

SPECIAL PROCUREMENT SPECIFICATIONS FOR THE PROCUREMENT OF A SERVICE FOR THE SELECTION AND PRODUCTION OF ANTIBODIES (ERC-2024-ADG Nab-Heart Project – Prof. Silvia Priori – CUP F13C25001050006)

ARTICLE 1 – SUBJECT MATTER OF THE CONTRACT

These Special Procurement Specifications concern the provision of a service for the selection and production, through the analysis of specific libraries, of a series of antibodies capable of binding to specific antigens within the framework of the ERC-2024-ADG Nab-Heart Project (Scientific Coordinator: Prof. Silvia Priori), associated with CUP F13C25001050006.

The service shall include the following activities, divided into the phases set out below:

Phase 1:

- Transfer of recombinant proteins and synthetic peptides from the laboratory of Prof. Silvia Priori, located at Istituti Clinici Scientifici Maugeri SpA SB, Via Salvatore Maugeri 10, 27100 Pavia, Italy;
- Transfer of quality control data from Professor Priori's laboratory;
- Purchase of relevant commercial anti-target antibodies and quality control of biotinylated target antigens (ELISA, pull-down).

The activities envisaged under this phase shall commence and be successfully completed within two months from the execution of the contract or from the date of the report authorising the urgent commencement of the service, where such commencement is ordered by the University Administration.

Phase 2:

- 2–3 rounds of antibody panning against the target protein(s)/peptides and off-targets using libraries of humanized VHH antibodies;
- Maximum of 6 selection streams;
- 1 Sanger sequencing run and ELISA screening of 48 clones per sample to identify the best results/candidates.

The activities envisaged under this phase shall commence and be successfully completed within two months from the completion of Phase 1.

Phase 3:

- Cloning of the selected polyclonal samples into a bacterial expression vector and screening of up to 10 96-well plates for the primary assessment of binding specificity (ELISA using recombinant target/off-target proteins), re-arraying and sequencing of VHH antibodies in 96-well plates (RA01), and re-arraying of unique results (RA02).

The activities envisaged under this phase shall commence and be successfully completed within two months from the completion of Phase 2.

Phase 4:

- Shipment of glycerol stocks of the best selected antibodies (up to 48) to Professor Priori's laboratory.

The activities envisaged under this phase shall commence and be successfully completed within six months from the completion of Phase 3.

Phase 5:

- Storage of bacterial clones of the best selected VHH antibodies for a maximum period of six months.

For each phase, the researchers of the University of Pavia and the representatives of the producing company, whose names shall be identified, shall compare and verify the results every two weeks by means of a call (Teams, Zoom, etc.).

The production of antibodies intended for research purposes shall be carried out in compliance with the requirements set forth in Legislative Decree No. 26/2014, implementing European Directive 2010/63/EU, as well as with the applicable regulations governing biological production (in vitro).

In particular, the in vitro production of antibodies (e.g. cell cultures and hybridomas) shall comply with the following biological safety and quality standards, with particular regard to:

- Legislative Decree No. 81/2008 (Consolidated Act on Occupational Health and Safety), governing the handling of biological agents and establishing the relevant biosafety containment levels (BSL-1, BSL-2);
- Good Laboratory Practice (GLP): international standards aimed at ensuring the reliability, traceability and quality of the scientific data produced.

ARTICLE 2 – CONTRACT VALUE

The maximum estimated amount for the service in question, subject to a bid reduction, is **€ 295,470.00** (VAT exempt pursuant to Article 72 of Presidential Decree No. 633/1972).

Financial coverage is guaranteed by funds specifically allocated for research purposes.

Considering the nature and characteristics of the service, no specific interference risks exist in connection with this procurement. Therefore, the safety costs arising from interference risks amount to **€0.00**.

ARTICLE 3 – TIMING AND PERFORMANCE OF THE SERVICE

The service shall be provided within 12 months from the execution of the contract or from the report authorising the urgent commencement of the service, where such commencement is ordered by the University Administration.

Within the above-mentioned deadline, glycerol stocks for bacterial production containing up to 48 humanized VHHs obtained at the end of the selection process shall be provided.

Upon completion of the contract, the Contractor shall produce up to 20 nanobodies.

The University of Pavia shall retain a right of first refusal to purchase up to the 10 best nanobodies, i.e. those that the research group of Professor Priori selects as being capable of most effectively modulating CaMKII (Ca²⁺/calmodulin-dependent protein kinase II), which shall become the property of the University.

ARTICLE 4 – PENALTIES

Failure to comply with the deadlines specified above, including failure to comply with the intermediate deadlines for the individual phases detailed in Article 1 above, except in cases of force majeure not attributable to the Company, shall result in the application of a penalty equal to 0.1 per mille (0.01%) of the contract value.

The contract shall be terminated pursuant to Article 1456 of the Italian Civil Code where the total amount of the penalties applied exceeds 10% of the contract value, without prejudice to the right to compensation for any greater damage suffered.

ARTICLE 5 – OBLIGATIONS AND COSTS BORNE BY THE CONTRACTOR

The Contractor shall comply with the provisions of these Special Procurement Specifications and shall provide a service meeting the general characteristics specified in Article 1.

The following shall be entirely borne by the Contractor, with no right of recourse against the University:

- compliance with the legislation in force concerning the production of antibodies;
- compliance with the safety regulations provided for under applicable legislation;
- compliance with all provisions arising from applicable laws, decrees and collective labour agreements concerning compulsory social insurance, occupational accident prevention, with particular regard to the requirements set forth in Legislative Decree No. 81/2008, as subsequently amended and supplemented, as well as any other obligation imposed on the employer;
- all costs and expenses relating to the service covered by the procurement.

The successful tenderer undertakes to perform the service in a professional and workmanlike manner and in compliance with all applicable technical and safety rules and requirements, including those that may be issued during the term of the contract, as well as in accordance with the conditions, procedures, deadlines and requirements set forth in these Special Procurement Specifications.

It is expressly agreed that any additional costs arising from compliance with the aforementioned rules and requirements shall be borne exclusively by the successful tenderer and shall, in any event, be deemed to be covered by the contractual consideration.

The successful tenderer expressly undertakes to indemnify and hold the University harmless against all consequences arising from any failure to comply with the applicable technical, safety and health rules and requirements.

In the event of failure by the successful tenderer to comply with the provisions of the preceding paragraphs, without prejudice to the University's right to compensation for damages, the University shall have the right to terminate the contract.

ARTICLE 6 – FORCE MAJEURE

If, for reasons not attributable to the Contractor, the Contractor is unable to perform the contractual service within the prescribed deadlines, it may submit a reasoned written request for an extension. If deemed justified, the extension shall be granted by the University.

The submission by the Contractor of requests for extensions of deadlines, amendments to contractual clauses or, more generally, communications and requests for clarification shall not automatically suspend the running of the contractual deadlines unless expressly accepted in writing by the University.

ARTICLE 7 – CONFORMITY VERIFICATION

Verification of conformity shall be carried out in accordance with Article 116 of Legislative Decree No. 36/2023, as subsequently amended and supplemented.

The verification shall be carried out and documented by means of a Certificate of Conformity Verification, to be issued within 30 days from completion of the services.

If the service performed does not correspond, even partially, to the quantities, requirements or contractual conditions, the RUP (Person Responsible for the Procedure) may, at its sole discretion, terminate the contract for breach of contract.

Upon completion of the verification activities, the appointed person shall issue the Certificate of Conformity Verification and forward it to the Contractor for acceptance. The Contractor shall sign it within 5 (five) days of receipt.

ARTICLE 8 – PAYMENTS

Payments shall be made according to one of the following options:

- 30% within two months from execution of the contract or from the urgent commencement of the service, subject to the successful completion of Phase 1;
- 50% within six months from execution of the contract or from the urgent commencement of the service, subject to the successful completion of Phase 3;
- 20% following the successful completion of the conformity verification.

Payment shall be made within 30 days of the issuance of a duly compliant invoice, subject to verification of the Contractor's social security and tax compliance.

Following acceptance of the offer and simultaneously with the issuance of the purchase order, the information required for electronic invoicing shall be provided.

Invoices shall also indicate the Tender Identification Code (CIG), the CUP, the details of the General Director's decision awarding the service, the relevant expenditure commitment number, as well as the payment details, including the IBAN.

A 20% advance payment may be granted in accordance with the procedures provided for under Article 125, paragraph 1, of Legislative Decree No. 36/2023.

ARTICLE 9 – GUARANTEES

The Contractor shall provide the final performance guarantee issued pursuant to Article 117 of Legislative Decree No. 36/2023.

The Contractor shall also provide an insurance policy covering civil liability for damage caused to third parties, with a coverage limit of no less than €500,000.00.

ARTICLE 10 – OBLIGATIONS CONCERNING THE TRACEABILITY OF FINANCIAL FLOWS

Pursuant to and for the purposes of Article 3, paragraph 8, of Law No. 136 of 13 August 2010, the successful tenderer undertakes to fully comply with the provisions of the aforementioned legislation concerning the traceability of financial flows.

Without prejudice to the other grounds for termination provided for in these Special Procurement Specifications, pursuant to Article 3, paragraph 9-bis, of Law No. 136/2010, failure to use bank or postal transfers, or other instruments capable of ensuring full traceability of payment transactions, shall constitute grounds for termination of the contract.

In the event of any change concerning the identification details of the dedicated bank accounts or the persons authorised to operate them, the Contractor shall promptly notify the University and, in any event, no later than seven days thereafter.

In the absence of such notification, the Contractor may not, inter alia, raise objections concerning any delays in payments or payments already made.

ARTICLE 11 – PROHIBITION OF ASSIGNMENT OF THE CONTRACT AND RECEIVABLES

Assignment of the contract in any form whatsoever is prohibited; any act to the contrary shall be null and void by operation of law.

Assignments of receivables shall be governed by the provisions of Law No. 52 of 21 February 1991.

Pursuant to Article 6 of Annex II.14 to the new Public Contracts Code, in order to be enforceable against contracting authorities, assignments of receivables must be executed by means of a public deed or authenticated private deed and must be notified to the debtor administrations.

Assignments of receivables shall be effective and enforceable against contracting authorities unless the latter reject them by means of a notice served on the assignor and assignee within **45 days** from notification of the assignment.

Public administrations may, in the contract entered into or in a separate instrument executed simultaneously therewith, grant prior acceptance of the assignment by the contractor of all or part of the receivables that are to become due.

In any event, the administration to which the assignment has been notified may raise against the assignee all objections that could have been raised against the assignor under the contract relating to works, services, supplies or design entered into with the assignor.

ARTICLE 12 – SUBCONTRACTING

Under penalty of nullity, without prejudice to Article 120, paragraph 1, letter d), of Legislative Decree No. 36/2023, the contract may not be assigned, nor may the entire performance of the services or works covered by the procurement contract be entrusted to third parties, nor may the predominant performance of the works relating to the overall set of predominant categories and contracts with high labour intensity be subcontracted.

Subcontracting is permitted in accordance with the provisions of Article 119 of Legislative Decree No. 36/2023.

ARTICLE 13 – TERMINATION, WITHDRAWAL AND INSOLVENCY PROCEEDINGS

Where a serious breach is identified, the RUP shall send the Contractor, by certified electronic mail (PEC), a formal notice to remedy the breach or to submit its counterarguments within **15 days** of receipt thereof.

If the Contractor fails to remedy the breach within the aforementioned period, or if the Person Responsible for the Procedure assesses the counterarguments negatively, the Contracting Authority shall proceed with the automatic termination of the contract pursuant to Article 1454 of the Italian Civil Code, without prejudice to any action for compensation for the greater damage suffered, including the additional expenditure incurred in entrusting the contract to another company, and any other action that the Administration may deem appropriate to protect its interests.

Early termination of the contract shall result in the enforcement of the final performance guarantee, application of any applicable penalty and, in any event, compensation for all resulting damages.

The University reserves the right to withdraw from the contract pursuant to Article 123 of the Public Contracts Code at any time, subject to at least **20 days' prior notice**, upon payment for services already performed, as well as one-tenth of the value of the services not performed.

In the event of judicial liquidation, compulsory liquidation or composition with creditors, or termination of the contract pursuant to Article 122 of the Code, or withdrawal from the contract pursuant to Article 88, paragraph 4-ter, of Legislative Decree No. 159 of 6 September 2011, or in the event of a judicial declaration that the contract is ineffective, the provisions of Article 124 of the Code shall apply.

ARTICLE 14 – EXPRESS TERMINATION CLAUSE

The University shall have the right to terminate the contract pursuant to Article 1456 of the Italian Civil Code by means of PEC, without the need for a prior formal notice of default, in the following cases:

- provision of a service different from that offered during the tender procedure or not corresponding to the contract in terms of qualitative characteristics;
- occurrence of grounds for exclusion pursuant to Articles 94 and 95 of Legislative Decree No. 36/2023;
- violation of occupational health and safety legislation;
- violation of the prohibition on assignment of the contract;
- violation of legislation concerning the traceability of financial flows;
- performance of the service by personnel who have not been lawfully employed or contracted;
- failure to comply with mandatory insurance, occupational accident, social security and welfare provisions concerning employees and worker-members, where applicable;
- violation of the Legality Protocol signed between the University and the Prefecture of Pavia referred to in Article 17 below;
- violation of confidentiality obligations.

ARTICLE 15 – LEGALITY PROTOCOL

The Contractor acknowledges that, on 26 November 2014, the University of Pavia entered into a Legality Protocol with the Prefecture of Pavia concerning the prevention of corruption and the implementation of administrative transparency, and unconditionally accepts the provisions thereof.

Violation of the clauses contained therein shall constitute grounds for termination of the contract pursuant to Article 1456 of the Italian Civil Code.

ARTICLE 16 – PROCESSING OF PERSONAL DATA

The Parties declare that they have been informed about the use of their personal data and authorise the processing thereof through electronic and/or paper-based systems for the purpose of fulfilling all legal obligations and, in any event, for purposes functional to the execution and performance of the relationship established by this contract, within the manner and limits necessary to pursue such purposes, including disclosure to third parties where required for the performance of the contract or pursuant to applicable legal provisions, in compliance with Regulation (EU) 2016/679 (GDPR) and Legislative Decree No. 196 of 30 June 2003, as most recently amended by Legislative Decree No. 101/2018.

The full privacy notices concerning the processing of personal data are available online on the respective websites of the Parties at the following addresses:

<https://privacy.Università di Pavia.it/> and ...

ARTICLE 17 – ANTI-MAFIA REQUIREMENTS AND EXPRESS TERMINATION CLAUSE

The contract shall be subject to a resolutive condition based on the negative outcome of the verification of the truthfulness of the declarations made by the Contractor, to be carried out through the final acquisition of the anti-mafia information.

Upon fulfilment of such condition, pursuant to and for the purposes of Article 94 of Presidential Decree No. 159/2011, the contract shall be terminated.

The termination referred to above shall also apply where elements relating to attempted mafia infiltration are established after execution of the contract.

In such case, the Contractor shall be entitled solely to payment of the value of the works already performed and reimbursement of the expenses incurred for the performance of the remaining works, limited to the benefits actually obtained.

ARTICLE 18 – CONFIDENTIALITY

The Contractor guarantees that the personnel assigned by it to perform this contract shall maintain confidentiality, vis-à-vis any unauthorised person or third party, with regard to confidential information obtained from the Contracting Authority in connection with the performance of the activities envisaged herein.

The Contracting Authority undertakes to identify, from time to time, the information subject to confidentiality obligations and to inform the Contractor accordingly, so that the Contractor may adopt the necessary measures to prevent any disclosure to unauthorised persons. The Contractor assumes the same obligation towards the University.

Information that is already known to the Parties, is in the public domain, or is disclosed by third parties entitled to disclose it and not subject to confidentiality obligations shall be excluded from this obligation. Any breach of confidentiality obligations for which either Party is responsible shall entitle the other Party to seek compensation for any damage suffered.

ARTICLE 19 – OWNERSHIP OF RESULTS

All scientific results, data, know-how, inventions, formulas, software, products, patents and other intellectual and industrial property rights (hereinafter, the “Results”) generated, developed or obtained in any manner whatsoever in the performance of the services covered by this contract – whether independently by the Economic Operator or within the framework of collaboration with the research personnel of the University of Pavia – shall belong fully, exclusively and unconditionally to the University. Pursuant to Article 65 of the Industrial Property Code (Legislative Decree No. 30/2005, as subsequently amended and supplemented), the Economic Operator acknowledges that the moral rights of inventorship belonging to researchers shall be transferred and exercised through the University of Pavia as their employing institution.

The University of Pavia shall have the exclusive right to file patent applications or applications for other forms of industrial property protection in its own name, both in Italy and abroad, and to undertake the related scientific, industrial and commercial exploitation.

In consideration of the assignment of exclusive ownership to the University of Pavia and of the contractual consideration already paid for the performance of the service, pursuant to Article 6 of the aforementioned Industrial Property Code (Legislative Decree No. 30/2005, as subsequently amended and supplemented), in the event of future and actual commercial exploitation of the patented Results by the University of Pavia or its successors in title, the Economic Operator who is able to demonstrate an actual inventive/scientific contribution may be granted fair compensation, to be determined by means of a separate and subsequent contractual agreement.

The recognition referred to in the preceding paragraph shall be conditional upon the Economic Operator's compliance with all confidentiality and technical cooperation obligations relating to the filing of patent applications, as well as with the provisions of the ERC Nab-Heart Grant Agreement (GA No. 101198414) concerning Intellectual Property (Articles 16 and 17 of the GA and Annex 5).

In accordance with Articles 16 and 17 and Annex 5 of the Grant Agreement for the ERC “Nab-Heart” Project, the UNIVERSITY OF PAVIA shall grant royalty-free access to the Results obtained to the entities affiliated with the Project (ICS Maugeri) and to the Consortium partners (CNIC), to the extent necessary for the performance of the research activities envisaged under the European project.

The Economic Operator acknowledges that the University of Pavia is subject to the European Union safeguard clauses. For a period of up to 4 (four) years following the completion of the ERC Project, any transfer of ownership of, or grant of exclusive licences to, the Results to entities established in non-EU countries shall be subject to prior notification to the European Commission/ERCEA (60 days) and to the absence of any objection by the latter.

The Economic Operator undertakes to maintain the strictest confidentiality with regard to all Results and not to disclose them to third parties prior to the formal filing of the relevant patent applications by the University of Pavia.

Should the Economic Operator breach the confidentiality provisions, improperly use the Results exclusively owned by the University of Pavia, or cause the loss of patent rights or the imposition of penalties/reductions in funding by the ERCEA/European Commission, the Economic Operator shall indemnify and hold harmless the University of Pavia, fully compensating it for all direct and indirect damages suffered by the University.

- a) acknowledgment and acceptance of the provisions of the ERC Nab-Heart Grant Agreement (GA No. 101198414) concerning Intellectual Property (Articles 16 and 17 of the GA and Annex 5);
- b) express acceptance of the exclusive ownership by the University of all generated Results, of the restrictions concerning transfers/licences to non-EU countries, and of the conditions governing their subsequent exploitation and valorisation;
- c) acceptance that all rights relating to inventions shall be vested in the University of Pavia as the entity pursuant to Article 65 of Legislative Decree No. 30/2005, as subsequently amended and supplemented.

ARTICLE 20 – COSTS AND TAX CHARGES

All stamp duty expenses, as well as any other expenses arising from this document, shall be borne entirely by the Contractor.

Pursuant to the provisions of Table A of Annex I.4 to Legislative Decree No. 36/2023, the contract shall be subject to stamp duty in the amount of €120.00, which the Contractor shall pay electronically using the “F24 Payments with Identifying Elements” form (F24 Elide). A copy of the relevant payment receipt shall be submitted to the University.

Participation in the procedure for the award of the service covered by these Special Procurement Specifications entails the full and unconditional acceptance of all the terms and clauses contained herein. For all matters not expressly provided for in these Special Procurement Specifications, reference shall be made to the provisions of the laws and regulations in force.

ARTICLE 21 – JURISDICTION

For any disputes that may arise between the parties in the performance of this document, in respect of which an amicable settlement procedure does not apply, the exclusive jurisdiction shall lie with the Court of Pavia.

Arbitration shall be excluded.

ARTICLE 22 – REFERENCE TO APPLICABLE LAW

For all matters not expressly provided for in the contract, reference shall be made to the applicable legislation in force.

This document has been drawn up in both Italian and English. In the event of any discrepancy, conflict or ambiguity between the two versions, the Italian-language version shall prevail for all purposes.