Reference: 079-22

JOB OFFER

Lleida Biomedical Research Institute is recruiting a:

- Head of the IRBLleida Clinical Trials Unit (UAC) -

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:

- Senior Department Head

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

Bachelor's degree in the field of health sciences.

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

Context and tasks to be developed:

The aim of the Clinical Trials Unit (UAC) is to provide support on the methodology, regulation and logistics of clinical trials with drugs, medical devices or advanced therapies led by researchers at the institution.

The selected person will join the Institute of Biomedical Research of Lleida (IRBLleida) to fill a position as head of the Clinical Trials Unit (UAC), corresponding to those provided for in Royal Decree Law 32/2021, of 28 December, on urgent measures for labour reform, the guarantee of employment stability and the transformation of the labour market. This Royal Decree-Law has highlighted the need to incorporate temporary positions occupied by temporary staff into the structural staff because the functions assigned to them form part of the ordinary and habitual activity, given that they have exceeded their strictly temporary dimension or have lost their own autonomy and substantive nature. For this reason, it is necessary to promote the structural dimensioning of these posts, which can no longer be considered temporary and be filled under a temporary employment regime, in accordance with the new regulatory framework for temporary contracts established in the Workers' Statute.

The stabilisation of this post was approved in the Agreement of the Board of Trustees of the IRBLleida on 3 June 2022 and published in the Official Journal of the Generalitat de Catalunya No. 8763 of 30 September 2022.

The head of the UAC must work proactively with all stakeholders to improve the management of clinical trials, increase the number of clinical trials and the number of patients recruited, and make proposals to

improve the use of existing tools to achieve these objectives. The head of the UAC will report organically to the IRBLleida Management Committee and the Scientific Directorate of the UAC.

The tasks to be carried out by the Head of the UAC are as follows:

Strategic direction

- He/she will be responsible for the recruitment and promotion of clinical trials at the highest level, in line with the strategic direction of IRBLleida.
- You will lead a multidisciplinary team, developing and implementing strategies to ensure that the conduct of clinical trials is consistent and efficient and meets all relevant regulatory standards.
- You will directly supervise the position of clinical trials administrative technician and the position of head of SCT Farma, which provides technical support to investigators as required.
- You will oversee the management and negotiation of contracts both with the pharmaceutical industry and in those cases where IRBLleida acts as a sponsor. It will review: prices and conditions of leadership, intellectual property, publications, etc... according to the different adaptations of the relevant regulations.
- Liaison with the Clinical Trials Pharmacy Service.
- It will liaise with: Farmaindústria, CRO's, Researchers, CEIm, HUAV Research, research centres as well as other internal and external agents, in order to achieve the growth of the clinical trials activity and guarantee an efficient use of resources.
- It will develop what is established in the IRBLleida's strategic plan in reference to the clinical trials activity.
- Participate in the design of future strategic plans for the growth of clinical trial activity sponsored by industry and also led by HUAV, HUSM and IRBLleida research staff.
- Review the fees of the Clinical Trials Unit, following IRBLleida's calculation procedures, so that they are eligible when applying for services to be justified in grants.
- It will monitor the economic and quality results of the Clinical Trials Unit to ensure its sustainability. It will report quarterly on these results to the IRBLleida steering committee.
- Supervise the processes of applying for grants for the Clinical Trials Unit with the aim of obtaining additional funding for its proper functioning.

- Represent the IRBLleida Clinical Trials Unit in the corresponding internal and external committees.

Clinical research

- Coordinate the smooth running of all trials in the Clinical Trials Unit by managing its staff: pharmaceutical, nursing, administrative, trial monitoring and coordination and other research staff that may be part of the unit.
- He/she will maximise the use of existing systems for recording information on the different clinical trials, patient recruitment, relevant contract dates and unit performance data. As well as to prepare reports to IRBLleida management on performance, budget planning and any other indicators required.
- Ensure that Good Clinical Practices are adhered to, from the initiation and training meetings of clinical trials to the conduct and completion of the trials.
- Develop, implement and monitor strategies to ensure that patient recruitment is met at the level set out in the trial objectives.

Human Resources Management

- Prepare the necessary documentation for personnel selection processes for the UAC, and participate in the selection committee.
- Promote a safe working environment by complying with relevant safety and health policies, procedures and hazard reporting practices.
- You will be the prevention officer for the unit. In taking up this position, you will be responsible for the following functions, but not exclusively:
    - Ensuring that all activities are carried out in accordance with biosecurity guidelines.
    - Supervise the workers under your care, including those who are incorporated into the work programme to ensure that they are aware of the guidelines and are competent to carry out the assigned tasks.
    - Plan and ensure that adequate levels of personnel, time, space and equipment are available to carry out the task safely.
    - Ensure that any new lines of research (or significant changes) involving human infectious (or suspect), GMO or toxin samples are communicated to the Biosafety Committee/Biological Risk Management (BSO) Advisor.

- Ensure that the BAU's risk assessments have been conducted, reviewed and approved by the Biosafety Committee in which he/she sits.
- Ensure that the proposed control measures are operational and in place before starting any new line of research or major changes to existing ones.
- Ensure that at-risk workers have been informed of the risk assessments and the provisions for any recommended preventive medical practices.
- Ensure that you are informed of any changes to your laboratory's Biological Risk Management (BRM).
- Ensure that you have an up-to-date list of chemical and biological products and the corresponding safety data sheets.
- Ensure that the list of work equipment and the corresponding updated instructions for use are available to personnel in a visible place.
- Ensure that all persons in their charge have received the necessary training in the Prevention of Occupational Risks prior to their incorporation.
- Ensure that the necessary protective equipment (PPE) is available and that the personnel of the CCU use it correctly.

Desirable but not required/ Nice to have

- Postgraduate qualification in the areas of clinical trial coordination, project management or a relevant clinical discipline.
- University degree related to business management.
- Experience in coordinating health-related research, including experience in setting up and conducting industry-sponsored clinical trials.
- Current Good Clinical Practice certification.
- Ability to: lead a multidisciplinary team, meet deadlines, drive improvements and create a culture of effective teamwork.
- Experience in working effectively with a wide range of stakeholders and managing complex internal and external relationships in a dynamic environment.
- Minimum level of English B2 or equivalent.
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The Offer – Working Conditions

- Type of contract: Indefinite with 6 months probationary period.

- Planned start date: Immediate
- Workday: Full time of 37.5 hours per week.
- Remuneration: 40.000 euros gross per year.

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.
- 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 4 January 2023 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 079 -22.

Selection process schedule for reference 079-22	
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

ANNEX I: SELECTION COMMITTEE

PRESIDENT

- Director of the Institute for Biomedical Research of Lleida
    - Dr. Diego Arango del Corro

CHAIRS

- Researcher IRBLleida
    - Dr. J.A. Schoenenberger
- Manager of IRBLleida
    - Ms. Eva López
- Deputy Director of IRBLleida
    - Dr. Joan Sayós

SECRETARY

- IRBLleida HR manager
    - Ms. Elena Moscatel

ANNEX II: SCALE OF MERITS

a) Academic curriculum and complementary training - 35 points

Valued:

- Postgraduate qualification in the areas of clinical trial coordination, project management or a relevant clinical discipline. 10 points
- University degree related to business management. 10 points
- Current certification of good clinical practice. 10 points
- English equivalent to B2 level. 5 points

b) Certified professional experience - 35 points

Valued:

- Proven experience in coordinating health-related research. 10 points
- Proven experience in setting up and conducting industry-sponsored clinical trials. 10 points
- Proven professional experience leading and training multidisciplinary teams. 5 points
- Experience in working effectively with a wide range of stakeholders and in managing complex internal and external relationships in a dynamic environment. 5 points
- Proven experience in the financial management of an area or department. 5 points

c) Competence test or interview - 30 points

Any application that does not obtain a score of more than 50 points will not be considered.

Information clause on the processing of personal data

Responsible party: Institut de Recerca Biomèdica de Lleida Fundació Dr. Pifarré (IRBLleida).

Purpose: Management of job offers.

Legitimation: The legal basis of the processing is the carrying out of a selection process to fill a job vacancy.

Addressees: The data will not be transferred to third parties, except in the legal obligations established by law.

Rights: Access, rectification and deletion of data, as well as other rights, as explained in the additional information.

Additional information: You can consult additional and detailed information on Data Protection on our website http://www.irblleida.org/en/legal-notice/.

The data provided by applicants will be incorporated into the processing system owned by IRBLleida in order to manage and resolve the selection process, and will be processed in a lawful, fair, transparent, adequate, relevant, limited, accurate and up-to-date manner, in compliance with the provisions of Regulation (EU) 2016/679 of the European Parliament and Organic Law 3/2018, of 5 December (LOPDGDD). The legal basis for the processing of data is the fulfilment of a legal obligation on the part of the controller reinforced with the consent of the data subject.

This data must be kept for the period of time strictly necessary to fulfil the aforementioned purpose, respecting in all cases the period determined by these rules and regulations governing the call for applications and the applicable archiving regulations.

The IRBLleida must communicate the data of the beneficiaries of the contracts to the Agency for the Management of University and Research Grants so that it can exercise its powers of management control as an entity attached to this Department.

Certain data may also be communicated to third parties in the public or private sphere, either because the intervention of these entities in the course of the aid management process may be necessary because it is correctly resolved, or because it is provided for in a regulation with the status of law.

As long as the interested party does not communicate otherwise, it will be understood that their details have not been modified and that they undertake to notify the IRBLleida of any variation.

Applicants and contracted persons may exercise their rights of access, rectification, limitation of processing, suppression, opposition to the processing of their data or exercise their right to portability by writing to IRBLleida (Avda. Rovira Roure, 80, 25198 Lleida), to the e-mail address protecciodedades@irblleida.cat or to the IRBLleida's Data Protection Delegate, dpd@ticsalutsocial.cat. You must attach a photocopy of your ID card or sign the e-mail with a recognised electronic signature. In the event of disagreement with the processing, you also have the right to lodge a complaint with the Catalan Data Protection Authority.