Reference: 022-22

JOB OFFER

Lleida Biomedical Research Institute is recruiting a:

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

The Institute

The IRBLleida aims to promote, develop, transfer, manage and disseminate research excellence, scientific and technological knowledge, teaching and training in the field of life sciences and health. To this end, it promotes relations and the exchange of knowledge between the research staff and research groups belonging to the various centres and entities in the biomedical field, which operate mainly in the Lleida area; it promotes collaboration with other institutions and entities, prioritising the implementation of joint projects; it raises funds to finance research activities of excellence of interest to the aforementioned centres and devices; and it manages the research resources entrusted to it by the various institutions and entities that form part of it. Within the territorial environment, it collaborates closely with:

- The University of Lleida (UdL) includes researchers from the Faculties of Medicine and Nursing and Physiotherapy.
- The Catalan Healthcare system includes healthcare staff from:

  o Catalan Health Institute (ICS): Arnau de Vilanova University Hospital (HUAV), the Lleida Primary Care and Community and Primary Care in the Alt Pirineu-Aran Health Region

  o Gestió de Serveis Sanitaris (GSS): Santa María University Hospital (HUSM), Pallars Regional Hospital and Mental Health, among others.

The IRBLleida is a CERCA institute with its own legal status: Fundació Institució dels Centres de Recerca de Catalunya (I-CERCA) de Catalunya, which is organised according to a model of good governance and operation that ensures efficiency, management flexibility, recruitment and promotion of talent, strategic planning and executive capacity. It is also a Health Research Institute (IIS) accredited 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:

- Senior Department Manager.

HR EXCELLENCE IN RESEARCH

Requirements (applications that do not comply with this point will be excluded):

- Bachelor's degree in the field of health sciences.

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 medicines, medical devices or advanced therapies led by researchers at the institution.

The head of the UAC has to work proactively with all the actors involved 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 person in charge of the UAC are as follows:

Strategic direction

- You will be responsible for recruiting and driving the conduct of clinical trials at the highest level, in line with the strategic direction of the 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 who require it.
- You will supervise the management and negotiation of contracts both with the pharmaceutical industry and in those cases where IRBLleida acts as a promoter. The following will be reviewed: 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: Farmaindustry, 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 the IRBLleida's strategic plan in reference to clinical trial activity.

- Participate in the design of future strategic plans for the growth of clinical trial activity sponsored by industry and also those 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 form 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, he/she will be responsible for the following functions, but not exclusively:

    - Ensure that all activities are carried out in accordance with the biosecurity guidelines.
    - Supervise the workers in their charge, 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 tasks assigned to them.
    - 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 (or suspect) infectious samples, GMOs or toxins 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.

Would be an asset:

- 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 English level B2 or equivalent.

The Offer – Working Conditions

- Type of contract: Indefinite contract for scientific-technical activities with a 6-month probationary period.
- Planned start date: Immediate.
- Working day: Full 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.

Documents and application deadline:

All applications must include:

- A motivation letter
- Full curriculum vitae with contact details and national identity card number.
- Provide 2-3 references to justify the required experience.

Deadline: Please submit your application by June 30, 2022. Latest time for the submission of applications: 14:00 h - Europe/Brussels

Those interested can apply to the 022-22 offer by filling out the form available at https://www.irblleida.org/ca/job-application/ and attaching a CV and a cover letter.

Selection process schedule for reference 022-22	
15 days	Publication and dissemination of the job offer: IRBLleida website, social networks, other employment websites according to the features of the job 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 - Communication of the selected candidate to HR
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.

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**.

Informative clause for the processing of personal data

Responsible: Institut de Recerca Biomèdica de Lleida Fundació Dr. Pifarré
Purpose: Management of job offers.
Legitimation: The legal basis of the treatment is the completion of a selection process to fill a position.
Recipients: The data will not be transferred to third parties, except in the legal obligations set by law.
Rights: Access, rectification and deletion of data, as well as other rights, as explained in the additional information.
Additional information: Additional and detailed information on Data Protection can be found our website http://www.irblleida.org/en/legal-notice/

IRBLleida is committed to the principles of merit-based recruitment and transparency (OTM-R) in accordance with the HRS4R seal requirements.

ANNEX I: SELECTION COMMITTEE

PRESIDENT

- IRBLleida Scientific director
  - Dr. Diego Arango

CHAIRS

- Researcher at IRBLleida
  - Dr. J.A. Shoenenberger

- Deputy Director of IRBLleida
  - Dr. Joan Sayós

SECRETARY

- IRBLleida HR and procurement manager
  - Ms. Elena Moscatel

ANNEX III: 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 certificate of good clinical practice. — 10 points
- English equivalent level B2 — 5 points

b) Certified professional experience. 35 points

- 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 building multidisciplinary teams. — 5 points
- Experience in working effectively with a wide range of stakeholders and 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.