**ANNEX 1**

**RESPONSIBLE DECLARATION FORM**

Mr. / Ms. ..............................., with ID no........................., acting on behalf of and representation of ..................................................... (bidder)., in his capacity as ................................................. and with sufficient powers to sign this affidavit, aware of the announcement of the contracting procedure for the award of the ................................................................... Contract with the reference number of the file ..................,

**DECLARES RESPONSIBLY:**

1.- That the specific identification data of ........... (bidder) are:

- Company name: [....]

- NIF [......]

- Postal address: [......]

- Contact person: [......]

- Telephone: [......]

- Fax: [......]

- Email: [......]

- Internet address (website address) (if applicable): [......]

- SME: YES/NO

2.- That the bidder is not participating in this contracting procedure together with others.

(*in case of affirmative answer)*

*(a) Indicate the role of the bidder within the group (main responsible, responsible for specific tasks, etc.): [......]*

*(b) Identify yourself to the other economic operators participating in the procurement procedure jointly: [......]*

*(c) If applicable, name of participating group: [......]*

3.- That, for the purposes of this contracting procedure, the authorised representatives of the bidder are:

- Name: [......]

- Position/Representation in which he acts: [......]

- Postal address: [......]

- Notary of the power of attorney: [......]

- Power of attorney deed date: [......]

- Telephone: [......]

- Email: [......]

- Tax ID number of the representative: [......]

4.- That the company it represents complies with the legally established conditions for contracting with the public sector and meets each and every one of the aptitude, capacity and solvency requirements (economic, financial, technical and professional) established in the Specifications governing this tender and is in a position to be able to accredit it at the time required.

Consequently, it undertakes when required by the Fundació Institut Hospital del Mar d'Investigacions Mèdiques to provide, within the required period, documentation accrediting the capacity, aptitude and solvency required for the procedure.

5.- That the company it represents and its directors and/or representatives are not involved in any of the cases of incapacity or prohibition to contract as determined in current legislation.

6.- That the company is up to date with its obligations related to the payment of taxes and Social Security contributions, both in the country in which it is established and in the Spanish State.

7.- That the company has not breached its obligations in the areas of labour, social or environmental legislation.

8.- That the company is not aware of any conflict of interest with the Hospital del Mar Medical Research Institute Foundation due to its participation in this contracting procedure.

9.- That you accept that the documentation attached to the Specifications is contractual.

10.- That the company they represent complies with and undertakes to comply with the ethical principles and rules of conduct indicated by the Hospital del Mar Medical Research Institute Foundation, assuming responsibility for non-compliance.

11.- That the company it represents has not unduly withdrawn its proposal or candidacy in an award procedure, nor has it made it impossible to award a contract in its favor because it does not comply with the provisions of article 150.2 of the LCSP, within the period indicated for this purpose intervening grief, fault or negligence, nor has it ceased to formalize a contract awarded in its favor for reasons attributable to it.

12.- That in relation to the tender for the reference contract indicated above and in accordance with the practice of the notifications derived from it, designates as the preferred means of receiving said notifications the email address: .........................

13.- That the company intends to subcontract (if applicable).......

14.- That the signatories of this declaration formally declare that the information they have provided in this tender for ........................... It is accurate and truthful and that they are aware of the consequences of a false statement.

15.- That the bidding entity undertakes to respect the content of the standard contractual clauses in accordance with the Implementing Decision (EU) 2021/915, provided for in Annex 15 of this Specific Administrative Clauses Specifications.

16.- That the bidding entity accepts the content of the clinical trial protocol.

17.- That the bidding entity declares that it is in a position to provide, when required by the contracting body, the documentation indicated in the Technical Specifications of the tender.

And for appropriate purposes, this responsible declaration is signed, in ............ from.................... from............

Electronic signature of the person formulating the proposal.

**ANNEX 2**

**MODEL FOR ASSESSING AWARD CRITERIA**

**Exp. No. ..................**

**COMPANY/EMPLOYER DETAILS**

Name/Company name N.I.F.

Telephone Fax Email

Mr./Ms. Residing in ................ on .................................................. Street number........................... and with NIF ....... declares that, aware of the conditions and requirements required to be the company awarded the contract of **..............................** with file number **............................**undertakes (on its own behalf / on behalf of the aforementioned company) to execute it strictly subject to the requirements and conditions stipulated below:

**COMMON ANNEX FOR THE 19 LOTS.**

**The bidder expressly declares compliance with all technical aspects and those relating to the assignment of means detailed in the Technical Specifications of the tender, with respect to the lot to which it is submitted.**

* **Economic offer:**

|  |  |
| --- | --- |
| **Description** | **Unit price per recruited patient (excluding VAT).** |
| Patient recruitment and monitoring service within the framework of the "LIVERATION" research project. Lot no. xx (indicate) |  |

Electronic signature of the person formulating the proposal

**ANNEX 3**

**MEANS OF ACCREDITING ECONOMIC, FINANCIAL AND TECHNICAL SOLVENCY, AND MANDATORY SPECIFIC DOCUMENTATION**

In accordance with article 92 of the LCSP, developed by regulations in article 11.5 of Royal Decree 1098/2001, of 12 October, approving the General Regulations of the Law on Public Administration Dealings, bidders are exempt from accreditation of economic, financial, technical or professional solvency, given that the estimated value of each of the lots does not exceed the amount indicated in said provision.

**ANNEX 4**

**ECONOMIC AND TECHNICAL ASPECTS SUBJECT TO NEGOTIATION/AWARD CRITERIA**

In accordance with articles 145.1, 169 and 170 of the LCSP and taking into account the object of the reference contract, the following automatic award criteria is proposed:

1. Economic and technical aspects subject to negotiation: Price.

2. Award criteria: Price, according to art. 146.1 of the LCSP.

**These award criteria will be common for the 19 lots.**

**Criteria evaluated automatically (100 points):**

In accordance with article 146.2 of the LCSP, the following will be used for the evaluation of offers according to criteria quantifiable through the mere application of formulas:

**- Economic offer: up to 100 points, according to the application of the following formula:**



Where:

Pv: Offer score to Rate

Ov: Offer to be assessed

Om: Better Offer

IL: Bidding Amount

VP = Weighting Value

Q: Economic criteria points

In the formula, the associated weighting value is equal to 1 (VP = 1).

Formula justification: Application of Directive 1/2020 on the application of formulas for the assessment and scoring of economic and technical proposals approved by the Directorate General of Public Procurement of the Generalitat de Catalunya.

In accordance with the provisions of article 170.2 of the LCSP and pursuant article 169.5 of the same law, the IMIM Foundation will negotiate with the bidder the initial offers and all subsequent offers submitted by it, except for the final offers referred to in the aforementioned article 169.8 of the LCSP.

**ANNEX 5**

**MODIFICATIONS TO THE CONTRACT**

Contractual modifications will be made in accordance with the provisions established in the LCSP and Directive 2014/24/EU, of 26 February 2014, on public procurement.

In accordance with article 204 of the LCSP, it is foreseen that a modification of the contract may be processed in the following cases:

* Increase or decrease in the number of patients to be recruited by one of the awarded centres, with prior authorisation from the IMIM Foundation. This assumption is considered in anticipation that one of the awarded centres will not be able to reach the marked figure of 30 patients and, therefore, it is necessary for one or more of the other awarded centres to increase the number of patients to be recruited in order to reach the figure of 570 patients required to carry out the study.

In the event of an increase, under no circumstances may the 36 patients recruited per centre be exceeded.

This possible modification will not affect the total number of patients to be recruited (570), nor will it mean an increase in the estimated value of the contract.

The formalization of the modification must be made by appearance, after hearing with the successful bidder, before the end of the contract.

In accordance with article 309.1 of the LCSP, in the service contract where the price is determined by execution units, the variation that occurs exclusively in the number of units actually executed over those provided for in the contract that may be included in the settlement up to 10% of the contract price will not be considered modifications.

The successful bidder shall be obliged to follow the services strictly subject to the rules established for him, without the right to claim compensation and for any reason may not reduce the pace of deliveries or suspend them.

**ANNEX 6**

**PENALTY REGIME**

**Defaults**

**These are very serious breaches:**

* The total and absolute stoppage of the execution of the services subject to this contract attributable to the contractor.
* Resistance to the requirements made by the Hospital del Mar Medical Research Institute Foundation or non-observance thereof, when it causes very serious damage to the execution of the contract.
* The use of work systems, elements, materials, machines or personnel other than those provided for in the contractor's specifications and offers, where applicable, when it causes very serious damage to the execution of the contract.
* Delays in response time and resolution of problems that affect the quality of the environment and safety in the workplace. A delay of 3 months will be considered a very serious breach.
* The falsification of the services entered by the contractor in the collection document.
* Failure to comply with the requirements relating to the subcontracting of benefits and the assignment of contracts.
* Failure to comply with the deadline for starting the execution of benefits.
* Failure to comply with the partial execution of the services defined in the contract that causes very serious damage.
* Recidivism in the commission of serious breaches.
* The application in offers or invoices of unit prices higher than the maximum applicable prices of said tender.

**These are serious breaches:**

* Resistance to the requirements made by the Fundació Institut Hospital del Mar d'Investigacions Mèdiques, or its non-observance, when it does not cause very serious damage.
* The use of work systems, elements, materials, machines or personnel other than those foreseen in the project, in the specifications and in the contractor's offers, where appropriate, when it does not cause very serious damage to the execution of the contract.
* Failure to comply with the requirements of a formal order established in this specification and in the applicable provisions for the execution of the contract.
* Delays in response time and resolution of problems that affect the quality of the environment and safety in the workplace.
* Failure to comply with environmental quality conditions and failure to communicate changes that may affect these quality conditions.
* Recidivism in the commission of minor breaches.

**These are minor breaches:**

* In accordance with current regulations, smoking is prohibited throughout the Fundació Institut Hospital del Mar d'Investigacions Mèdiques, both indoors and outdoors. Failure by the workers of the successful bidder to comply with the smoking ban inside the centres and venues will be considered a minor misdemeanor.
* Failure to comply with the requirements of a formal order established in this specification and in the applicable provisions for the execution of the contract, which does not constitute serious breach.

**Hardships**

Irrespective of the obligation to compensate for damages that may arise, if any, the Fundació Institut Hospital del Mar d'Investigacions Mèdiques may apply the following penalties, based on the degree of damage, dangerousness and/or repetition:

1. Very serious breaches: discounts on the contract price for each commission of this type of breach. The amount of each penalty will be established according to the damage and may represent up to 10% of the total amount of the contract.
2. Serious breaches: discounts on the contract price for each commission of this type of breach. The amount of each penalty will be established according to the damage and may represent up to 5 per 100 of the total amount of the contract.
3. Minor breaches: discounts on the contract price for each commission of this type of breach. The amount of each penalty will be established according to the damage and may represent up to 2 per 100 of the total amount of the contract.

In the processing of the case, the contractor will be given a hearing so that he can make allegations, and the contracting body will decide.

A minor breach can become serious, and a serious one can become very serious in case of lack of due diligence in complying with the requirements made by the IMIM Foundation to the contractor. Therefore, the same breach may lead to the application of penalties corresponding to minor, serious or very serious breaches, as appropriate.

In the event that the contractor becomes in default with respect to the fulfillment of the deadlines established in the contract, the penalties established in art. 193.3 of the LCSP, without prejudice to those that may correspond in accordance with the provisions of this PCAP.

In those contracts in which the contractor has the obligation to present a work program, failure to comply with the partial deadlines established therein will be considered very serious breaches and may lead to the application of the penalties provided for this type of breach, or the termination of the contract.

In accordance with article 192 of the LCSP, these penalties will be proportional to the seriousness of the breach and their total amount will not exceed 50% of the contract budget.

**ANNEX 7**

**ESSENTIAL OBLIGATIONS OF THE CONTRACT**

The successful bidder is obliged to carry out the service in the best possible conditions and to comply with all the obligations arising from the Technical Specifications of the tender.

You are also obliged to:

1. The contractor is obliged to comply with current provisions on labor, Social Security and occupational health and safety.

It is also obliged to comply with current provisions on the social integration of people with disabilities, fiscal and environmental.

1. The successful bidder must use Catalan in their relations with the IMIM Foundation, derived from the execution of the object of the contract. In any case, the contractor and, where appropriate, the subcontractors, are subject in the execution of the contract to the obligations derived from Law 1/1998, of 7 January, on language policy and the provisions that develop it.
2. Submit at all times to the instructions given by the person responsible for the contract of the Hospital del Mar Institute of Medical Research Foundation.

.

1. Designate a person responsible for the smooth running of services, who will act as liaison to the person responsible for the contract of the Hospital del Mar Medical Research Institute Foundation.
2. Keep reservation of data or background that are not public or notorious and that are related to the object of the contract, of which you have been aware on the occasion of it.
3. Provide all sufficient personnel to carry out the object of the contract, in accordance with the established technical conditions and with full responsibility, to offer execution to the full satisfaction of the IMIM Foundation. All personnel carrying out the service will depend solely on the contractor awarded, for all purposes without any link of civil service or employment dependence with the Hospital del Mar Medical Research Institute Foundation.
4. Be responsible for all damages caused to third parties and to Fundació Institut Hospital del Mar d'Investigacions Mèdiques Mar or to the personnel dependent on it.
5. The execution of the contract is at the risk and venture of the successful bidder.
6. The subcontracting or assignment of the contract may not be carried out without the express authorisation of the Fundació Institut Hospital del Mar d'Investigacions Mèdiques and in accordance with articles 215 and 214 of the LCSP.
7. Compliance with the special implementing conditions established in Annex 14 of the PCAP.
8. The successful bidder must inform the Fundació Institut Hospital del Mar d'Investigacions Mèdiques if they fail to comply, at any time, during the duration of the contract, with any of the requirements and whether it is a circumstantial and punctual breach or not. In the event that the established minimum mandatory requirements for available means or service levels are not met, the Fundació Institut Hospital del Mar d'Investigacions Mèdiques may terminate the contract unilaterally and without obligation to compensate the supplier.
9. In the event that an exclusive negotiated procedure has been processed without advertising in accordance with article 168 of the LCSP, the successful bidder will be obliged to notify the IMIM Foundation of the loss of exclusivity when this occurs.

**ANNEX 8**

**DISTRIBUTION OF LOTS, ANNUITIES AND BILLING TYPES**

DISTRIBUTION OF LOTS:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Lots** | **Description** | **Taxable base** | **21% VAT** | **Total** |
| **1** | Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at the Hôpital de Beaujon (Paris, France). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **2** | Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at the Hôpital Paul Brousse (Paris, France). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **3** | Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at the Hôpital de Strasbourg (Strasbourg, France). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **4** | Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at the Hospital Policlinico Tor Vergata (Rome, Italy). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **5** | Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Ospedale San Raffaele (Milan, Italy). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **6** | Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Ospedale Miulli (Acquaviva delle Fonti, Italy). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **7** | Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at the Instituto Tumori Napoli (Naples, Italy). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **8** | Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at the Ospedale San Camilo Forlanini (Rome, Italy). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **9** | Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at the University Clinical Centre Ljubljana (Ljubljana, Slovenia). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **10** | Patient recruitment in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Szpital Uniwersytecki im. Karola Marcinkowskiego w Zielonej Górze (Zielona Góra, Poland). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **11** | Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Uniwersytecki Szpital Kliniczny im. Norberta Barlickiego w Łodzi (Łodz, Poland). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **12** | Patient recruitment in a pragmatic clinical trial and subsequent follow-up and its comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Uniwersyteckie Centrum Kliniczne Warszawskiego Uniwersytetu Medycznego/ Centralny Szpital Kliniczny (Warsaw, Poland). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **13** | Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and their comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at SPSK im. Andrzeja Mielęckiego Śląskiego Uniwersytetu Medycznego w Katowicach (Katowice, Poland). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **14** | Patient recruitment in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Kantonspital Winterthur (Winterthur, Switzerland). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **15** | Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at the General Hospital of Athens "Laiko" (Athens, Greece). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **16** | Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at the Agios Savvas Hospital (Athens, Greece). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **17** | Patient recruitment in pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at Metaxa Anticancer Hospital (Pireas, Greece). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **18** | Recruitment of patients in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world environments at General University Hospital of Larissa (Larissa, Greece). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **19** | Patient recruitment in a pragmatic clinical trial and subsequent follow-up and comparability with other therapeutic alternatives in terms of quality of life and patient experience in real-world settings at the General Hospital of Athens "Ippokrateio" Vas (Athens, Greece). | 15.000,00 € | 3.150,00 € | 18.150,00 € |
| **TOTAL** | **285.000,00 €** | **59.850,00 €** | **344.850,00 €** |

DISTRIBUTION OF ANNUITIES: Expected start date on June 1st, 2024.

Sum of Lots No. 1 to 19 (recruitment of 30 patients/centre):

|  |  |  |  |
| --- | --- | --- | --- |
| **Year** | **Taxable base** | **21% VAT** | **Total** |
| **2024** | 171.000,00 € | 35.910,00 € | 206.910,00 € |
| **2025** | 57.000,00 € | 11.970,00 € | 68.970,00 € |
| **2026** | 0,00 € | 0,00 € | 0,00 € |
| **2027** | 0,00 € | 0,00 € | 0,00 € |
| **2028** | 57.000,00 € | 11.970,00 € | 68.970,00 € |
| **Total** | **285.000,00 €** | **59.850,00 €** | **344.850,00 €** |

BILLING TYPES:

Payment to the contractor will be made upon presentation of an invoice issued in accordance with current regulations on electronic invoicing, within the deadlines and conditions established in article 198 of the LCSP.

In accordance with the provisions of Law 25/2013, of 27 December, on the promotion of electronic invoicing and the creation of the accounting register of invoices in the public sector, invoices must be signed with an advanced signature based on a recognised certificate, and must necessarily include the contracting file number.

The format of the electronic invoice and signature must comply with the provisions of Annex 1 of Order ECO/306/2015, of 23 September, which regulates the procedure for processing and annotating invoices in the Accounting Register of invoices within the scope of the administration of the Generalitat de Catalunya and the public sector that depends on it.

The e.FACT platform is the general entry point for electronic invoices of the Administration of the Generalitat de Catalunya and its Public Sector.

Thus, the successful bidder must submit their invoices to the e.FACT service of the Open Administration Consortium of Catalonia (AOC), in its capacity as General Point of Entry for Electronic Invoices of the Public Sector of Catalonia. For more information you can consult this link:

<http://economia.gencat.cat/ca/70_ambits_actuacio/tresoreria_i_pagaments/factura-electronica/>.

The generation of these invoices will correspond to the services carried out duly formed by the Technical Services of the contracting entity.

The invoice must identify the file number with which the contract has been tendered.

The payment(s) of the service will be made in accordance with the content of the LCSP and only by bank transfer and upon receipt of the invoice to the Accounting Department of the contracting entity, through the channels described above.

During the term of the contract there will be no price increase.

Any modification to VAT will be subject to review, and no other increase may be affected.

The invoicing must be issued with rounding to two digits, in accordance with the provisions of article 11 of Law 46/1998, of December 17, on the introduction of the euro.

The monitoring of the status of invoices can be consulted on the website of the Department of the Vice-Presidency and of the Economy and Finance in the Treasury and Payments section (consultation of the status of invoices and payments of documents), from the day after the invoice is registered.

In the event of a delay in payment, the contractor has the right to receive, under the legally established terms and conditions, late payment interest and the corresponding compensation for collection costs in the terms established in Law 3/2004, of 29 December, which establishes measures to combat late payment in commercial transactions.

The contractor may transfer the collection rights under the terms and conditions established in article 200 of the LCSP. For the effectiveness of this transfer of rights to the Fundació Institut Hospital del Mar d'Investigacions Mèdiques, it must have been notified reliably, that is, by means of documentation that allows proof of the conclusion of the contract and the capacity of the parties involved.

**ANNEX 9**

**MANDATORY DOCUMENTATION TO BE INCLUDED IN THE ENVELOPE**

The documentation listed below must be submitted by means of a telematic offer available through the Public Procurement Services Platform of the Generalitat de Catalunya.

* **General documentation** (in accordance with the provisions of Clause 5.3 of this PCAP). The following documentation must also be included electronically signed:
	+ Model of Annex 1 of the PCAP.
* **Documentation relating to the award criteria in Annex 4**, which must comply with the provisions of the Technical Specifications of the tender **and must comply with the indications contained in Annex 2 of this PCAP,** signed electronically by the bidder or person representing them. Thus, it will be necessary to include:
* Model of Annex 2 of the PCAP.

**ANNEX 10**

**ETHICAL PRINCIPLES and RULES OF CONDUCT TO WHICH BIDDERS AND CONTRACTORS MUST ADAPT THEIR ACTIVITY**

In accordance with article 55.2 of Law 19/2014, of 29 December, on transparency, access to public information and good governance, the administrations and bodies included in the scope of application of this law must include, in the specifications of contractual clauses and in the rules for calling for subsidies or grants, the ethical principles and rules of conduct to which contractors and beneficiaries must adapt their activity. and shall determine the effects of an eventual breach of these principles.

In compliance with this legal provision, the ethical principles and rules of conduct to which bidders and contractors must adapt their activity in their contractual relations in the field of public procurement in the public sector of Catalonia are published.

These principles and rules of conduct must be included in all specifications of clauses or documents regulating contracting.

Likewise, and in accordance with article 3.5 of Law 19/2014, public sector contracts must include the obligations of successful bidders to provide information established by this Law, without prejudice to compliance with transparency obligations.

1.- Bidders and contractors must adopt ethically exemplary conduct, refrain from performing, encouraging, proposing or promoting any type of corrupt practice and inform the competent bodies of any manifestation of such practices that, in their opinion, is present or may affect the procedure or contractual relationship. In particular, they will refrain from any action that may violate the principles of equal opportunities and free competition.

2.- In general, bidders and contractors, in the exercise of their activity, assume the following obligations:

1. Observe the principles, rules and ethical canons of the activities, trades and/or professions corresponding to the services covered by contracts.
2. Do not carry out actions that jeopardize the public interest in the scope of the contract or the benefits to be tendered.
3. Report irregular situations that may arise in public procurement processes or during the execution of contracts.

3.- In particular, bidders and contractors assume the following obligations:

1. Immediately notify the contracting body of possible conflict of interest situations. In any case, situations of conflict of interest constitute those contained in article 24 of Directive 2014/24/EU.
2. Not request, directly or indirectly, that a public official or employee influence the award of the contract.
3. Not to offer or provide public officials or employees with advantages for themselves or for third parties with the intention of influencing a contractual procedure.
4. Respect the principles of free markets and competitive competition and refrain from conduct aimed at or likely to have the effect of preventing, restricting or falsifying competition, such as collusion or fraudulent competition behaviour (offers of receipt, elimination of offers, allocation of markets, rotation of offers, etc.).
5. Not to use confidential information, known through the contract and/or during the tender, to obtain, directly or indirectly, an advantage or benefit.
6. Collaborate with the contracting body in the actions that it carries out for the monitoring and/or evaluation of compliance with the contract, particularly providing the information requested for these purposes.
7. Comply with the obligations to provide information that transparency legislation and public sector contracts impose on successful bidders in relation to the reference Administration or Administrations, without prejudice to compliance with the transparency obligations that correspond directly to them by legal provision.
8. Report acts of which it becomes aware and that may lead to an infringement of the obligations contained in this clause.

4.- Failure to comply with the obligations contained in the previous section by bidders or contractors shall be foreseen as a cause, in accordance with public procurement legislation, of termination of the contract, without prejudice to those other possible consequences provided for in current legislation.

**ANNEX 11**

**ETHICS CLAUSE**

1. Senior managers, managerial staff, command positions, administrative positions and personnel at the service of the Public Administration and its public sector, who intervene, directly or indirectly, in the public procurement procedure are subject to the Code of Principles and Conduct recommended in public procurement and their provisions will be applied transversally to any action that forms part of any phase of the procurement procedure in accordance with the degree of intervention and responsibility in contractual procedures.

The presentation of the offer by bidders will imply their adherence to the Code of Principles and Conduct recommended in public procurement in accordance with the ethical and integrity commitments that form part of the contractual relationship.

2.1. Bidders, contractors and subcontractors assume the following obligations:

1. Observe the ethical principles, norms and canons of the activities, trades and/or professions corresponding to the services covered by the contracts.
2. Do not carry out actions that jeopardize the public interest in the scope of the contract or the benefits to be tendered.
3. Report irregular situations that may arise in public procurement processes or during the execution of contracts.
4. Refrain from conduct aimed at or likely to have the effect of preventing, restricting or falsifying competition, such as collusion or fraudulent competition behaviour (offers of receipt, elimination of offers, allocation of markets, rotation of offers, etc.).
5. At the time of submitting the bid, the bidder must declare whether he has any situation of possible conflict of interest, for the purposes of the provisions of article 64 of the LCSP, or an equivalent relationship with respect with interested parties in the project. If during the execution of the contract a situation of this nature occurs, the contractor or subcontractor is obliged to inform the contracting body.
6. Respect confidentiality agreements and rules.
7. In addition, the contractor must collaborate with the contracting body in the actions carried out by it to monitor and/or evaluate compliance with the contract, particularly by providing the information requested for these purposes and that transparency legislation and public sector contract regulations impose on contractors in relation to the Administration or administrations of reference, without prejudice to compliance with the transparency obligations that correspond directly to them by legal provision.

2.2. Bidders, contractors and subcontractors, or their subsidiaries or related companies, undertake to strictly comply with tax, labour and social security legislation and, specifically, not to carry out financial operations contrary to tax regulations in countries that do not have rules on capital control and are considered tax havens by the European Union.

2.3. All these obligations and commitments are considered special conditions for the execution of the contract.

2.4. The consequences or penalties for non-compliance with this clause will be as follows:

* In case of non-compliance with sections a), b), c), f) and g) of section 2.1, a minimum penalty of 0.60 euros is established for every 1000 euros of the contract price, excluding VAT, which may be increased justifiably and proportionally depending on the seriousness of the facts. The seriousness of the facts will be determined by the damage caused to the public interest, the repetition of the facts or the obtaining of a benefit derived from the breach. In any case, the amount of each of the penalties may not exceed 10% of the contract price, excluding VAT, nor may its total exceed in any case 50% of the contract price.
* In the event of non-compliance with the provisions of letter d) of section 2.1, the contracting authority shall report the facts to the competent authorities in matters of competition.
* In the event of non-compliance with the provisions of letter e) of section 2.1, the contracting body will inform the Commission of Ethics in Public Procurement of the Generalitat de Catalunya so that it can issue the relevant report, without prejudice to other penalties that may be established.
* In the event that the seriousness of the facts requires it, the contracting body will inform the Anti-Fraud Office of Catalonia or of the control and audit bodies that are competent due to the matter.

**ANNEX 12**

**Single European Procurement Document (ESPD)**

 It doesn't apply.

# ANNEX 13

# DOCUMENT CONFIDENTIALITY STATEMENT

**FILE NUMBER:**

Mr./Ms..................................................................., with address at ................................., ............................................................................ Street No. ..........., provided with D.N.I. number ....................................................................................., in the name and representation of the company ...................................................................., domiciled at ....................................., Calle ................................................, provided with N.I.F. no. ..........................

 For the purposes of completing the provisions of article 133 of the LCSP, I declare under my responsibility that the documents listed below are confidential:

-File:.... page:......

-File:.... page:......

 None of the documents included in my offer are confidential.

***NOTES:***

*1.- In the event that no field is complemented, it will be understood that the information provided by the bidder is not confidential.*

*2.- Information that has been published in the Public Registers (RELI) will not be considered confidential.*

*3.- In order not to interfere with the principles of publicity and transparency of procedures and freedom of access to tenders, all documents will NOT be considered confidential except for those specific documents that the bidder indicates that affect technical or commercial secrets and confidential aspects of the offers. In this sense,* ***bidders must specify and justify the reasons why the documents marked as confidential are confidential, as well as if there are commercial or technical secrets susceptible to protection,*** *being the Contracting Body the one that ultimately and in case of discrepancy, will issue a reasoned resolution on the confidentiality or not of the documents marked as such.*

Electronic signature of the person formulating the proposal.

# ANNEX 14

# SPECIAL CONDITIONS OF EXECUTION

The special conditions of mandatory execution are the following:

1. The successful bidder will maintain, during the term of the contract, the working and social conditions of the workers employed in the execution of the contract, set at the time of submitting the offer, according to the applicable agreement. This condition can be accredited by an affidavit submitted by the contractor, when required.
2. In accordance with the provisions of articles 3.5 and 55.2 of Law 19/2014, of December 29, on transparency, access to public information and good governance, the contractor undertakes to provide the information established in said law.
3. It will perform the service object of the contract, in accordance with Annex 10 and Annex 11 of this Specification, relating to the "Ethical principles and rules of conduct to which bidders and contractors must adapt their activity" and the "Ethics clause" respectively.
4. The successful bidder assumes, as a special condition of execution, the obligation to guarantee equal treatment of all patients and their rights.

These conditions are an essential obligation of the contract and their breach may be penalized as a very serious misconduct or cause of contractual termination.

**ANNEX 15**

**MODEL OF CONTRACT REGULATING THE ASSIGNMENT OF PERSONAL DATA PROCESSING**

**STANDARD CONTRACTUAL CLAUSES**

**In accordance with the Commission Implementing Decision (EU) 2021/915 of 4 June 2021 on standard contractual clauses between controllers and processors referred to in Article 28(7) of Regulation (EU) 2016/679 of the European Parliament and of the Council and in Article 29(7) of Regulation (EU) 2018/1725 of the European Parliament and of the Council.**

**SECTION I**

***Clause 1***

***Purpose and scope of application***

1. The purpose of these standard contractual clauses (hereinafter, "specifications") is to ensure compliance with Article 28(3) and 4 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data. and repealing Directive 95/46/EC (General Data Protection Regulation).
2. The controllers listed in Annex I have given their consent to be bound by this specification of clauses in order to guarantee compliance with Article 28, sections 3 and 4, of Regulation (EU) 2016/679 and/or Article 29, sections 3 and 4, of Regulation (EU) 2018/1725.
3. This specification of clauses applies to the processing of personal data specified in Annex II.
4. Annexes I to IV form part of the specifications.
5. This specification of clauses is understood without prejudice to the obligations to which the controller is subject under Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.
6. This specification of clauses does not in itself guarantee compliance with the obligations relating to international transfers contemplated in Chapter V of Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.

***Clause 2***

***Invariability of the specifications***

1. The parties undertake not to modify the specifications, except to add or update information in the annexes.
2. This is not obvious because the parties include in a broader contract the standard contractual clauses contained in this specification, nor because they add other additional clauses or guarantees provided that they do not directly or indirectly contradict the specifications of clauses or prejudice the fundamental rights or freedoms of the interested parties.

***Clause 3***

***Interpretation***

1. When this specification of clauses uses terms defined in Regulation (EU) 2016/679 or in Regulation (EU) 2018/1725, they shall be understood to have the same meaning as in the corresponding Regulation.
2. This specification of clauses must be read and interpreted in accordance with the provisions of Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.
3. No interpretations may be made of this specification of clauses that conflict with the rights and obligations established in Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 and/or that prejudice the fundamental rights or freedoms of the interested parties.

***Clause 4***

***Hierarchy***

In case of contradiction between this specification of clauses and the provisions of related agreements between the parties that are in force at the time this specification of clauses is agreed or begins to apply, this specification of clauses will prevail.

***Clause 5***

***Incorporation clause***

*Not applicable*

**SECTION II**

**OBLIGATIONS OF THE PARTIES**

***Clause 6***

***Description of treatment or treatments***

Annex II specifies the details of the processing operations and, in particular, the categories of personal data and the purposes for which the personal data are processed on behalf of the controller.

***Clause 7***

***Obligations of the parties***

**7.1. Instructions**

1. The person in charge will process the personal data only following documented instructions from the person in charge, unless obliged to do so by virtue of Union or Member State law that applies to the processor. In this case, the person in charge will inform the person responsible for this legal requirement prior to treatment, unless this right prohibits it for important reasons of public interest. The person in charge may also give subsequent instructions at any time during the period of processing of personal data. These instructions must always be documented.
2. The processor will immediately inform the person in charge if the instructions given by the person in charge infringe, in the opinion of the person in charge, Regulation (EU) 2016/679, Regulation (EU) 2018/1725 or the applicable provisions of Union or Member State law regarding data protection.

**7.2. Purpose limitation**

The person in charge will process the personal data only for the specific purposes of the treatment indicated in Annex II, except when he follows additional instructions from the person in charge.

**7.3. Duration of processing of personal data**

The processing by the person in charge will only be carried out during the period specified in Annex II.

**7.4. Security of the treatment**

1. The person in charge will apply, as a minimum, the technical and organizational measures specified in Annex III to guarantee the security of personal data. One of these measures may consist of protection against security breaches resulting in accidental or unlawful destruction, loss or alteration of personal data, or unauthorized communication or access to such data ("breach of personal data security"). In determining an adequate level of security, the parties will duly take into account the state of the art, the costs of application, the nature, scope, context and purposes of the treatment, and the risks involved in the treatment for the interested parties.
2. The processor will only grant access to the personal data processed to the members of its staff to the extent strictly necessary for the execution, management and monitoring of the contract. The person in charge will ensure that the persons authorized to process the personal data received have undertaken to respect confidentiality or are subject to a confidentiality obligation of a statutory nature.

**7.5. Sensitive data**

If the processing affects personal data revealing ethnic or racial origin, political opinions, religious or philosophical convictions, or union membership, genetic data or biometric data aimed at unambiguously identifying a natural person, data related to health or data relating to the sexual life or sexual orientation of a natural person, or data relating to criminal convictions and offences ("sensitive data"), the person in charge will apply specific restrictions and / or additional guarantees.

**7.6. Documentation and compliance**

1. The parties must be able to demonstrate compliance with this specification.
2. The person in charge will promptly and adequately resolve the queries of the person in charge related to the treatment in accordance with this specification of clauses.
3. The person in charge will make available to the person in charge all the information necessary to demonstrate compliance with the obligations contemplated in this specification of clauses and that derive directly from Regulation (EU) 2016/679 and Regulation (EU) 2018/1725. At the request of the person in charge, the person in charge will allow and contribute to the performance of audits of the treatment activities covered by this specification of clauses, at reasonable intervals or if there are indications of non-compliance. When deciding whether to carry out an examination or an audit, the person in charge may take into account the relevant certifications that are in the possession of the person in charge.
4. The person in charge may choose to carry out the audit by himself or authorize an independent auditor. Audits may also consist of inspections of the premises or physical facilities of the manager and, where appropriate, be carried out with reasonable notice.
5. The parties shall make available to the competent supervisory authorities, at their request, the information referred to in this clause and, in particular, the results of audits.

**7.7. Appeal to sub-processors**

1. The person in charge may only subcontract to a sub-processor the treatment operations carried out on behalf of the person in charge by virtue of this specification of clauses with the specific prior written authorization of the person in charge. The person in charge must submit the request for specific authorisation at least 15 working days before the hiring of the sub-processor in question, together with the information necessary for the person in charge to resolve the request. The list of sub-processors authorised by the person in charge can be found in Annex IV. The parties shall keep Annex IV updated.
2. When the processor hires a sub-processor to carry out specific processing activities (on behalf of the controller), he will do so by means of a contract that essentially imposes on the sub-processor the same data protection obligations as those imposed on the processor under this specification. The processor will ensure that the subprocessor complies with the obligations to which he is subject under this specification of clauses and Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.
3. The person in charge will provide the person responsible, at the request of the latter, a copy of the contract with the sub-processor and any subsequent modification thereof. To the extent necessary to protect trade secrets or other confidential information, such as personal data, the processor may expurgate the text of the contract before sharing the copy.
4. The person in charge will continue to be fully responsible to the person responsible for compliance with the obligations imposed on the sub-processor by his contract with the person in charge. The person in charge will notify the person in charge of the breaches by the sub-person in charge of the obligations attributed to him by said contract.
5. The person in charge will agree with the sub-processor a third-party beneficiary clause under which, in the event that the person in charge disappears de facto, ceases to exist legally or is insolvent, the person in charge will have the right to terminate the subprocessor's contract and order him to delete or return the personal data.

**7.8. International transfers**

1. Transfers of data to a third country or to an international organization by the processor may only be carried out following documented instructions from the person in charge or by virtue of an express requirement of Union law or of the Member State to which the processor is subject; shall be carried out in accordance with Chapter V of Regulation (EU) 2016/679 or Regulation (EU) 2018/1725.
2. The controller agrees that, when the processor resorts to a sub-processor in accordance with clause 7.7 to carry out specific processing activities (on behalf of the controller) and these activities involve a transfer of personal data within the meaning of chapter V of Regulation (EU) 2016/679, the processor and the subprocessor can ensure compliance with Chapter V of Regulation (EU) 2016/679 using standard contractual clauses adopted by the Commission, in accordance with Article 46(2) of Regulation (EU) 2016/679, provided that the conditions for the use of these standard contractual clauses are met.

***Clause 8***

***Help for data controllers***

1. The person in charge will promptly notify the person in charge of the requests received from the interested party. It will not respond to this request by itself, unless the person in charge has authorized it to do so.
2. The person in charge will help the person in charge to fulfill their obligations when responding to requests for the exercise of rights of the interested parties, taking into account the nature of the treatment. In compliance with the obligations attributed to him by letters a) and b), the person in charge will comply with the instructions of the person in charge.
3. In addition to the obligation of the person in charge to assist the person in charge under clause 8, letter b), the person in charge will also help the person in charge to guarantee compliance with the following obligations taking into account the nature of the treatment and the information available to the person in charge:
	1. the obligation to carry out an assessment of the impact of processing operations on the protection of personal data ("impact assessment") when it is likely that a type of processing poses a high risk to the rights and freedoms of natural persons;
	2. the obligation to consult the competent control authorities before proceeding with the processing when an impact assessment related to data protection shows that the treatment would entail a high risk if the controller does not take measures to mitigate it;
	3. the obligation to guarantee that personal data are accurate and up to date, informing the person in charge without delay if the person in charge discovers that the personal data being processed is inaccurate or has become obsolete;
	4. the obligations under Article 32 of Regulation (EU) 2016/679.
4. The parties shall establish in Annex III appropriate technical and organizational measures that oblige the person in charge to assist the person in charge in applying this clause, as well as the object and scope of the aid required.

***Clause 9***

***Notification of personal data security breaches***

In the event of a breach of the security of personal data, the processor will collaborate with the person in charge and help him comply with the obligations attributed to him by articles 33 and 34 of Regulation (EU) 2016/679 or articles 34 and 35 of Regulation (EU) 2018/1725, where appropriate, taking into account the nature of the treatment and the information available to the processor.

**9.1. Violation of the security of personal data processed by the controller**

In case of breach of the security of personal data in relation to the data processed by the person in charge, the person in charge will help the person in charge in the following:

1. Notify the competent supervisory authorities of the breach of personal data without undue delay once they become aware of them, where appropriate (unless it is unlikely that such a breach of security constitutes a risk to the rights and freedoms of natural persons).
2. Collect the following information, which, in accordance with [OPTION 1] Article 33(3) of Regulation (EU) 2016/679 / [OPTION 2] Article 34(3) of Regulation (EU) 2018/1725, must appear in the notification of the controller, which must include at least:
	1. the nature of the personal data, including, where possible, the categories and the approximate number of data subjects affected, and the categories and approximate number of personal data records affected;
	2. the likely consequences of a breach of the security of personal data;
	3. The measures adopted or proposed by the controller to remedy the breach of the security of personal data, including, where appropriate, the measures adopted to mitigate possible negative effects.

When and to the extent that all the information cannot be provided at the same time, the initial notification will provide the information available at that time and, as it is collected, additional information will be provided without undue delay.

1. Comply, in accordance with article 34 of Regulation (EU) 2016/679, with the obligation to notify the interested party without undue delay of the breach of the security of personal data when it is likely that the breach of security entails a high risk to the rights and freedoms of natural persons

**9.2. Violation of the security of personal data processed by the processor**

In case of a breach of the security of personal data processed by the person in charge, he will notify the person in charge without undue delay once the person in charge has proof of it. This notification must include at least:

1. a description of the nature of the security breach (including, where possible, categories and the approximate number of data subjects and data records affected);
2. the data of a contact point where more information can be obtained about the breach of the security of personal data;
3. its likely consequences and the measures taken or proposed to remedy the security breach, including measures taken to mitigate possible negative effects.

When and to the extent that all the information cannot be provided at the same time, the initial notification will provide the information available at that time and, as it is collected, additional information will be provided without undue delay.

The parties shall establish in Annex III the other elements to be provided by the processor when assisting the controller in complying with the obligations attributed to him by articles 33 and 34 of Regulation (EU) 2016/679, articles 34 and 35 of Regulation (EU) 2018/1725.

**SECTION III**

**FINAL PROVISIONS**

***Clause 10***

***Breach of the clauses and termination of the contract***

1. Without prejudice to the provisions of Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725, in the event that the processor fails to comply with the obligations attributed to him in this specification of clauses, the person in charge may order the person in charge to suspend the processing of personal data until he returns to comply with this specification of clauses, or terminate the contract. The person in charge will promptly inform the person in charge in case he cannot comply with this specification of clauses for any reason.
2. The person in charge will be entitled to terminate the contract with regard to the processing of personal data by virtue of this specification of clauses when:
	1. The processing of personal data by the person in charge has been suspended by the person in charge in accordance with letter a) and this specification of clauses is not complied with again within a reasonable period and, in any case, within a period of one month from the suspension;
	2. the processor substantially or persistently fails to comply with this specification of clauses or the obligations attributed to him by Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725;
	3. the processor fails to comply with a binding resolution of a competent jurisdictional body or of the competent control authorities in relation to the obligations attributed to them by this specification of clauses, Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.
3. The person in charge will be entitled to terminate the contract with regard to the processing of personal data by virtue of this specification of clauses when, after having informed the person in charge that his instructions violate the legal requirements demanded by clause 7.1, letter b), the person in charge insists that these instructions be followed.

After the termination of the contract, the person in charge will delete, at the request of the person in charge, all the personal data processed on behalf of the person in charge and will accredit the person in charge who has done so, or return all personal data to the person in charge and delete the existing copies, unless the law of the Union or of the Member States requires the storage of personal data. Until the data is destroyed or returned, the processor will continue to guarantee compliance with this specification.

**ANNEX I**

**Parts list**

**Responsible(s):** *[Identity and contact details of the controller or data controllers and, where appropriate, the data protection officer]*

|  |  |
| --- | --- |
| 1. | Entity: Hospital del Mar Medical Research Institute Foundation  |
|  | Address: Carrer Dr. Aiguader, 88, 08003 Barcelona (Spain). |
|  | Representative: Joaquín Arribas López |
|  | Position: Director |
|  | Contact details: jarribas@researchmar.net |
|  |  |
|  |  |
| 2. | Data Protection Officer: Roc Mas Vélez |
|  | Address: Passeig Marítim, 25-29, 08003 Barcelona (Spain). |
|  | E-mail: protecciodedades@researchmar.net |

**Processor(s):** *[Identity and contact details of the processor or processors and, where appropriate, the data protection officer]*

|  |  |
| --- | --- |
| 1. | Entity::...................... |
|  | Address:....................... |
|  | Representation:........................ |
|  | Charge:....................... |
|  | Contact details: ..................... (email) |
|  |  |
|  |  |
| 2. | Data Protection Officer: ...................... |
|  | Address:...................  |
|  | Email:..................... |

**ANNEX II**

**Description of treatment**

*Categories of interested parties whose personal data are processed:*

* Identification data (name, surnames, age, identification number, etc.).
* Data related to the provision of services (patient number, medical history number, etc.).
* Health data (diagnosis, data relating to medical tests, blood tests, anamnesis, etc.).

*Categories of personal data processed*

* Patients treated at the centre of the person in charge of treatment.

*Sensitive data processed (where applicable) and restrictions or guarantees applied that take full account of the nature of the data and the risks involved, such as, for example, strict limitation of purpose, access restrictions (including exclusive access by personnel who have taken a specialised course), a record of access to data, restrictions on subsequent transfers or additional security measures.*

Personal data, especially special categories of data, must be processed in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) and Compliance with national regulations applicable to data security. Personnel participating in data processing activities must be subject to a commitment to confidentiality, as well as having received adequate training and instructions to guarantee the security of the personal data processed.

The data collected will be used by the parties exclusively to achieve the purposes described, as well as those that are compatible according to the applicable regulations.

*Nature of the processing*

The data processing will be carried out in accordance with the provisions of the protocol of the research project "*Unraveling the impact of Radiofrequency in liver surgery: the key to decrease local recurrence?* (Lliveration)", as well as according to the life cycle of the data in the collection.

International data transfers to third states or international organizations are not foreseen.

*Purpose(s) of the processing of personal data on behalf of the data controller*

The data processing aims to achieve the objectives proposed in the framework of the project "*Unraveling the impact of Radiofrequency in liver surgery: the key to decrease local recurrence?* (Lliveration)", in the manner identified in the protocol of said project.

*Duration of treatment*

The duration of treatment is established in relation to the duration of the research project "*Unraveling the impact of Radiofrequency in liver surgery: the key to decrease local recurrence?* (Lliveration)", as well as for the legal time of conservation of data appropriate in accordance with the applicable regulations.

*In case of processing by (sub)processors, please also specify the purpose, nature and duration of processing.*

**ANNEX III**

**Technical and organizational measures, especially technical and organizational measures to guarantee data security**

1. **Encryption:**
* The confidentiality and integrity of the information processed must be guaranteed, both stored in information management systems and in transit through the network, for which encryption mechanisms must be used:
	+ Information "**on the transmission line**" using encryption based on TLS certificates 1.2 or higher.
1. **Management of "Logs" and audit:**

The Parties shall have a log management and audit system:

* + It must enable periodic user review, to ensure that they are configured at the appropriate level of privilege and activate the accounts that should be so (eliminating personnel who have unsubscribed and their account remains active). The frequency will depend on each Organization.
* User interactions with the patient data management system must be recorded and stored in a secure environment for at least 2 years.
* Annotation records should include, as far as possible, sufficient information to track the activity of an individual/user with a timestamp, including access, modifications, insertions and searches performed.
* The patient data management system must provide a complete audit trail of the navigation performed by the account of the user accessing.
* The Parties shall periodically audit data processing systems.
1. **Vulnerability management:**
* The patient data management system must be developed using secure coding standards and be protected against web application attacks.
1. **Requirements:**
	* **Equipment:** the equipment used for data processing must, as far as possible, comply with the following security criteria:
	* The hard drive must be encrypted.
	* You must have installed, operational and properly configured an antivirus system that will update the signatures daily.
	* You must have a firewall correctly configured in accordance with the security policy defined by the promoter.
	* You must have the latest updates to your operating system installed.
	* Access must be password protected or robust unlock pattern.
	* It must be a dedicated team used exclusively for the rehearsal tasks carried out on behalf of the promoters.
	* All services and connection interfaces that are not necessary must be disabled.
	* The work profile configured in the teams for users will lack administration privileges, unless their functions make it indispensable.
* **Personal:** Users with access to data processing equipment must:
	+ Avoid installing and using applications that have not been formally approved by the person responsible for the systems.
	+ Review and periodically delete residual information that may have been stored on the device, such as temporary files or downloaded documents.
	+ Once the work that requires access to the patient's data management systems has been completed, proceed to close the session.
* **Work Environment:**
	+ The workplace must meet minimum privacy conditions, such as in a limited access area (including remote work), preventing other people from having access.
	+ If it is necessary to work from public access spaces, additional protection measures will be adopted to preserve the confidentiality of the information processed, such as the use of privacy filters on device screens.
	+ Work with information on paper should be avoided and never disposed of without the use of secure mechanisms (paper shredder or specific containers for confidential documentation).
	+ You will have to work from encrypted networks, never from free and/or free Wi-Fi networks.
	+ In the event of any anomaly that may affect the security of the information and the protection of the data processed, this circumstance must be communicated to the head of systems and/or data protection of your organization.

**ANNEX IV**

**List of subprocessors**

***CLARIFICATION NOTE:***

*This annex must be completed when the specific authorisation of one or more sub-processors is required [clause 7.7, letter a), option 1].*

The person in charge has authorised the following sub-managers to be used: