BIOMEDICAL RESEARCH INSTITUTE OF LLEIDA
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https://www.irblleida.org/en/technical-scientific-services/clinical-research-support-unit-usic/

Diputació de Lleida

DL L 154-2023

Clinical Research Support Unit *(USIC)*

IRB Lleida
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