

## BIOMEDICAL RESEARCH INSTITUTE OF LLEIDA

Arnau de Vilanova University Hospital

Av. Alcalde Rovira Roure, 80 · 25198 Lleida  
Biomedical Research Institute of Lleida  
Biomedicine II building. Ground floor - Clinical Trials Unit

### Contact:

Dr. Alicia Sánchez de la Torre

*USIC Coordinator*

asanchez@irblleida.cat

Tel. +34 973 00 37 46

Dr. Joan Antoni Schoenenberger

*USIC Scientific Director*

jas.lleida.ics@gencat.cat

Tel. +34 973 70 52 00 (Ext. 2675)

Laura Rumi Carrera

*Clinical Trials Pharmacist*

lrumi@irblleida.cat

Tel. +34 973 00 37 52

Clinical Research Support Unit (USIC)

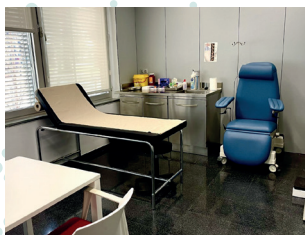
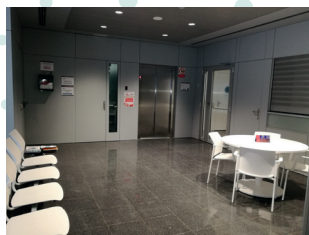
usic@irblleida.cat

Tel. +34 973 00 37 46 / +34 674 10 36 69



  
**Diputació de Lleida**

<https://www.irblleida.org/en/technical-scientific-services/clinical-research-support-unit-usic/>



DLL 154-2023

# Clinical Research Support Unit (USIC)

**IRB** *leida*<sup>B</sup>  
Institut de Recerca Biomèdica

The **Clinical Research Support Unit (USIC)** constitutes a research **support** infrastructure whose purpose is to provide researchers with the necessary **resources**, both material and human, for the execution of clinical trials and other research projects from their initial stages through completion, guaranteeing quality service and compliance with the principles of Good Clinical Practice at all times.

### Infrastructure

- Medical offices equipped with computers connected to the Arnau de Vilanova University Hospital and Santa Maria University Hospital network
- Reception and waiting room for participants and family members
- Laboratory designed to process biological samples
- Clinical Trials Pharmacy
- Medication storage room
- Refrigeration equipment room with controlled temperature and probes with calibration certificates
- Consumables and materials warehouse
- Meeting area for external inspections and/or audits
- Active clinical studies archive and external archive for documentation custody

### Education/Certificates in Clinical Trials

- Good Clinical Practice
- IATA Certificate for Infectious Substances Transport

### Experience in Clinical Trials

- Experience in Phase I, II, III and IV Clinical Trials, Case-Control Studies, Observational Studies, National and International Studies
- **Clinical areas:** Cardiology, Internal Medicine, Endocrinology and Nutrition, Anesthesiology, Rehabilitation and Pain Therapy, Functional Unit for Nosocomial Infections, Angiology and Vascular Surgery, Pneumology, Nephrology, Neurology, Hematology, Ophthalmology, Oncology, Pediatrics, Urology, Traumatology, Digestive Diseases and Rheumatology

### What do we offer?

#### METHODOLOGICAL SUPPORT

Design and drafting of all the necessary/essential documentation for the study (Protocol, Case Report Form (CRF), Informed Consent Form, etc.)  
Design and management of electronic CRF (REDCap)

#### MONITORING

Preparation of monitoring plan adapted to risk evaluation  
Monitoring of all participating centers in multicenter studies  
Preparation, development and elaboration of site visit reports  
Database revision and source documents verification  
Preparation and management of site files: investigator, promoter, pharmacy

#### DATA MANAGEMENT

Data record in source documents and CRF  
Queries management  
Recordkeeping and updating of study information on multiple platforms

#### ADMINISTRATIVE MANAGEMENT / REGULATION

Management of contracts with participating sites  
Management of requests, clarifications, amendments and notifications to CEIm and regulatory agencies  
Civil liability insurance policy applications

#### COORDINATION AND NURSING

Participate in site and research team selection  
Participate in study feasibility evaluation  
Analysis of the circuits and technical needs, space and personnel of each clinical trial  
Conducting meetings with investigators  
Facilitate communication between medical services and external parties involved in the study  
Maintenance of necessary site files: researcher, promoter, pharmacy  
Facilitate the process of recruitment and obtaining informed consent  
Control and management of nursing procedures and complementary tests  
Coordination of visits and follow-up controls  
Comprehensive patient care support  
Pharmacovigilance: management of adverse events  
Management of possible audits  
Custody of clinical trial documentation  
Contact with monitors and preparation of documentation for external monitoring

#### LABORATORY TECHNICIAN

Processing of biological samples and management of their shipment to the central laboratory

#### PHARMACY

Management and preparation of study medication