Committee.

The Contract Awarding Committee may request that bidders submit any additional information it deems fit for the purpose of clarification concerning Envelope No. 2, which must be provided to the Contract Awarding Committee within the deadline established to this end and which shall under no circumstances be longer than 5 days.

5. Once the criteria that depend on value judgments have been assessed, bidders shall be notified of the date for opening the documents contained in Envelope 3. This date shall likewise be published on the Contracting Profile. The opening of Envelope 3 will be carried out in a public event.

Prior to the opening of Envelope 3, the entity shall previously disclose the grades obtained by accepted bidders concerning the submissions contained in Envelope 2 through the Contracting Profile and on the day of the public opening of Envelope 3.

Moreover, when appropriate, any bidders that have been excluded shall be notified of their exclusion and of the grounds for the same, and Envelope 3 shall be opened for those submissions that have been accepted.

Prior to the opening of the first submission, attending bidders shall be invited to make any questions they might have or request any explanations they see fit. The Contract Awarding Committee will provide the appropriate clarifications and answers, but it will not be able to process any documents that were not delivered during the period for the submission of bids, as well as any corrections or amendments to defects or omissions.



Once the submissions contained in Envelope 3 have been opened and the documents attached in each of them has been verified, the Contract Awarding Committee will state which offers have been excluded on the grounds of not fulfilling the conditions laid out in these Specific Administrative Bidding Conditions.

The submissions contained in Envelope 3 will be studied, assessed and analyzed in accordance with the award criteria that can be assessed automatically as stated herein.

6. Once submissions have been assessed and after having excluded any submissions that failed to comply with the requirements of these Conditions, the Contract Awarding Committee will propose a ranking in decreasing score order and will formulate a proposal for award to the candidate who obtained the highest score, which it will, in turn, submit to the contracting organism.

Any technical reports that may be deemed fit may be requested for the drafting of the ranking proposal.

7. Once the proposal from the Contract Awarding Committee has been accepted by the contracting organism, the appropriate service will request the bidder who submitted the best bid to provide the following documents within a period of ten (10) working days counting from the day following that on which the request was received, in accordance with the provisions of article 145 of the LSCP:

➤ **In the event that the company is not recorded in the ROLECE or the RELI:**

**(i) Documents certifying legal personality and capacity to enter into contracts:**

a) Individuals (single-person companies and professionals) must submit their National Identity Document (DNI) or the document substituting it and their Tax Identity Number (NIF) in the event that it is not featured on the aforementioned DNI.

b) Companies must provide their Tax Identity Number as well as the deed or document of incorporation, the articles of incorporation or founding deed and any modifications thereto, containing the rules whereby its activity is regulated and having been duly recorded, as may be required by applicable commercial legislation, in the Commercial registry. Whenever said recording is not required, certification will be carried out through the submission of the deed or document of incorporation, the articles of incorporation or founding deed and any modifications thereto, containing the rules whereby its activity is regulated and having been duly recorded, as may be required, in the appropriate public registry.

c) If the entrepreneur is acting through a representative or is a company, it shall be necessary to submit:

c.1.) A public deed of power of attorney that has been duly recorded in the appropriate public registry.

c.2.) The National ID Number and Tax Identity Number of the representative and of the signor of the financial offer.

d) The capacity to act of non-Spanish companies from member states of the European Community or signatories of the agreement on the European Economic Space must be



certified through their recording in the appropriate records in accordance with the legislation of the state in which they were incorporated or by submitting a sworn statement or a certification under the terms established by regulations with any applicable European laws.

e) The capacity to act of foreign companies not included in the section above must be certified in accordance with the rules established in article 68 of the LCSP.

f) As it has been stated above, bids may be submitted by unions or joint ventures of companies constituted temporarily to this effect, and it shall not be necessary to formalize it in a public deed until the bid has been awarded to them. The aforementioned contractors shall be jointly liable before the contracting entity.

In such cases, both in what concerns individuals and corporations, each one of the joint venture's members shall have to certify their capacity to enter into contracts, legal personality and representation. It shall be compulsory to the names and information of those constituting said union, the share held by each of them and appointing a single representative or agent with sufficient powers to exert the rights and fulfil the obligations derived from the contract until the termination thereof.

Bidders who are a part of a temporarily incorporated group or joint venture may not participate in the same tender individually or in more than one joint venture.

In the event that part or the entirety of the stated documents have already been submitted to the contracting entity and have not been subject to any amendments or updates and therefore being fully valid, the bidder shall not have to provide the same again whenever he or she provides a duly filled in certificate of the validity of the aforementioned documents as per the model of **Appendix No. 3** under his or her own responsibility.

**(ii) Documents to certify economic, financial, professional or technical solvency:** as per the provisions of clause 6 of these Conditions.

**(iii) When required, by justifying the constitution of a definitive security, when required.** In the event that bidders should fail to submit the definitive securities by the established deadline, the proposal for award shall be made to the next candidate by score, providing him or her with the appropriate deadline to constitute the aforementioned security.

**(iv) Other documents:**

**a)** Registration with the Economic Activities Tax, under the heading that is appropriate to the object of the contract, and the latest tax receipt for the same, as long as the bidder carries out activities that are subject to and not exempt from the aforementioned tax.

Moreover, in the event that the selected company is eligible for exemption from this tax pursuant to article 82 of Legislative Royal Decree 2/2004, of 5 March, whereby the Consolidated Text of the Law governing local tax agencies is approved, the bidder shall have to submit an affidavit stating the legal grounds for exemption and the statement document for the taxpayers' census.





**b)** A specific document certifying that the company is up to date with its tax obligations issued by the Tax Administration in compliance with article 43 of General Tax Law 58/2003, of 17 December.

**c)** A positive administrative certification issued by the Catalan Regional government certifying that the company is up to date with its tax obligations with the aforementioned administration.

**d)** A positive certification issued by the competent authority certifying that the company is up to date with all Social Security obligations.

**e)** In the event that solvency through external means is used, the submission of a commitment as per article 75.2 of the LCSP.

**f)** A commitment for the ascription of means as per article 76.2 of the LCSP.

➤ **Should the company be registered in the ROLECE or the RELI:**

**(i)** A document certifying recording in the ROLECE or the RELI and a certificate on the validity of the information contained therein. Should any of the information stated above not be featured in the RELI, said information shall have to be provided separately.

**(ii)** In the event that solvency through external means is used, the submission of a commitment as per article 75.2 of the LCSP.

**(iii)** A commitment for the ascription of means as per article 76.2 of the LCSP.

**(iv)** When required, by justifying the constitution of a definitive security, when required. In the event the successful bidder should fail to submit the definitive securities by the established deadline, the proposal for award shall be made to the next candidate by score, providing him or her with the appropriate deadline to constitute the aforementioned security.

Failure to fulfil this requirement within the established deadline shall be construed as a withdrawal of the submission by the bidder, from whom 3% of the base tender value, without VAT, shall be demanded, as a penalty. This shall be made collected from the provisional security, if it has been constituted.

In this case, the same documents shall be requested from the following order in which the submissions were ranked.

### **III. AWARDING AND UNDERWRITING OF THE CONTRACT**

#### **CLAUSE 13.- AWARDING OF THE CONTRACT**

1. The contracting organism will award the contract to the submission that displays the best value for money through a justified decision it will notify to all bidders and that it will publish on the Contracting Profile of the entity within a maximum of five (5) working days from the



constitution of the definitive security, when applicable, and once the documents stated in the clause above have been submitted.

The decision on the awarding of the contract must be justified based on the criteria for award contained herein, it must specify the reasons for which any bids are rejected as well as the features and advantages of the selected submission, including a statement of the total and partial scores obtained by all accepted companies in each of the criteria for award. Acceptance of the award decision drafted by the Contract Awarding Committee by the contracting organism shall be deemed to be sufficient grounds for said decision.

Moreover, the award decision shall state the deadline within which the contract will have to be underwritten.

In the absence of acceptable submissions in accordance with the award criteria, this invitation to tender shall be declared null and void.

2. Submitted bids, both those that have been accepted and those that have been excluded and not opened, shall be archived.

Moreover, the contracting organism may declare the invitation to tender null and void whenever any factual or legal circumstances may arise that would logically and reasonably impose the prevalence of public interest in view of the needs the contract is intended to satisfy, and it may likewise desist from or renounce the award procedures for reasons of public interest that have been duly justified in the report.

3. Should the contracting organism refuse with the award proposal formulated by the Contract Awarding Committee, it shall have to justify the grounds for said refusal in the decision.

4. Once the deadlines established in article 158 of the LCSP for the awarding of the contract have expired without the issuance of an award decision, bidders shall be entitled to withdraw their submissions without the right to indemnities. Nevertheless, the contracting organism may request from contractors that they maintain their submissions for a longer period of time after having notified bidders and made a publication on the Contracting Profile, maintaining the bid with those bidders who may choose to accept the extension.

#### **CLAUSE 14.- FORMALIZATION OF THE CONTRACT**

1. The contract shall be formalized, within fifteen (15) working days from the day on which the notification of award has been made.

Nevertheless, in the event that the contract should be susceptible to a special contract appeal, the contract will not be formalized before fifteen working days after the delivery of the award notification to bidders.



Services that depend on the contracting organism shall request the formalization of the contract from the successful bidder within a period of no more than five days counting from the day after the request was received, and after the deadline stated in the paragraph above, in the absence of any appeals entailing the suspension of the formalization of the contract. Procedures will be carried out in the like manner once the administration competent for the resolution of the appeal has lifted the suspension.

2. Whenever the contract may not have been formalized within the allotted period of time for reasons attributable to the successful bidder, he or she shall be liable to pay an amount equivalent to 3% of the base bidding value without VAT as a penalty. This shall be made collected from the provisional security, if it has been constituted.

In this case, the contract would be awarded to the next bidder in the order in which the submissions were ranked, after the submission of the documents established in clause 12 hereof.

3. The contract may not be executed prior to its formalization.

4. The contract must be formalized in the headquarters of the contracting organism and in writing, through a private deed, according to the model attached hereto. The contract shall be concluded with its formalization.

The successful bidder may request that the Contract be formalized as a public deed. In that case, the bidder would bear the expenses arising from the same.

#### **CLAUSE 15.- DEFINITIVE SECURITY**

The successful bidder must constitute the definitive security for the amount of 5% of the award value, without VAT, prior to formalising the contract. **Said security may be submitted in the ways established in article 108 of the LCSP.**

If it is a bank guarantee, said guarantee must be formalized according to the guarantee model included in **Appendix No. 4. A** attached hereto, and the guarantor will have to comply with all legal requirements.

If it is a surety insurance contract, said contract will have to have been duly executed under the conditions established by regulations with an insurance company authorized to operate in Spain in the surety insurance branch, and it shall be necessary to deliver the contract certificate to the contracting organism.

Said insurance must be formalized in the appropriate policy which must be formalized in a certificate, the model whereof is attached as **Appendix No. 4.B** hereto, and the insurance company shall have to comply with all legal requirements.



Moreover, the definitive security may be constituted through a price deduction. This deduction shall be made from the first bill issued by the successful bidder and, should the value thereof not be sufficient to constitute the entirety of the security, it would be withheld from subsequent bills issued by the successful bidder until the entirety of the guaranteed amount is covered. No payments shall be made to the successful bidder until the definitive security is entirely constituted.

Whenever, as a consequence of the modification of the contract and for any reason whatsoever, the price of the same should increase or decrease, the security thus constituted would be readjusted by the necessary amount in order to maintain the due proportionality between the security and the base contract budget in force from time to time.

The return or cancelling of the definitive security shall be carried out once the deadline for the warranty has expired and the contract has been successfully carried out or terminated for reasons not attributable to the contractor and following the procedures stated therein.

#### **IV. GENERAL CONSIDERATIONS**

##### **CLAUSE 16.- PAYMENTS TO THE SUCCESSFUL BIDDER**

The successful bidder will issue the bill for the equipment provided. Said bill must be sent to the following email address: [factures@vhir.org](mailto:factures@vhir.org).

Each bill issued must state the period to which it corresponds, the breakdown of expenses per item, and it must also contain the reference "**LICI-2022-028 CRO SERVICES FOR (MuCCUA study / CRESCER Project)**".

Effective payment for services provided will be made through bank transfer within 30 days after the date of the bill.

The contracting entity shall pay for the services once they have been carried out fully or in part and once the bill has been sent to its records. In accordance with this guideline, payments in advance for part or the entirety of the contract price are not considered.

##### **CLAUSE 17.- RISK AND PERIL AND PRICE REVISIONS**

The execution of the contract shall be carried out at the risk and peril of the successful bidder.



The successful bidder shall not be entitled to price revisions in view of the features of this contract<sup>2</sup>.

## **CLAUSE 18.- MANAGEMENT AND MONITORING OF THE EXECUTION OF THE CONTRACT**

The contract manager appointed by the contracting entity shall carry out the following tasks:

- Supervising the execution of the awarded contract.
- Ensuring fulfilment of the obligations undertaken by the successful bidder, including both those stated in the conditions and in the submission or bid.
- To send any order and instructions that may be required to ensure proper performance of the service to the successful bidder.
- To carry out an interlocutory role with the technical coordinator or manager appointed by the successful bidder.
- To ensure that the contracted company certifies compliance with the obligation to enroll all employees assigned to the execution of the contract to the Social Security scheme. To this end, the contract manager may request the payrolls and TC1 and TC2 forms from the successful bidder with each bill in order to certify payment of wages and Social Security contributions for the employees executing the contract, and to attach these documents to each approved bill.

## **CLAUSE 19.- CONDITIONS FOR THE EXECUTION OF THE CONTRACT AND ESSENTIAL OBLIGATIONS OF THE CONTRACT**

### 1. Special conditions for the execution of the contract.

The following are established as special conditions for the execution of the contract:

- Payment of bills from subcontractors and/or providers arising from the works that are the object of these Conditions by the contractor must be carried out within the deadlines established by Law 3/2004, of 29 December, whereby measures to combat arrearage in commercial operations are established. Moreover, and in accordance with the terms of the contract, the contracting company must provide documents to justify effective compliance with the terms of payment to subcontracting companies that may be required by the contract manager and, in any case, once the works have been completed.
- The commitments undertaken by the successful bidder in his or her bid concerning sustainable public contracting.

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<sup>2</sup> Price revisions shall only be possible under the circumstances established in articles 103 and 19.2 of the LCSP.



## 2. Essential obligations of the contract:

- The contractor will be bound by the bid he or she has submitted, the fulfilment whereof in the entirety of its terms shall be an essential obligation of the contract.
- Compliance with the special conditions for execution established in clause 23.1 hereof shall be an essential obligation of the contract.
- Effectively dedicating or assigning the personal and/or material means stated and undertaken in the offer to the execution of the contract.
- The obligations established in these Conditions and in the model Contract which are attributed the nature of essential obligations of the contract.
- Effectively dedicating or assigning the personal and/or material means stated and undertaken in the offer to the execution of the contract.
- Compliance of the services that are the object of the provision to the prescriptions established in the Technical Specifications and in the bid submitted by the successful bidder.

## **CLAUSE 20.- OBLIGATIONS OF THE SUCCESSFUL BIDDER**

As well as the obligations established in currently obligation, the successful bidder shall undertake the following obligations:

- a. To specify, at the request of the contracting entity, which specific people will carry out the provisions, and to notify it of any replacements or changes in said employees, certifying that their professional situation is legally valid.
- b. To appoint a person in charge of supervising proper performance of the work and personal behavior and of acting as a liaison with the contracting entity and the contract manager.
- c. To cover the publication expenses for the invitation to tender established herein. To this end, the contracting entity will discount said amounts from the first bill issued or from the following ones, as may be required.
- d. To carry out a proper environmental management of the execution of the contract, adopting as many measures as may be required to minimize its possible impacts (minimizing its acoustic and environmental impact, properly managing waste and wrappers, etc.) in accordance with currently applicable legislation.



- e. Not to disclose any information or facts that are not public or widely known information concerning the object of the contract and which were disclosed to the bidder within the context of the same.
- f. To ensure strict compliance with the provisions of (EU) Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and the free movement of such data and by which the Directive 95/46 / EC (hereinafter, "RGPD"), and remaining current legislation that develops it.
- g. To comply with currently applicable tax, labor and social legislation and general regulations on workplace health and safety. To this end, the successful bidder will be bound to provide, at the request of the contracting entity, the contractors' and subcontractors certificate issued by the tax administration covering the entirety of the contract period.
- h. To issue any documents required for compliance with the contract drafted in Catalan and to use said language when carrying out the contract.
- i. To underwrite a civil liability insurance policy for an amount sufficient to cover liabilities of any nature that may arise from the execution of the contract.
- j. To ensure that all of the actions in this contract guarantee respect for the principles of non-discrimination and equal treatment with regard to non-discrimination on the grounds of sex, sexual orientation, gender identity, ideology, nationality, race, ethnicity, religion, age, disability or of any other nature, and to guarantee the dignity and freedom of individuals.
- k. To facilitate and provide the information stated in Law 19/2014, of 29 December, on transparency, access to public information and good government.
- l. To comply with the following obligations concerning the ethical principles and rules of conduct to which contractors must suit their activity in development of the provision of article 55.2 of Law 19/2014, of 29 December, on access to public information and good government:
  - To adopt an ethically exemplary behavior, abstaining from fostering, proposing, promoting or carrying out any manner of corrupt behavior both with regard to what the Criminal Code defines as corruption as well as to ethically abhorrent behaviors, to notify competent administrations of any manifestation of these practices that may, in their view, be present or may affect contractual procedures or relations, and not to carry out any actions that may violate the principles of equality of opportunities and freedom of competition.
  - To observe the ethical principles, rules and standards of the activities, trades and/or jobs that correspond to the provisions that are the object of the contract.



- Not to carry out any actions that may endanger public interest with regard to the field of the contract or contracted services.
- To denounce any irregular situations that may arise throughout the contracting process during the execution thereof.
- To immediately notify any possible situations of conflict of interest, understood as any situation in which members of the staff of the awarding power of a contracting service provider acting in the name of the awarding power may participate in the development of the contracting procedure or may influence the results of the aforementioned procedure whilst having a direct or indirect financial, economic or personal stake that could compromise their impartiality and independence in the context of the contracting procedure, to the contracting organism. Moreover, the bidder must likewise consider the provisions concerning conflicts of interest contained in Directive 2014/24/EU.
- Not to directly or indirectly request that holders of public office or civil servants may influence the awarding, continuation or maintenance of the contract in one's own interest or in that of third parties.
- Not to offer or provide public office holders or civil servants any personal or material advantages for themselves or for third parties, regardless of any personal or professional bonds that may or may not exist between them, or to people who participate or who may influence contracting procedures.
- To respect the principles of the free market and of competition, abstaining from engaging in behaviors intended to or that may impede, restrict or distort competition such as, for instance, collusion or fraudulent competition (sheltered offers, elimination of offers, assignation of markets, offer rotation, etc.), as well as to denounce any actions or behavior to this end concerning the invitation to tender or the contract that may come to the bidder's attention.
- Not to make use of any confidential information disclosed in the context of the invitation to tender or the execution of the contract to directly or indirectly obtain advantages or benefits of any nature for one's own interest.
- Not to attempt to exert undue influence on the decision making process of the awarding power or to obtain confidential information that may provide the bidder with undue advantages in the bidding process or to negligently provide false information that may exert significant influence on decisions concerning exclusion from selection for or the awarding of the contract".
- To collaborate with the contracting organism in any actions it may carry out to monitor and/or assess the fulfilment of the contract, especially by providing any information that may be requested from the bidder to this end.
- To comply with the obligations to provide information required from successful bidders by legislation on transparency and public sector contracting concerning the administration or administrations in question, notwithstanding compliance with any obligations on transparently that may be directly required by law.
- To denounce any actions of which the bidder may have knowledge and that may imply an infraction of the obligations stated above.





## **CLAUSE 21.- RECEIPT, LIQUIDATION AND WARRANTY PERIOD**

Confirmation of the correct execution of the services will be certified through an acceptance report to be signed by representatives of both parties once they can be received and have been carried out to the satisfaction of the contracting party.

Settlement of the contract shall be agreed within thirty days after receipt of the provisions or after the contracting entity has received the bill, if it is later than the date of receipt.

The conditions of the warranty are established in **section I** of the Summary Chart.

## **CLAUSE 22.- SUBCONTRACTING AND ASSIGNMENT**

1. The successful bidder may subcontract part of the contract.

The successful bidder may notify the contracting organism of his or her intention to subscribe subcontracts in writing, after the awarding of the contract and, at the latest, at the beginning of the execution thereof. Said notification shall contain a statement on which part of the provision is intended to be subcontracted as well as the identity, contact information and the legal representative or representatives of the contractor. The successful bidder will likewise have to duly justify the suitability of the subcontractor to carry out the works based on the technical and human resources at its disposal and its experience, and it will have to certify that it is not affected by a prohibition to contract.

2. Pursuant to the terms of Additional Disposition 51 of the LCSP, it is possible for the contracting organism to make direct payments to subcontractors whenever the terms of payment established in article 216 of the LCSP are not complied with.

Payments made by the contracting organism shall be understood to have been made on behalf of the main contractor. Arrears in payments arising from the main contractor disagreeing with a bill submitted by a subcontractor shall under no circumstances be attributable to the contracting entity.

3. The contractor shall under no circumstances contract individuals or corporations who are banned from contracting or unable to contract with the public sector pursuant to currently applicable legislation.

4. The assignation of the rights and obligations emanating from the contract to third parties is forbidden.

## **CLAUSE 23.- DELAYS IN THE PROVISION OF SERVICES**



The successful bidder will be bound to fulfil the contract within the total period established for the performance thereof as well as any partial deadlines that may have been established for its successive execution. Notices of default by the successful bidder shall not require prior notification from the contracting entity.

Should the successful bidder incur in delays concerning the fulfilment of partial or overall deadlines for reasons attributable to itself, the contracting entity shall be entitled to terminate the contract.

During the processing of the report, a hearing will be granted to the successful bidder in order to lodge pleadings within five working days, upon which the contracting organism will issue a ruling after issuing the appropriate reports.

The successful bidder may suspend fulfilment of the contract on the grounds of non-payment whenever the arrears are for a period of over four months.

#### **CLAUSE 24.- LIABILITY IN EXECUTION AND PENALTIES**

1. The successful bidder shall be bound to compensate the contracting entity or its dependent staff for any damages arising from willful or negligent failure to comply with the obligations arising from the award of the contract. The successful bidder shall likewise be held liable for any damages to third parties during the execution of the contract.

2. In the event of failure to fulfil the obligations undertaken by the successful bidder or the defective fulfilment thereof, the contracting entity shall be entitled to terminate the contract or to compel the bidder to fulfil it.

3. In the event of failure to fulfil contractual obligations or the defective fulfilment thereof shall give rise to the application of penalties. The classification of infractions for the purposes of this contract is as follows:

##### Slight:

- ✓ Failure to collaborate with personnel from the contracting entity.
- ✓ Failure to partially execute the services defined in the contract that is not qualified as a severe infraction.
- ✓ Failure to warn the contracting entity of the inclusion of new personnel or of any changes in staff.
- ✓ Failures to comply with regulations on Workplace Health and Safety that are qualified as slight infractions in their specific regulations.



Severe:

- ✓ Resisting requests made by the contracting entity or failing to observe them.
- ✓ Failure to partially execute the services defined in the contract that is not qualified as a very severe infraction.
- ✓ Failure to have replacement staff for any given service.
- ✓ Working longer workdays than those allowed by labor laws and, in the event that this should happen due to a contingency, failing to inform the contracting entity.
- ✓ Permitting access to the premises of the contracting entity to individuals who are not party to the contracting service due to action or omission.
- ✓ Failure to provide all information concerning the service provision that may have been requested by the contracting entity in due time and in an appropriate manner.
- ✓ Repeat slight offenses.
- ✓ Failure to provide service coverage over a period of time due to a lack of replacement staff or for other reasons, whenever it is not a very severe offense.
- ✓ Failures to fulfil obligations arising from general workplace health and safety regulations and especially the ones arising from the plan on workplace health and safety in service provisions that are qualified as severe offenses in their specific regulations and that are not very severe offenses.

Very severe:

- ✓ Failure to provide the services due to abandonment or other causes.
- ✓ Passivity, sloppiness and laziness in the performance of the service.
- ✓ Resisting requests made by the contracting entity or failing to observe them that give rise to very severe harm to the execution of the contract.
- ✓ The use of work systems, items, equipment or personnel other than those established in the Conditions and in the submissions of the successful bidder, if applicable, whenever it gives rise to very severe harm.
- ✓ Failure to provide staff for the execution of the established minimum services.
- ✓ Very severe failures to comply with provisions concerning subcontracting, when applicable.



- ✓ Misrepresentation of the provisions billed by the successful bidder.
- ✓ Repeat severe offenses.
- ✓ Using personnel that lack knowledge of their obligations or previous training.
- ✓ Failures to fulfil obligations arising from general workplace health and safety regulations and especially the ones arising from the plan on workplace health and safety in service provisions that are qualified as very severe offenses in their specific regulations.
- ✓ Failure to comply with provisions on third party safety in the provision of services.

When processing the report, the successful bidder will be given a hearing to lodge any pleadings it deems fit, which will be ruled upon by the contracting entity.

4. Regardless of the compensation of damages, in the event of non-compliances that do not give rise to the termination of the contract, the contracting entity may apply the following penalties, ranked according to their level of harm, danger and/or reiteration:

- VERY SEVERE infractions: 3% of the value of the contract
- SEVERE infractions: 1% of the value of the contract
- SLIGHT infractions: 0.5% of the value of the contract

The penalties may be paid through a deduction from the bill or bills to be paid to the successful bidder.

The contracting entity reserves the right to terminate the contract on the grounds of repeated defects in the execution of the service whenever over three of the penalties described in the sections above are applied.

## **CLAUSE 25.- TERMINATION**

1. The contract may be terminated for any of the reasons established in article 211 and 313 of the LCSP.

2. Beyond the grounds for termination established in the aforementioned article and the ones established herein, the following shall be grounds for termination:

- Failure to begin the provision of services on time.



- Non-compliance or faulty compliance with the conditions for the execution of the contract established in these Specific Administrative Bidding Conditions and the Technical Specifications.
- Failure to comply with the essential obligations of the contract.
- All other grounds for termination established by law for this type of contract.
- Manifest and proven technical inability or negligence concerning the development of the tasks that are the object of this contract, refusal or manifest resistance by the successful bidder to suit him or herself to the instructions issued by the contracting entity to suit the contract to its needs, repeated failure to attend work meetings, failure to comply with any partial deadlines that may be established, the omission of information and any attitude or negligence that may affect the development of the contract.
- Situations established as grounds for a ban from contracting that may arise after the finalization of the contract.
- Being in a situation of control or association in what concerns the other candidates or bidders, having colluded with other participants in the bidding process and having subcontracted tasks to other companies that participated in this bid without permission from the contracting entity.
- Not treating information or facts that were not public or common knowledge concerning the object of the contract and that were disclosed to the successful bidder on the occasion of the contract with due respect.
- Failure to comply with the partial execution of the provisions defined in the contract whenever they may give rise to very severe damages.
- Repeated failures to comply with any of the special conditions for execution established herein that do not have the nature of essential obligations of the contract.

## **CLAUSE 26.- EXECUTION**

The execution of the contract will be exclusively directed and managed by the successful bidder, who shall assume all corporate risks arising from the same. The successful bidder shall appoint the individuals who will execute the services, establish the tasks to be carried out in accordance with the general instructions of the contracting entity and will issue the appropriate directions to ensure that the contract is correctly performed at all times.

The successful bidder will provide its own technical, material, organisation and human resources to ensure the correct execution of the contract and will appoint qualified and



specialized staff to carry out the tasks that are the object of the contract on its behalf and in its name, and it will likewise ensure that said staff is endowed with the appropriate qualifications, training and professional level for the services to be provided. The successful bidder may under no circumstances dissociate itself from the execution of the contract.

## **CLAUSE 27.- CHANGES TO THE CONTRACT**

1. With regard to possible changes to the contract that may take place, the framework established in sub-section 4, section 3 of Chapter I, Title I of the LCSP shall apply based on whether or not specific grounds for changes have been established.

2. The maximum positive modification of the contract price for the reasons established herein is set at the percentage specified in the **section** on modifications, letter **A)** of the summary chart of these Conditions. Any subsequent changes that may be agreed upon during the execution of the contract for the reasons established in the Conditions shall under no circumstances surpass the aforementioned percentage. This percentage shall not be affected by any modifications that may have to be carried out on the basis of circumstances not foreseen herein and in accordance with applicable legislation.

3. The causes that may be grounds for changes to the contract are as follows:

Subjective causes:

- A. Total or partial succession of the initial contractor owing to a corporate restructuring in compliance with the requirements and conditions established in article 98 of the LCSP, whenever it does not involve other substantial modifications to the contract nor is it intended to avoid the application of the Directive.
  
- B. The substitution of the initial contractor as a consequence of the assignment of the Contract to a third party under the terms established in article 214 of the LCSP. In this case, previous and express authorization would be required from the contracting organism for the authorization of the contract, and the assignee would have to be endowed with full capacity to contract with the public sector, have the level of solvency required in the Conditions and not be in a situation of incapacity or prohibition to contract with the public sector pursuant to currently applicable legislation. The assignee of the contract would be subrogated in all of the rights and obligations of the assignor.

Objectives:

No specific clauses for modification of the contract are established.

4. The procedure to modify the contract will be as follows:



- An explanatory report from the contract manager justifying the need to modify the contract.
- A legal report from the contracting department issuing a ruling on its appropriateness.
- Hearing procedures for the contractor over the course of ten working days and an appearance in which he or she shall state that he or she has been informed of the extent of the new works in question.
- Approval of the modification and attribution by the competent contracting organism at the proposal of the contract manager, with prior budgetary approval.
- Readjusting the definitive security.

5. Any modifications that may be approved shall be binding to the contractor. In consequence, the successful bidder undertakes to accept any changes to the contract proposed by the contracting organism whenever they are compliant with the conditions herein or the Contract and undertakes to execute it once the appropriate agreement has been adopted.

In such cases, the contractor will be bound to continue to carry out the works strictly adhering to the rules that may be established in consequence, and he shall not be entitled to claim any manner of indemnity nor to slow down the rhythm of the work or to suspend it for any reason whatsoever.

There will be no limits to downward modifications to the contract. In the event that a downward modification should exceed twenty per cent of the award value, the successful bidder may request the termination of the contract and the settlement of the work carried out, upon which he or she shall not be entitled to any further indemnities or payments for any loss of earnings incurred.

## **CLAUSE 28. - DATA PROTECTION**

In accordance with 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 the free movement of such data and for which Directive 95/46 / EC (hereafter "RGPD") is repealed, and the remaining regulations in force are hereby informed of the following:

- a.- The person in charge of the processing of his data is the Vall d'Hebron University Hospital Foundation - Research Institute - "VHIR" -, with NIF G-60594009, domiciled in Barcelona -08035- Passeig Vall d'Hebron 119-129, Edifici Mediterrània, 2nd floor and telephone (34) 934 89 30 00.



b. - Your data will be exclusively dealt with in order to be able to qualify, evaluate and compare the proposals of the bidders and to comply with the purposes established in the public procurement regulations that are applicable to the contracting entity. Likewise, if it ends up being the successful bidder they will be treated for the execution of the contract. And for the intended purposes, the time necessary to fulfil these purposes will be preserved, and in any case until it is requested for its deletion, and may be maintained to determine possible responsibilities that may be derived.

c. - The recipient of the data will be the VHIR. The data will not be ceded, with the exception of third parties that carry out verification tasks or those third parties who, when executing the contract, necessarily have to access the same. No automated decisions will be taken regarding personal data processed, including the development of profiles and international data transfer is not expected. In general, personal data will not be communicated to third parties without prior express consent, except for a legal obligation under the RGPD for persons who are legitimized to demand them.

d. - The legal basis of the treatment is the application of pre-contractual and contractual measures, and in case of being the successful bidder for the execution of a contract.

e. - You have the rights of access, rectification, deletion, portability, limitation, and opposition that may be exercised at any time. In compliance with Regulation (EU) 2016/679, the VHIR has appointed a Data Protection Officer, being his contact information [dpd@ticsalutsocial.cat](mailto:dpd@ticsalutsocial.cat). The legal unit of the Foundation will resolve the doubts, complaints, clarifications, suggestions and will be taken care of the exercise of rights through the email: [lopd@vhir.org](mailto:lopd@vhir.org), or by mail to the address Passeig Vall d'Hebron 119-129, Edifici Mediterrània, 2nd floor. 08035 Barcelona. You can also file a complaint with the Competent Authority responsible for Data Protection.

f. - The documentation required to tender in this procedure that contains personal data is necessary for the participation in the same.

g.- In relation to the documentation submitted by the bidders that contains personal data of natural persons (workers, technical personnel, collaborators, etc.), the bidder guarantees that he has previously obtained the express consent of the people affected to facilitate said information to the contracting entity in order to tender in the present procedure.

h.- The presentation of the offer and the documentation requested implies that the tenderer authorizes the contracting entity to treat the said information in the informed terms and, in the event that it is awarded, in the framework of the execution of the contract.





i. - The successful bidder undertakes to comply with all the provisions of the RGPD, in relation to the personal data to which he has access during the validity of this contract. The document or information that is issued or to which the successful bidder has access to the benefit of the obligations derived from the contract, which corresponds to the contracting entity as Responsible for the processing of personal data, is confidential and cannot be Object of total or partial reproduction by any means or support, nor processing nor computer editing, nor transmission to third parties will be possible outside the strict scope of the direct execution of the contract, not even between the rest of the Personnel that the successful adjudicator has or can have

j. - The contract adjudicator, as responsible for the processing of the personal data that are the responsibility of the contracting entity as Responsible for the treatment, undertakes to use them with the sole and exclusive purpose of providing them with the services, and for that reason it commits itself to sign with the Responsible, a contract of treatment order in accordance with the one established in article 28 of the RGPD.

## **CLAUSE 29.- CONFIDENTIALITY**

The successful bidder and his or her contributors are bound to respect the confidential nature of all information to which they have access during the execution of the contract as may be declared as such in the contract or by the entity or which must be processed as such owing to its nature.

This duty for confidentiality shall subsist for a minimum of five years, unless the contract is established for a longer period of time.

Likewise, the bidder must expressly determine which documents and/or information in his or her submission to be of a confidential nature.

## **CLAUSE 30.- APPEALS SYSTEM**

1. Pursuant to article 44 ordinal FF of the LCSP, special contracting appeals may be lodged against the invitation to tender, the conditions and contract documents establishing the conditions that will govern contracting, as well as any formalities adopted during the award procedure, whenever they exert a direct or indirect influence on the same, determine the impossibility of carrying on with the procedure or lead to a situation of helplessness or irreparable harm to their legitimate rights or interests, the acts whereby the admission or non-admission of candidates are agreed, including any bids that are excluded on the grounds of being abnormally low pursuant to the application of article 149 of the LCSP, against the award decision and changes to the contract based on non-compliance with the provisions of articles 2014 and 2015 of the LCSP.



2 Appeals may be lodged by individuals and corporations the legitimate rights or interests whereof have been harmed or may be affected by the decisions being appealed and, in all cases, by bidders.

3. The period of time to lodge special contracting appeals shall be 15 working days counted in accordance with the terms of article 50 of the LCSP, depending on the act being appealed.

4. The appeal may be submitted before the registry of the Contracting Organism, before the registry of the competent organism for ruling on the appeal or in any of the places established in article 16.4 of Law 39/2015, of 1 October, on Common Administrative Procedures for the Public Administrations.

Two months after the day following the lodging of the appeal, in the absence of notifications on the resolution thereof, the interested party may deem the appeal to have been waived for the purpose of lodging a contentious administrative appeal.

5. The appeal must state the act being appealed, the grounds for the appeal, the means of proof put forward by the appellant and, when appropriate, the request for the adoption of provisional measures, attaching the documents required by article 50 of the LCSP.

Barcelona, April 28<sup>th</sup> of 2022

## **THE CONTRACTING ORGANISM**

**Dr. Joan X. Comella Carnicé**

Director

Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR).



**APPENDIX No. 1**

**MODEL FOR THE FINANCIAL BID OFFER AND REFFERENCES THE ASSESSMENT  
 WHEREOF DEPENDS ON AUTOMATIC FORMULAE**

Mr / Ms ..... whose address is No. ...., street, from company....., the Tax Identity No. whereof is....., having been informed of the invitation to tender and the conditions and requirements for the award of the 2022-028 CRO SERVICES FOR (MuCCUA study / CRESCER Project), hereby undertakes (in his or her own name or on behalf of the company he or she represents) to carry them out strictly subject to the conditions below:

**Lot 1: Deliver the Certificate on the Financial Statement (CFS) according the rules set by the European Commission or other Public Funding Agency.**

A) Financial bid offer

CONCEPTE	MAXIMUM UNIT PRICE (VAT excluded)	MAXIMUM UNIT PRICE OFFERED (VAT excluded)
2022-028 CRO SERVICES FOR (MuCCUA study / CRESCER Project)	<b>90.000,00€</b>	

Signature and stamp of the bidding company

Validity of the bid.....4 months  
 (bids for a value and/or period of time greater than that of the invitation to tender shall be excluded from the procedure)



## APPENDIX No. 2

### CRITERIA FOR AWARD

**Criteria that can be assessed through automatic formula (up to a maximum of 51 points)**

#### ECONOMIC OFFER:

This criterion for award (economic offer) will be assessed automatically according to the formula below:

$$P_v = \left[ 1 - \left( \frac{O_v - O_m}{IL} \right) \times \left( \frac{1}{VP} \right) \right] \times P$$

$P_v$  = Bid Score to Rate

P = Economic criteria points

$O_m$  = Best Offer

$O_v$  = Offer to be Valued

IL = Bid Amount

VP = Weighting Value

\* If after applying the automatic formula to a submitted offer, the resulting value is negative, zero (0) points will be directly assigned to the economic part.  $P_v = 0$ .

#### **\* Delimitation of allegedly abnormal or disproportionate bids**

Since the price offered (Economic Offer, Envelope C) is one of the objective criteria that will be used to select the winning proposal, **any bid that is at least 5% below the arithmetic mean of the set will be considered presumed abnormal/disproportionate or reckless of the economic offers received by the bidders or, in the case of a unique bidder, 10% of the net bid budget.**

Specifically, under the provisions of Article 149.4 LCSP, the offer will be rejected if it is found to be abnormally low due to non-compliance with the applicable subcontracting obligations, environmental, social or labor, national or international, as well as non-compliance with the sectoral collective agreements in force.

**Criteria to be assessed through value judgments (up to a maximum of 49 points)**

#### TECHNICAL OFFER

**Drafting of work proposal..... (up to 40 points)**

It must include:



- Activities plan and detailed description of the services ..... (15 points)
- Quality and control plans, which includes a system of indicators for the evaluation of partial results (follow-up of visits, drafting of reports summarizing the achievements, next steps, etc.)..... (10 points)
- Timelines and events schedule ..... (05 points)
- Budget (per activities and total) ..... (05 points)
- Detailed description of the eCRF system .....(05 points)

**Memory of experience.....(up to 09 points)**

Bidders must present a report of experience explaining their participation in clinical trials.

- Presentation of the organization (“About” information).....(02 points)
- Memory of experience..... (05 points)
- CV of the responsible Project manager and brief presentations of the team..... (02 points).

**Bidding companies that do not submit all the documentation relating to the criteria that can be assessed by value judgments will be excluded from the reference tender.**

A minimum total score of 32 points is required in the technical assessment so that the bidding companies can continue in the selection process and opt for the criteria that can be evaluated with automatic formulas. **Failure to obtain 32 points or more in the technical bid will be excluded from this tender procedure.**

**TOTAL SCORE: from 0 to 100 points.**



**APPENDIX No. 3**

.....  
.....

....., on the ..... of .....

To Whom It May Concern:

The undersigned ....., hereby certifies:

- That the documents requested in the Specific Administrative Bidding Conditions that govern this invitation to tender to certify the legal personality and capacity to contract of the bidder have not changed from those held by you and that were submitted on ..... to participate in the procedure .....
- That the tax identification number card is the one held by you, which was submitted on ..... to participate in the procedure .....
- That the documents to certify my representation as a signor of the submission have not been changed or revoked with regard to those held by you and that were submitted on ..... to participate in the procedure .....

In witness whereof I hereby sign this on the ..... of .....

Signature



#### **APPENDIX No. 4.A**

#### **BANK GUARANTEE MODEL**

*(Witnessed by a notary public pursuant to art. 197.1 bis of the Notary regulations, validated by the legal counsel of the Government Depositary, the State Attorney General or the equivalent organisms of the other administrations)*

The bank ..... and, in its name and on its behalf, ..... acting as ..... and in accordance with the powers emanating from the power of attorney executed before the Notary Public of....., Mr/Ms ..... on ....., number ..... of his or her records, and which are stated to be entirely in force, is hereby constituted as the joint guarantor of the company....., in the interest and benefit of \_\_\_\_\_, and up to the amount of Eur (...% of the value of the Contract), for the purpose of guaranteeing the exact fulfilment by the aforementioned company of each of the obligations specified in the appropriate award contract for the services ".....".

The aforementioned guarantee is provided by the bank....., expressly and formally renouncing any benefits of exclusion, division, order and any others that may be applicable as the case may be, and, to this effect, the Bank hereby declares that it wishes to commit itself and jointly and severally commits itself with the company ..... until the liquidation of the aforementioned services and the expiry of the warranty term, to unconditionally pay, within a maximum period of eight days following the request, the sum or sums stated in the request up to the guaranteed amount of (...% of the value of the Contract) EUROS, and the Bank hereby expressly and solemnly renounces any exceptions or reserves to the delivery of the amounts to be claimed for it regardless of the grounds or reasons for the same, even in the event that..... or third parties, whichever they may be, should manifest their opposition or claims to the same.



**APPENDIX No. 4.B**

**SURETY INSURANCE CERTIFICATE MODEL FOR THE DEFINITIVE SECURITY**

*(Witnessed by a notary public pursuant to art. 197.1 bis of the Notary regulations, validated by the legal counsel of the Government Depository, the State Attorney General or the equivalent organisms of the other administrations)*

Certificate number .....

..... (hereinafter, the insurer), the registered address whereof is ....., street, and the Tax Identity Number whereof is ....., duly represented by Mr / Ms ....., endowed with sufficient powers to bind it in this deed, as results from.....

**HEREBY INSURES**

....., the bearer of National ID No. / Tax ID No. ...., as the policyholder, before \_\_\_\_\_, hereinafter the insured party, up to the amount of EUR ..... (...% of the value of the Contract)....., for the purpose of guaranteeing the exact fulfilment by the insured party of each of the obligations resulting from the award of the execution of the services corresponding to .....

Failure to pay the premium, whether it is a single payment, the first payment or any of the following ones, shall not entitle the insurer to terminate the contract, nor will it be null and void, nor will the coverage of the insurer be suspended, nor will the insurer be exempted from his or her obligations in the event that the insurer should have to put the warranty into effect.

The insurer shall not be entitled to oppose any exceptions that may befall to him against the policy holder against the insured party.

The insurer hereby undertakes to indemnify the insured party at the first request from \_\_\_\_\_, to unconditionally pay the sum or sums that may be stated in the request up to the insured amount within a maximum period of eight days after the date of the request.

This surety insurance shall remain in force until the liquidation of the contract and the end of the warranty period.

In ....., on the ..... of .....

Signed:  
The insurer





### APPENDIX No. 5

#### BREAKDOWN OF THE BASE BUDGET FOR TENDER

Direct costs <sup>3</sup>	90.000,00€
....	
....	
Wage costs ( <i>whenever wage costs are a part of the cost</i> )	
TOTAL	90.000,00€
Indirect costs	0,00 €
...	
General structural costs	
Industrial profits	
TOTAL	Sum of indirect costs
TOTAL COSTS (direct + indirect). Net budget.	90.000,00€

<sup>3</sup> **Direct costs:** costs that are very clearly associated to the product without the need for any kind of distribution. Raw materials. Direct labour.

**Indirect costs:** costs that cannot be directly attributed to a product or cost centre. Indirect Production Costs (IPC): indirect labour, supply or production costs. General Indirect Costs (GIC): costs not required for manufacturing, such as commercial, administrative and financial costs.



## **APPENDIX No. 6**

### **CONTRACT MODEL**

Barcelona, on \_\_\_\_\_ 20\_\_

#### **THE PARTIES**

On one hand, el Dr. Joan X. Comella Carnicé, of legal age, the bearer of National Identity Document N°. 4 40881366Q and whose address for the purpose hereof is Barcelona Passeig Vall d'Hebron 119-129, 08035.

And on the other, Mr. / Ms. \_\_\_\_\_, of legal age, the bearer of National Identity Document No.\_\_\_\_\_, and whose address for the purpose hereof is \_\_\_\_\_.

#### **THEY INTERVENE**

The former, in the name and on behalf of the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (hereinafter, VHIR), the registered address whereof is Barcelona al Passeig Vall Hebron nº. 119-129, Tax Identity Code G-60594009. He is acting as the Authorized Director, being especially authorized for entering into this contract by virtue of the public deed of power of attorney authenticated by the Notary Public of Barcelona, Mr. Andrés Sexto Carballeiro, on the 22<sup>nd</sup> of September 2009, under number 1106 of his records.

The latter, in the name and on behalf of " \_\_\_\_\_," (hereinafter, the successful bidder), the registered address whereof is \_\_\_\_\_, Tax Identity No. \_\_\_\_\_, recorded in the Commercial Registry of \_\_\_\_\_ under Volume \_\_\_\_, folio \_\_\_\_, sheet No. \_\_\_\_, entry \_\_\_\_\_. Mr / Ms \_\_\_\_\_, is acting as the representative of the Company, being especially authorized for entering into this contract by virtue of the public deed of power of attorney authenticated by the Notary Public of \_\_\_\_\_, Mr / Ms \_\_\_\_\_, on the \_\_\_\_\_, under number. \_\_\_\_\_ of his or her records.

#### **THEY STATE**

I.- That the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR) is an entity that was incorporated through the public deed authenticated on 22 September 2009 by the Notary Public of Barcelona Andrés Sexto Carballeiro.

II.- Pursuant to its Articles of Incorporation, the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR) is a non-profit foundation endowed with legal personality and full capacity to act and which was incorporated to promote, develop, transfer, manage and disseminate research, scientific and technical knowledge, innovation, teaching and training in the field of life and health sciences. The VHIR is a part of the public sector of the Catalan Regional Government and it is deemed to be a non-governmental awarding power.

III.- The VHIR, in fulfilment of the purpose for which it was incorporated, has called a procedure for the awarding of a contract to carry out the contracting of a CRO specialized



in the management of phase I-IV clinical trials, research training, capacity building and clinical trial auditing. for the data management, medical writing and biostatistical services for the study “Mother and Child interventions for Chronic Undernutrition in Angola. A community cluster and cost-effectiveness trial” (MuCCUA study) as part of the **project “Operative Research Against Chronic Child Malnutrition in Angola” (CRESCER project)**- of the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR). having published the appropriate invitation to tender on the contracting profile of the entity on the \_\_\_\_\_.

IV.- The competent contracting organism of the de la Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR) on the grounds of the value of the contract has issued the ruling dated on \_\_\_\_\_, whereby it awards the contract stated in point III above to \_\_\_\_\_.

V.- The Contractor has certified its capacity to enter into contracts and undertake responsibilities and its legal personality, especially for the purposes of this Contract, before the VHIR, and it has constituted the definitive security required in the Specific Administrative Bidding Conditions that govern this contract, which has been put at the disposal of the VHIR for the purposes established herein.

VI.- The parties hereby formalize the aforementioned contract, which shall be governed by the following

## CLAUSES

### 1.- OBJECT

1.1.- The purpose of this call for tenders is to hire CRO specialized in the management of phase I-IV clinical trials, research training, capacity building and clinical trial auditing. for the data management, medical writing and biostatistical services for the study “Mother and Child interventions for Chronic Undernutrition in Angola. A community cluster and cost-effectiveness trial” (MuCCUA study) as part of the project “Operative Research Against Chronic Child Malnutrition in Angola” (CRESCER project)- of the Fundació Hospital Universitari Vall Hebron - Institut de Recerca (VHIR).

This contract shall be executed subject to the following attached documents:

- The Specific Administrative Bidding Conditions as appendix No. 1.
- The Technical Specifications as appendix No. 2.
- The Technical and the financial bid submitted by the successful bidder, as appendix No. 3.
- The Requirements, as appendix No.4.
- The Award Agreement, as appendix No.5.

The parties hereby state that they possess true and faithful copies of the documents that have been stated as defining for this Contract, said copies having been signed by the parties and being an integral part of this Contract.



## 2.- PRICE

The total value of the contract is established for the value of \_\_\_\_\_ Euros, plus the sum of \_\_\_\_\_ Euros which corresponds to Value Added Tax (hereinafter, VAT).

All headings described in the offer have been included in the value of the contract. Moreover, all costs, risks, benefits and taxes are deemed to be included therein with the exception of VAT, which is stated under a separate heading.

The VHIR shall only pay the successful bidder for those services that are effectively provided, and the VHIR shall under no circumstances be bound to spend the entire estimated value of the contract / budget for tender.

## 3.- BILLING AND MEANS OF PAYMENT

The contractor will invoice the service through its corresponding monthly invoice, which must be sent to the following email address: [factures@vhir.org](mailto:factures@vhir.org)

Each invoice issued must detail the period to which it corresponds, the breakdown / description of expenses by concept, as well as indicate the references “**LICI-2022-028 CRO SERVICES FOR (MuCCUA study / CRESCER Project)**”.

The effective payment of the executed services will be made by bank transfer, with a maturity of 30 days / invoice date.

The contracting entity pays for the services once they have been carried out in part or in full and once the invoice has been entered in its register. According to this parameter, the advance payment of part or all of the contract price is not contemplated.

Under no circumstances will the contractor be entitled to a price review for any reason.

The VHIR will only pay the successful bidder for the services actually provided, without, in any case, the VHIR being obliged to exhaust the estimated value of the contract/bid budget.

## 4.- LENGTH OF THE CONTRACT

4.1.- The duration of the service object of this tender will coincide with the validity of the aforementioned project, which is until **February 14 of 2025**, the completion date of the project's “Operative Research Against Chronic Child Malnutrition in Angola” (CRESCER project).

The date of the beginning for the services will be the date of formalization of the contract,



The duration of the contract is foreseen without prejudice to the guarantee period established in section I of the Table of Characteristics of the Particular Terms and Conditions governing this contract, as well as the obligations of confidentiality and protection of personal data provided in accordance with the corresponding clauses of this contract.

The length of the contract is established notwithstanding the warranty period established in section I of the summary chart of the contract, as well as the agreements regarding the non-disclosure and protection of personal information pursuant to the appropriate clauses hereof.

Under no circumstances will the contract be renewed tacitly.

4.2.- The contract may be extended for a further twenty-four (24) months, in accordance with the corresponding clauses of these specifications.

4.3.- The place where the service provisions will be carried out will be established in section E of the Summary Chart of the Specific Administrative Bidding Conditions that govern the contract.

#### 5.- DEFINITIVE SECURITY

5.1.- The successful bidder has constituted a definitive security for the amount of \_\_\_\_\_ Euros. This amount corresponds to the percentage of the Contract value established in section H of the Summary Chart and in clause 15 of the Specific Administrative Bidding Conditions that govern the contract.

5.2.- This security is common and enforceable upon the first request, with an unconditional compulsory nature and an express and solemn waiver of all exceptions and reservations and, among others, of the benefits of exclusion, order and division.

5.3.- The security will respond for the exact fulfilment by the contractor of each of the obligations resulting from this contract and shall remain in force until the expiry of the warranty period and the contract has been satisfactorily completed or terminated for reasons not attributable to the contractor and following the procedures established therein.

The security thus constituted will respond for any possible terminations of the contract, the application of penalties, compensation for damages arising from non-fulfilment of the contractor's obligations and, in general, for the faulty fulfilment of the obligations befalling the contractor.

5.4.- In any of the cases considered in the paragraph above, the VHIR may freely and of its own free will act against the aforementioned security and, in consequence, to dispose of the appropriate amounts, notwithstanding the actions, claims or appeals the contractor may lodge, which shall under no circumstances suspend the free availability of the security for the VHIR, whose only obligation would be to return the sums thus used when appropriate.



5.5.- In the event that the amount of the security should prove insufficient to cover the damages suffered by the VHIR, said institution may claim the difference that was not covered by the security from the contractor and, if necessary, it may discount it from the amounts pending payment to the contractor. The remainder shall be paid directly and immediately by the contractor at the request of the VHIR.

## 6.- LABOUR AND TAX OBLIGATIONS

6.1.- The contractor will have to be up to date with its corporate obligations at all times in what regards taxes, labor, social security, trade unions and health and safety, and it will be strictly and rigorously responsible for any non-compliances with the above obligations on an exclusive basis, as the VHIR shall decline any liability for said non-compliances.

6.2.- Pursuant to Law 54/2003, of 12 December, reforming the legal framework on workplace health and safety and of Royal Decree 171/2004, of 30 January, developing article 24 of Law 31/1995, of 8 November, on workplace health and safety, the successful bidder is bound to comply with currently applicable legislation on workplace health and safety. In particular, the successful bidder shall comply with the terms of the Specific Administrative Bidding Conditions on this subject.

6.3.- The successful bidder undertakes to exert the management powers inherent to its status as an employer concerning its staff in a real, effective and constant manner, undertaking all obligations regarding the staff assigned to the execution of the contract in what concerns the negotiation and payment of wages, social security enrolment and contributions, and the payment of benefits, sabbaticals, leaves, holidays, replacements, workplace health and safety, the disciplinary regime, trade union relations and any other rights and obligations arising from its own work contracts on an exclusive basis.

6.4.- The relationship between the parties is of an exclusively commercial nature and there is no employment link between the VHIR and the staff of the service provider, even when said staff should have to carry out tasks on VHIR premises. Therefore, on the basis of the existence of this contract or compliance therewith, the staff of the service provider shall not be deemed to be VHIR employees either de jure or de facto owing to the fact that it will exclusively depend on the direction of the aforementioned company for all intents and purposes, including the aspects of labor relations and social security.

The service provider shall be responsible for the management and organization of the work, issuing, when appropriate, work orders and instructions to its employees and undertaking the obligations to remunerate and contribute as an entrepreneur.

## 7.- COMMITMENT ON THE ENVIRONMENT AND GOOD PRACTICES

The contractor guarantees a high level of environmental conduct in the execution of the services that are the object of this Contract to the VHIR. The service provider shall be fully and exclusively liable for compliance with all applicable environmental regulations, holding the VHIR harmless, and undertakes to carry out any actions required to maximize energy



efficiency and to minimize the environmental impact in accordance with the documents attached to this Contract and to regulations in force from time to time.

## 8.- LIABILITY IN THE EXECUTION OF THE CONTRACT

8.1.- Subject to the provisions of this contract, each party shall be held liability for any full or partial breach of any of their obligations arising from this contract and shall have to indemnify the other party for any damages arising from said breach.

The liability and obligation to indemnify established herein are understood notwithstanding the possibility to terminate the contract and the penalties established in the following clause.

In particular, the contractor will be held liable for any losses, degradation or loss in value of the equipment owned by the VHIR and required for the execution of the contract, as well as for any damages that may be directly or indirectly caused to third parties or to the facilities and assets of the VHIR during the execution phase of the contract and until the receipt thereof by the VHIR.

The contractor will likewise be liable for the quality of the services provided as well as for the consequences that may arise from any omissions, mistakes or improper methods applied during the execution of the contract for the VHIR or for third parties.

8.2.- Likewise, the service provider shall be held liable for any environmental damages that may arise pursuant to the provisions of Law 26/2007, of 23 October, on environmental responsibility, and Law 11/2014, of 3 July, whereby Law 26/2007, of 23 October, on environmental responsibility is modified.

8.3.- The contractor shall be liable to pay the value of any penalties that may imposed to the VHIR as a consequence of non-compliance with or failure to observe the conditions established in documents of a contractual nature, in licenses, authorizations or permits, as well as for any breach or non-observance of applicable municipal, regional or state regulations by the service provider.

8.4.- The parties will notify each other of the assessment of these damages as appropriate, upon which the other party will have thirty (30) calendar days to issue a disclaimer. Failing that, the assessment shall be deemed to have been accepted by the party to which the claim has been made, upon which the claimant will issue the appropriate bill.

## 9.- PENALTY SYSTEM

9.1. Failure to comply with or faulty compliance with contractual obligations shall be grounds for the penalties established in clause 24 of the Specific Administrative Bidding Conditions.

9.2. The penalties established in this section are of a cumulative and not substitutive nature.

For the purposes of article 1.153 of the Civil Code, a contractor to whom a penalty has been applied shall not only have to fulfil the penalty within the terms established in the paragraph



below, but also to fulfil any obligations regarding non-compliance or arrears in execution for which he or she is being penalized

Penalties shall be deducted from sums pending payment. In the event that there are no sums pending payment, penalties shall be withdrawn from the definitive security that may have been provided, as the case may be. In the event that the penalties should have been levied from the aforementioned security, the service provider shall be bound to increase the security by the appropriate amount until it reaches the 5% of the award value.

The application and payment of penalties shall not imply a waiver by the VHIR for any indemnities to which it may be entitled for damages caused by non-compliances attributable to the service provider.

## 10.- TERMINATION OF THE CONTRACT

10.1.- This contract may be terminated on the grounds of any of the reasons laid out in clause 25 of the Specific Administrative Bidding Conditions attached hereto as Appendix 1.

10.2.- Consequences of the termination

Termination of the contract, regardless of the reasons for the same, shall be understood without prejudice to any rights that may have been acquired or any liabilities that may have been incurred due to failures to pay, the obligation to provide indemnities for damages, or of any other rights and obligations that may arise and that may be demanded at the time of the termination or that may remain after said termination in accordance with the terms of this contract.

Moreover, the termination or expiry of the contract shall not affect the obligations established for the parties which, owing to their nature or the terms of this contract, shall survive the termination of the same, especially the non-disclosure obligation.

At the end of the contract, the contractor shall return any documents and equipment that may have been provided to the VHIR and that are being held by the contractor to the VHIR, observing the duty to maintain secrecy and confidentiality as stated in the confidentiality clause.

The termination of the contract for any reason other than the expiry of the established deadline or by mutual agreement shall entitle the contractor to claim for compensation for any damages that may arise from said termination whenever it has been caused by a breach of the obligations undertaken by the VHIR pursuant to this Contract.

## 11.- SUBCONTRACTING AND ASSIGNING THE CONTRACT

The subcontracting and assignment regime is the one regulated in clause 22 of the Specific Administrative bidding conditions and attached hereto as Appendix 1.





## 12.- RECEIPT OF THE WORK AND WARRANTY PERIOD. CIVIL LIABILITY POLICY

12.1.- The execution of the contract shall be carried out at the risk and peril of the successful bidder.

12.2.- The successful bidder shall ensure that the services provided in compliance with the object of this contract shall be in conformity with the specifications agreed upon by the parties.

12.3.- Once the provision described herein has been carried out and its fulfilment of the technical requirements and the offer submitted by the successful bidder and, when applicable, once the appropriate documentation has been submitted, the appropriate works receipt report shall be drafted. The warranty period shall be counted from this point onwards.

In the event that issues concerning the works carried out should arise at the time of the drafting of the receipt report, the works will not be understood as having been received, but rather, a maximum period of ten (10) days will be given to the service provider to amend any flaws that may have been detected.

Once the term stated in the paragraph above has passed, the actions intended to verify the suitability of the works and their subsequent receipt will be carried out.

12.4.- The works receipt report will have to be issued by the VHIR within 15 working days counting from the date of submission of the documents in question as well as of any other documents the VHIR may have requested.

If the aforementioned deadline should expire without the issuance of the aforementioned receipt report for the works or services carried out, these will be understood to have been received.

12.5.- Moreover, throughout the duration of the contract, the contractor will undertake to maintain the civil liability insurance policy that was contracted, for an amount sufficient to cover the liabilities of any type that may be derived from the execution of the contract.

The validity of the aforementioned civil liability insurance policies will have to be certified throughout the validity of the contract, including any possible extensions, by submitting a copy of the receipt for payment thereof to the contracting organism.

## 13.- CONFIDENTIALITY, INTELLECTUAL AND INDUSTRIAL PROPERTY AND FULFILLMENT OF REGULATION (EU) 2016/679 AND OF THE ORGANIC LAW ON THE PROTECTION OF DATA THAT DEVELOPS

The contractor declares to know and agrees to comply with the provisions of clause 28 of the Specific Administrative Terms and Conditions regarding the protection of personal data.



The contractor declares to know and agrees to the fulfilment of what is provided in the clause "Confidentiality, Protection of personal data and Intellectual and Industrial Property" of the Technical Specifications in the field of intellectual and industrial property.

Likewise, the contracting company will be obligated to respect the confidential nature of all the information to which it has access in the terms established in clause 29 of the Specific Administrative Terms and Conditions.

#### 14.- ORGANISATION. INTERLOCUTORS FOR THE CONTRACTING PARTIES

14.1.- In compliance with the obligations arising from this contract, the contractor shall appoint an interlocutor endowed with sufficient capacity, knowledge and experience to supervise, coordinate and ensure the proper correct provision of the services to be executed and to carry out an interlocutory role with the VHIR to monitor the execution of the contract.

The VHIR shall likewise appoint a person in charge of monitoring the execution of the works endowed with sufficient attributions to define and analyse the level of the works to be carried out, to coordinate them and to validate the end results of the services provided.

The following individuals are hereby appointed to represent the VHIR and of the contractor:

On behalf of the contractor: Mr/Ms [●]

On behalf of the VHIR: Mr/Ms [●]

The VHIR may request the replacement of the interlocutor appointed by the contractor at any time whenever there are justified grounds. In this case, the successful bidder will propose a substitute with a suitable profile within one working day from the notification of the request for substitution.

14.2.- The successful bidder for the service will ensure that a stable staff is assigned to the works that are the object of this contract with low rates of turnover within its possibilities, excepting cases in which the replacement of certain people may be requested by the VHIR or the successful bidder, for justified reasons.

14.3.-The VHIR shall be entitled to inspect and be informed on the execution of the services that are the object of the contract, and it will be able to request documents concerning the preparation, management and monitoring of the same in order to check the technical features of the services provided. Moreover, it may implement any quality control systems it sees fit and issue any guidelines it may deem necessary for the strict fulfilment of this contract.

#### 15.- CHANGES TO THE CONTRACT



This contract may be modified in accordance with the provisions of section Q of the Summary Chart and Clause 27 of the Specific Administrative Bidding Conditions that govern this contract.

#### 16.- LEGAL FRAMEWORK

This contract is subject to Spanish civil, commercial and procedural legislation, notwithstanding the rules contained in subsection 4, section 3 of Title I, Book II of the LCSP, on contract modifications, that may apply.

#### 17.- JURISDICTION

Civil jurisdiction shall be competent to settle disputes between the parties with regard to the effects, fulfilment and termination of the contract that is the object of this tender, pursuant to article 27 of Law 9/2017, on Public Sector Contracts. In the event that they should file legal action, the parties hereby expressly submit to the jurisdiction and competence of the Courts and Tribunals of the city of Barcelona, expressly waiving any others that may apply to them.

In witness whereof, this document is hereby signed in two counterparts at the date and place stated in the heading.

VHIR

THE SUCCESSFUL BIDDER

Mr - \_\_\_\_\_

Mr / Ms - \_\_\_\_\_



## ANNEX NO. 7

### TYPE OF DATA PROCESSING AGREEMENT

Barcelona,..... of ..... of 202 .....

#### TOGETHER

On the one hand, Dr. Joan X. Comella Carnicé, as Director of the **FUNDACIÓN HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA (VHIR)**, with address at Passeig de la Vall d'Hebron 119-129, Edificio Mediterrània, 2<sup>a</sup> Planta, 08035 Barcelona and CIF G-60594009, acting as **CONTROLLER** (hereinafter, "**VHIR**" or the "**Controller**").

On the other party, ..... and NIF ..... , acting as **PROCESSOR** (hereinafter, "**Processor**").

They may be collectively referred to as the "Parties". And, mutually recognizing the sufficient legal capacity to contract and be bound,

#### EXPOSE

1. That the VHIR is a private Foundation whose objective is to promote, promote and favor research, scientific and technological knowledge, teaching and training in the field of the Vall d'Hebron University Hospital, of the Autonomous University of Barcelona and of the areas of influence. Likewise, the VHIR's fundamental objective is to promote quality biomedical research in basic, clinical, epidemiological and health technology evaluation aspects, in order to favor the transfer of knowledge that allows a better diagnosis, processing and prevention of problems health of our society. And within the framework of its activities, the VHIR owns and processes a large amount of particularly sensitive personal data.

2. That the person in charge of the processing is ..... and is dedicated to .....

3. That on date ....., the VHIR and the Person in Charge of processing signed a service provision contract consisting of performing services of .....

4. That in order to carry out the contract mentioned in the previous Exhibit, the person in charge will process personal data on behalf of VHIR.

5. That the purpose of this is to define the conditions under which the person in charge of the processing will process the personal data on behalf of the person responsible for the processing, in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016 (hereinafter, the "RGPD") and Organic Law 3/2018, of December 5, Protection of Personal Data and Guarantee of Digital Rights (hereinafter, the "LOPDGDD").

In accordance with this, the parties sign this contract that will be governed in accordance with the following:

#### CLAUSES



**1. Object and purpose of the order**

By means of the present, the person in charge of the processing is empowered to treat on behalf of the Responsible, the personal data necessary to carry out the contract for the provision of services dated .....

The purpose of the processing is .....

In particular, the person in charge of the processing will carry out the following data processing:

Type of processing to be carried out:	
<input type="checkbox"/> Collection	<input type="checkbox"/> Dissemination
<input type="checkbox"/> Registration	<input type="checkbox"/> Interconnection
<input type="checkbox"/> Structuring	<input type="checkbox"/> Comparison
<input type="checkbox"/> Modification	<input type="checkbox"/> Limitation
<input type="checkbox"/> Conservation/ Storage	<input type="checkbox"/> Disposal
<input type="checkbox"/> Extraction	<input type="checkbox"/> Destruction
XConsult	<input type="checkbox"/> Others (describe):
<input type="checkbox"/> Communication for transmission	

The means used by the Person in Charge to carry out the Processings on behalf of the Responsible Party will be:

Medios del tratamiento		
Computer	Physicists	Mixed

This processing will be carried out in accordance with the provisions of the RGPD and the LOPDGDD.

**2. Identification of the affected information**

For the execution of the services derived from the fulfillment of the object of this order, the data processed by the person in charge of the processing on behalf of the person in charge will be data of: .....

**3. Duration**

This contract will be an annex to the contract for the provision of services dated ....., so its duration and termination is contingent, ending on date ... ..

Upon completion of the contract for the provision of services and the actions described above, the Person in Charge undertakes to return to the Responsible the personal data and, where appropriate, the media where they are stored. The return will entail the total erasure of the existing data in the computer equipment used by the person in charge.

However, the person in charge authorizes the person in charge to keep a copy with all the records duly blocked, adopting the relevant security measures, while responsibilities are derived from the execution of the contracted service, being able to keep them blocked for a maximum of five years. will proceed to destruction.

**4. Obligations of the Data Controller**

The person in charge of the processing and all his personnel are obliged to:



#### 4.1. Confidentiality and secrecy

The person in charge of the processing will designate the people of his workforce (hereinafter, "authorized personnel") who will be the only people authorized to access the personal data subject to processing by the person responsible for the processing.

The Person in Charge will maintain an updated list of authorized personnel at the disposal of the Controller and if he requests it, a copy of it must be given to him.

The person in charge guarantees that the authorized personnel are aware of the security and confidentiality obligations derived from the RGPD and the LOPDGDD, and that they undertake, expressly and in writing, to respect confidentiality and comply with the corresponding security measures.

Likewise, both the manager and the authorized personnel undertake to use the personal data that is the object of processing, or those that they collect for inclusion, only for the purpose of this order. In no case may you use the data for your own purposes.

They also undertake to maintain the duty of secrecy with respect to the personal data to which they have had access by virtue of this, even after their object ends.

The Manager guarantees the necessary training in the protection of personal data of the persons authorized to process personal data and will control at all times the respect of the instructions given by the Responsible in relation to the processing of the data, verifying compliance by the authorized personnel of the procedures established to guarantee data security and compliance with applicable regulations.

#### 4.2. Use and communication of the data by the person in charge

The Manager will treat the data in accordance with the documented instructions of the person in charge. If the person in charge of the processing considers that any of the instructions provided by the controller infringes the RGPD or any other provision on data protection, he will inform the controller.

He will not communicate personal data to third parties, unless he has the express authorization of the Responsible, in the legally admissible cases.

The person in charge can communicate the data to other managers of the processing of the person in charge, in accordance with the instructions of the person in charge. In this case, the Controller will identify, in advance and in writing, the entity to which the data must be communicated, the data to be communicated and the security measures to be applied to proceed with the communication.

#### 4.3. International transfers

If the Processor must transfer personal data to a third country or an international organization, it is necessary to request the prior written authorization of the Controller. And he may not, in any case, proceed to any International Transfer of data until he has obtained this authorization in writing.

However, if the person in charge must transfer personal data to a third country or an international organization, by virtue of the law of the European Union or of the Member States that applies, he / she will inform the person in charge of this legal requirement in advance, except that this right prohibits it for important reasons of public interest.

In the event that the international transfer is subject to express authorization from the control authority, the person in charge of the processing will refrain from making it until the person



responsible for the processing communicates the obtaining of this authorization. The person in charge of the processing undertakes to provide her assistance and provide all the information that is necessary so that the person in charge can process said authorization.

In any case, the person in charge of the processing must provide all the information or documentation that allows the controller to demonstrate his diligence in complying with the RGPD and the LOPDGDD in relation to said international transfers.

#### 4.4. Outsourcing

The person in charge may not subcontract any of the services that are part of the contract for the provision of services that involve the processing of personal data, with the exception of the auxiliary services necessary for the normal operation of the services of the manager.

If it is necessary to subcontract any service that involves the processing of personal data, this fact must be communicated in advance and in writing to the Responsible, one month in advance, indicating the processing that it is intended to subcontract and clearly and unequivocally identifying the subcontractor company and its Contact information. Subcontracting can be carried out if the Controller gives the express approval in writing.

The subcontractor, who will also be in charge of the processing, is also obliged to comply with the obligations established in this document for the person in charge of the processing and the instructions issued by the person in charge.

It is the responsibility of the initial manager to regulate the new relationship so that the new manager is subject to the same conditions (instructions, obligations, security measures ...) and with the same formal requirements as him, regarding the proper processing of personal data, and the guarantee of the rights of the affected persons.

The person in charge must deliver to the person in charge the copy of the contract signed with the sub-manager for review and filing, in order to be able to demonstrate diligence in compliance with the applicable regulations. Likewise, the person in charge may, at any time and through the person in charge, request the sub-manager to deliver all the documentation related to the technical and organizational measures implemented by him for the protection of personal data.

In the event of non-compliance by the sub-manager, the initial manager will remain fully responsible to the person in charge of fulfilling the obligations.

#### 4.5. Collaboration and support to the Responsible

The person in charge must collaborate and support the Responsible, specifically in the following:

- a) Carrying out impact assessments related to data protection, when appropriate.
- b) Carrying out prior consultations with the supervisory authority, when appropriate.
- c) The preparation of the response to the exercise of the interested parties in the following rights:
  1. Access, rectification, deletion and opposition
  2. Limitation to processing
  3. Data portability
  4. If it is not subject to automated individualized decisions (including profiling).



When the affected persons exercise any of these rights before the person in charge, the latter must:

1. Notify the Responsible by email at the address [lopd@vhir.org](mailto:lopd@vhir.org). The communication must be made immediately and in no case beyond the day following the business day on which the request was received, together, if applicable, with other information that may be relevant to resolve the request.
2. Provide assistance to the Responsible in relation to this exercise of rights, complaint or claim, so that the Responsible can attend it with due diligence and accuracy.
3. Ensure that no member of its staff or, where appropriate, no Sub-Manager responds to the interested party without express written authorization from the Responsible Party and, where appropriate, always following the written instructions of the same.
4. Maintain a record of complaints, claims or requests for the exercise of rights exercised by the interested parties, including a copy of the request, the measures taken to respond to this request and any other communication maintained with the interested party in relation to it.

#### 4.6. Right of information

The person in charge will keep and make available to the person in charge all the necessary information and / or in any relevant way in relation to the processing of personal data entrusted to demonstrate compliance with their obligations, as well as to carry out the audits or inspections they carry out. the Controller or another auditor authorized by him.

Based on this, the person in charge will designate a data protection delegate and will communicate the identity and contact details to the person in charge, provided that it is applicable according to article 37.1 of the RGPD.

The Processor will keep a record of all the categories of processing activities carried out on behalf of the person in charge.

The Responsible Party reserves the right to be able to verify or audit, at any time and with a maximum notice of 3 calendar days, by itself or by third parties, compliance with the obligations derived from this, including the obligations related to the processing of personal data, as well as the security measures adopted by the person in charge of the processing.

The person in charge of the processing will authorize the person or persons who designate the person in charge in order to verify that the processing is carried out ensuring the confidentiality and security interventions required by current legislation, guaranteeing at all times full access to any equipment and / or documents related to the provision of the services that are the object of the contract.

#### 4.7. Security measures

The person in charge of the processing will implement the security measures that appear in annex 1 to this.

In any case, it will be necessary to implement mechanisms that allow:

- a) Pseudonymisation and encryption of personal data.
- b) The capacity to guarantee the permanent confidentiality, integrity, availability and resilience of the processing systems and services.
- c) The ability to restore the availability and access to personal data quickly, in the event of physical or technical incidents.
- d) The process of regular verification, evaluation and assessment of the effectiveness of the technical and organizational measures to guarantee the effectiveness of the processing.





Likewise, the risks of destruction, loss, accidental or illegal alteration, communication or unauthorized access will be taken into account when evaluating the adequacy of the security level.

If the Manager modifies the security measures implemented at any time, he will immediately notify the Data Controller, who will analyze whether the security measures that the Manager offers meet the minimum requirements demanded by the Manager.

In the event that the Data Controller concludes that said security measures are not sufficient, it may terminate the service provision contract immediately without any penalty or compensation in favor of the Processor, and the latter may not demand the payment or return of any amount.

#### 4.8. Notification of data security breaches

The Person in Charge of Processing will notify the Responsible, without undue delay, and in any case before the maximum period of 12 hours, and through email or telephone with subsequent written communication, of the breach of security of personal data in charge of the that he has knowledge, together with all the relevant information for the documentation and communication of the incident.

Notification will not be necessary when it is unlikely that this security breach constitutes a risk to the rights and freedoms of natural persons.

The notification must at least:

- a) Describe the nature of the breach of security of personal data, including, when possible, the categories and approximate number of affected interested parties, and the categories and approximate number of affected personal data records.
- b) Communicate the name and contact details of the data protection officer or other contact point where more information can be obtained.
- c) Describe the possible consequences of the breach of security of your personal data.
- d) Describe the measures adopted or proposed to remedy the breach of security of personal data, including, where appropriate, the measures adopted to mitigate the possible negative effects.

If it is not possible to provide all the above information simultaneously, the information will be provided gradually without undue delay.

In no case shall the Person in Charge communicate anything to any competent control authority without the prior written consent of the Responsible Party, unless the Applicable Legislation to the Person in Charge so requires, so that and whenever possible it will inform the Responsible of the processing.

The Data Controller will collaborate with the Controller to assist with the investigation and repair of any security breach.

In cases where, according to the RGPD, a data security breach must be communicated to the interested parties, this communication will be made by the Responsible, without undue delay and in clear and simple language.

#### 4.9. Data destination



Once the relationship of those that is caused by this contract and the actions described in it has ended, the person in charge will return to the person in charge the personal data and, where appropriate, the media where they are stored. The return will entail the total erasure of the existing data in the computer equipment used by the person in charge. However, the person in charge authorizes the person in charge to keep a copy with all the records duly blocked, adopting the pertinent security measures, while responsibilities are derived from the execution of the contracted service, being able to keep them blocked for a maximum of five years. will proceed to destruction.

## 5. Communications

In order to facilitate compliance with the obligations derived from this document, the parties provide the following contact information:

### Controller

Name: Vall d'Hebron University Hospital Foundation - Research Institute (VHIR)

Telephone: +34 93 489 30 00

Address: Paseo del Vall d'Hebron 119-129, Mediterranean Building, 2nd floor, 08035, Barcelona

DPO data: In compliance with the RGPD, the VHIR has appointed a data protection delegate, and his contact information is dpd@ticsalutsocial.cat. From the VHIR Legal Unit, all doubts, complaints, clarifications, suggestions will be resolved and the exercise of the rights of the interested parties will be addressed, through the email lopd@vhir.org.

### Processor

Name: .....

Telephone: .....

Address: .....

DPO data: .....

And in proof of conformity, the parties sign this contract, in the place and on the date indicated in the heading.

## FUNDACIÓN HOSPITAL UNIVERSITARI VALL D'HEBRON – INSTITUT DE RECERCA (VHIR)

### CONTROLLER

Dr. Joan X. Comella Carnicé

.....

### PROCESSOR

Mr. ....



## APPENDIX 7.1

### TECHNICAL AND ORGANIZATIONAL MEASURES

The person in charge of the processing guarantees that he has implemented all the necessary measures for the processing of personal data, which include:

- a) Pseudonymisation and encryption of personal data.
- b) The capacity to guarantee the permanent confidentiality, integrity, availability and resilience of the processing systems and services.
- c) The ability to restore the availability and access to personal data quickly, in the event of physical or technical incidents.
- d) The process of regular verification, evaluation and assessment of the effectiveness of the technical and organizational measures to guarantee the effectiveness of the processing.

The measures adopted are the following:

a) When sending personal data, these are compressed and encrypted with a key so that no third party can access the information contained herein. In addition, the minimum personal data necessary to carry out the appropriate work is included in each case.

b) Periodic system operations, which involves the intrinsic tasks in the information systems and support systems, with a daily, weekly, monthly, and annual frequency, to ensure the integrity of the systems and their availability. Among them are the physical and visual verification of the data center (access, temperature, etc.), the review of logs, copy systems and monitoring system.

c) Backup service that guarantees the replacement of data and information systems in the event of a physical and technical incident, with rapid replacement of data in the event of loss or accidental deletion. This service runs with different data retentions: daily (2 weeks), weekly (4 weeks), monthly (12 months) and annually (5 years).

d) Information systems monitoring system, communications equipment and support systems. The correct operation of the systems is ensured for as long as possible, with the reduction of reaction time in the event of an incident that affects the normal operation of the systems.

e) Implementation of different security systems that ensure the integrity of the data, such as: (i) Physical security: the data center has fire extinguishing systems, secure access by means of a guarded key, and temperature control. (ii) Perimeter security: the organization has an active-passive cluster system in the form of a perimeter firewall that prevents logical unauthorized access from the outside and from the inside. (iii) Information systems with complex passwords that do not allow the creation of simple passwords. (iv) Software security, with the updating of corporate software with the latest security patches, and the implementation of an antivirus system. In addition, the system is complemented with measures that avoid data encryption using cryptography techniques.