Reference: 001-24

JOB OFFER

Lleida Biomedical Research Institute is recruiting a:

- Clinical Trial Monitor -

The Institute

The Biomedical Research Institute of Lleida Fundació Dr. Pifarré (IRBLleida) was established with the aim of creating synergies between basic, clinical and epidemiological research, making biomedical research a key driver to improve current clinical practice. IRBLleida covers a chain of translational research, from basic research, aimed at understanding the physiological and pathological mechanisms of the human body, to research that studies the behavior of diseases in large population groups.

The Biomedical Research Institute of Lleida (IRBLleida) was founded in 2004 through a cooperation agreement between the University of Lleida (UdL) and the Catalan Healthcare system. IRBLleida integrates research groups of the faculties of Medicine and Nursing and Physiotherapy of the UdL. On the other hand, we incorporate research groups from:

1. The Catalan Health Institute (ICS) both at the hospital level (Arnau de Vilanova University Hospital - HUAV) and the primary healthcare of Lleida and the Alt Pirineu-Aran Health Region,
2. The healthcare provider Gestió de Serveis Sanitaris (GSS; Santa María University Hospital - HUSM, Pallars Regional Hospital and Mental Health, among others).

IRBLleida has been a CERCA institute since 2013, and as such is organized according to a model of good governance and operation that ensures efficiency, management flexibility, talent recruitment and promotion, strategic planning and executive capacity. It is also one of the 34 Spanish Health Research Institute (IIS) recognized by the Carlos III Health Institute and the Government of the Generalitat, as established by Law 16/2003, of 28 May, on the cohesion and quality of the national health system.

In December 2014, the Lleida Biomedical Research Institute's received the 'HR Excellence in Research' logo from the European Commission. This is a recognition of the Institute's commitment to developing an HR Strategy for Researchers, designed to bring the practices and procedures in line with the principles of the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers (Charter

and Code).

Please, check out our Recruitment Policy

Professional profile of the person hired:

- Clinical Trial Monitor

Requirements (excluding applications that do not complete this section):

- Bachelor's degree or university degree in science or any equivalent qualification.
- Master's degree in Clinical Trials.
- Willingness to travel.

These requirements must be met at the beginning of participation in the program.

Context and tasks to be developed:

The selected person will join the Scientific-Technical Service (SCT) Clinical Research Support Unit (USIC) of the IRBLleida as a Master Technician, and will perform the following tasks for the project PP10814 "Clinical Research Support Platform" funded by the carlos III health institute (isciii), file PT23/00121.

- Participation in the working groups of the ISCIII Clinical Research Support Platform.
- Preparation of the monitoring plan and in the monitoring of the centres participating in the clinical studies (visiting the participating centres before, during and after the clinical study).
- Preparation, development and reporting of site visits.
- Database review and verification of source documents.
- Preparation and maintenance of necessary files (investigator, sponsor, pharmacy).
- Ensuring monitoring and compliance with clinical protocols, Good Clinical Practice standards and current legislation on clinical trials, observational studies and other biomedical research projects.
- Resolution of queries.
- Reporting to the project manager any deviation from the protocol, improperly obtained informed consent, notification of AAG/Manes, or any relevant aspect that occurs in the assigned clinical trials.
- Support and preparation of documents related to the statistical analysis plan, queries plan, statistical report and final clinical report.

- Collaboration in tasks of the Methodological Support team of the SCT USIC (Design and drafting of all the necessary documentation for the study (Protocol, Data Collection Notebook (CRD), Informed Consent, etc.); Design and management of the electronic CRD REDCap).
- Collaboration in tasks of the SCT USIC Clinical Trials Administrative Management team (Management of contracts with participating centres; Management of requests, clarifications, amendments and notifications to the CEIm and regulatory agencies; Application for civil liability insurance policy).

This contract is financed by the Instituto de Salud Carlos III and co-financed by the European Regional Development Fund "Co-financed by the European Union" with file code PT23/00121, by virtue of the Resolution of the Directorate of the Instituto de Salud Carlos III, O.A., M.P. of 18 December 2023, by which grants are awarded for the ISCIII Platform units to support R&D&I in Biomedicine of the 2023 call of the Strategic Action in Health 2021-2023.

Desirable but not required/ Nice to have

- Master's Degree in Clinical Trial Monitoring
- Current Good Clinical Practice Certificate.
- Previous experience in a similar position within the Pharmaceutical Industry, CRO (Contract Research Organization) or Hospital field.
- Training in Clinical Trial Management or similar.

  Experience in the clinical research area as CTA (Clinical Trial Assistant) of clinical trials.
- Previous experience in the design of clinical trials or research projects.
- Experience with the use of electronic data collection notebooks, with particular emphasis on RedCAP.
- Fluent spoken and written Catalan and Spanish.

  English (Minimum level B2).

  Previous experience in clinical research as a clinical trial monitor.

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The Offer – Working Conditions

- Type of contract: Indefinite for technical scientific activities, in accordance with the provisions of Article 23 of Law 17/2022, of 5 September, which amends Law 14/2011, of 1 June, on Science, Technology and Innovation.

  The contractual modality is that of indefinite duration, with specific clauses linked to the financing of the project in accordance with art. 49 1.b) and art. and 52.e). of Royal Legislative Decree 2/2015, of 23 October, approving the revised text of the Law on the Statute of Workers.
- Professional category: Senior Research Technician G1
- Planned start date: Immediate
- Working day: Full time 37.5 hours per week
- Remuneration: 38.000€ gross/year **YES** including employer's social security contributions
- Activity funding: PP10814 Plataforma ISCIII Soporte para la Investigación Clínica PT23/00121
- Duration of the contract: The work programme of the project foresees that the personnel costs will be developed over a period of 3 years.

If there are changes in the work programme and/or budget of the project, the possibility to modify the period will be assessed (the duration of the contract is linked to the specific funding of the project/convention).

We provide a highly stimulating environment with state-of-the-art infrastructures. To check out our training and development portfolio, please visit our website in the training section.

We offer and promote a diverse and inclusive environment and welcomes applicants regardless of age, disability, gender, nationality, race, religion or sexual orientation.

The IRBLleida is committed to reconcile a work and family life of its employees and are offering the possibility to benefit from flexible working hours. In addition, as a result of different company agreements, the following improvements are recognized:

- Paid leave to go to the doctor for personal health reasons.
- Paid leave to accompany a first-degree relative under 18 years of age, over 70 years of age or with first-degree disability to the doctor.
- Holidays that coincide with Saturday or Sunday are moved to the Monday immediately following.

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- A special 6-hour working day is established on Holy Thursday, April 23, June 23, December 24, December 31 and January 5.

Documents and application deadline:

All applications must include:

- A motivation letter.
- Full curriculum vitae.
- The deadline for submission will end on 30 jaunary 2024 at 14.00 hours.

Those interested can apply for the offer by filling in the form (https://www.irblleida.org/ca/job-application/) and sending your CV and a cover letter, indicating the name of the offer for which you are applying and the reference 001 -24.

Selection process schedule for reference 001-24	
Minimum 15 days	Publication and dissemination of the job offer: IRBLleida website, "Empléate" portal, social networks, other employment websites depending on the vacancy offered.
Next 2 working days	Transfer of the CVs to the Selection Committee
Next 5 working days	Meeting of the Selection Committee: - Interview of the pre-selected candidates - Evaluation of the candidates and meeting minutes certifying the candidate awarded with the position
Next 5 working days	Completion of the paperwork required to formalize the employment contract
Immediate	Approximate contract starting date
Express selection process	
When an employee must be replaced urgently, for instance, to cover a sick leave, scientific reasons justifying the incorporation on a specific day, specification in a resolution, etc., an express selection process could be undertaken. This selection process will follow the same procedure as the ordinary one, but the duration of several steps will be reduced, *i.e.* publication of the job offer, submission of applications, evaluation and selection process.	

The contract will be in accordance with the provisions of **article 15 of Royal Legislative Decree 1/1995, of 24 March**, approving the text of the Workers' Statute Act, in accordance with the provisions of **article 2 of Royal Decree 2720/98, of 18 December (B.O.E. of 8 January 1999), Law 12/2001, of 9 July (B.O.E. of 10 July)** and concordant provisions.

The principle of equality between men and women is taken into account, in accordance with Organic Law 3/2007, of 22 March, for the effective equality of women and men. IRBLleida has an Equal Opportunities Plan for men and women and a Protocol for the prevention and eradication of sexual harassment.

The principle to equal opportunities and treatment, as well as the real and effective exercise of rights by people with disabilities on equal terms with other citizens, through the promotion of personal autonomy, universal accessibility, access to employment, inclusion in the community and independent living and the eradication of any form of discrimination, in accordance with **articles 9.2, 10, 14 and 49 of the Spanish Constitution** and the International Convention on the Rights of Persons with Disabilities and the international treaties and agreements ratified by Spain, in accordance with the provisions of **Royal Legislative Decree 1/2013, of 29 November**.

L'IRBLleida es compromet amb els principis de reclutament i transparència basats en mèrits (OTM-R) d'acord amb els requisits de segell HRS4R

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ANNEX I: SELECTION COMMITTEE

PRESIDENT

- Manager IRBLleida
  - Ms. Eva López

CHAIRS

- Researcher at IRBLleida
  - Dr. Albert Lecube

- Researcher at IRBLleida
  - Dra. Alicia Sánchez

SECRETARY

- IRBLleida HR manager
  - Ms. Elena Moscatel

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ANNEX III: SCALE OF MERITS

a) **Academic curriculum and complementary training – 35 points.**

Valued:

➢ Master's Degree in Clinical Trial Monitoring	10 points
➢ Good Clinical Practice Certificate in force	5 points
➢ Training in Administrative Management of Clinical Trials or similar	10 points
➢ Catalan and Spanish spoken and written fluently and correctly	5 points
➢ English (Minimum level B2)	5 points

b) **Certified professional experience. 45 points**

Valued:

➢ Previous experience in clinical research as a clinical trial monitor	15 points
➢ Previous experience in a similar position within the Pharmaceutical Industry, CRO (Contract Research Organization) or Hospital environment	5 points
➢ Experience in the clinical research area as CTA (Clinical Trial Assistant) of clinical trials	10 points
➢ Previous experience in the design of clinical trials or research projects	10 points
➢ Experience with the use of electronic data collection notebooks, with particular emphasis on RedCAP	5 points

c) Competence test or interview - 20 points

<u>Any application that does not obtain a score of more than 50 points will not be considered</u>

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Information clause on the processing of personal data

Responsible for the processing

Identity: **INSTITUTO DE INVESTIGACIÓN BIOMÉDICA DE LLEIDA (BIOMEDICAL RESEARCH INSTITUTE OF LLEIDA)**

TAX ID: G25314394

Address: Avda. Alcalde Rovira Roure nº80, 25198, Lleida

E-mail: protecciodedades@irblleida.cat

Purpose of data processing and conservation

At the **INSTITUTO DE INVESTIGACIÓN BIOMÉDICA DE LLEIDA (hereinafter referred to as IRBLLEIDA)** we process the information you provide as an interested party in order to manage the processing of your CV and application.

The data obtained will be kept for a period of up to 12 months, to cover future applications if they are not updated before or until the interested party objects to their processing.

Legitimation for data processing

The legal basis for the processing of your data is the consent of the interested party when contacting the **INSTITUTO DE INVESTIGACIÓN BIOMÉDICA DE LLEIDA.**

Recipients of your data

Your data will be communicated to third parties and collaborators related to the organisation. Apart from these entities, your data will not be communicated to third parties.

Rights of interested parties

The owners of the data processed by IRBLLEIDA have the right at all times to access their data, rectify it, oppose its processing or delete it if they believe it is no longer necessary for the purposes for which it was collected. In addition, if you wish, you may request the portability of your data and limitation of their processing. In the latter case, we will only keep them for the exercise or defence of claims. You may also revoke your consent at any time.

To exercise these rights, you may contact **IRBLLEIDA** by e-mail at protecciodedades@irblleida.cat. Likewise, if you consider that your rights have been infringed, you may lodge a complaint with the Catalan Data Protection Authority.