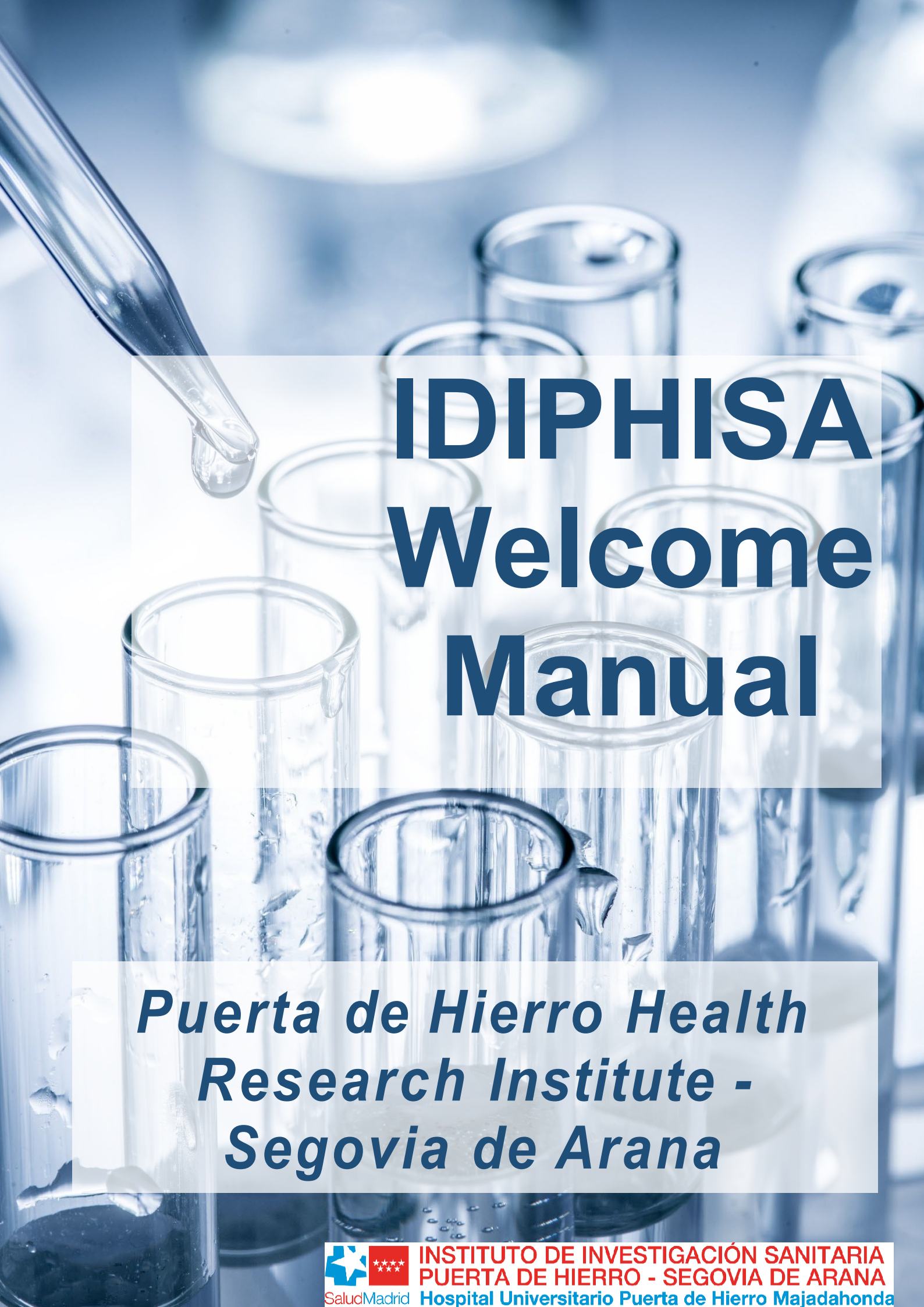


IDIPHISA Welcome Manual

Puerta de Hierro Health Research Institute - Segovia de Arana

INSTITUTO DE INVESTIGACIÓN SANITARIA
PUERTA DE HIERRO - SEGOVIA DE ARANA
SaludMadrid Hospital Universitario Puerta de Hierro Majadahonda

INDEX

1 LETTER FROM THE SCIENTIFIC DIRECTOR

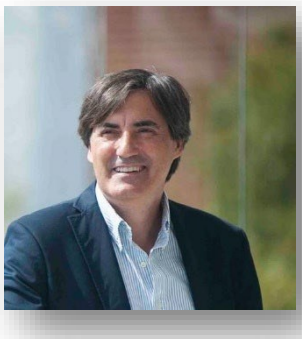
On behalf of the Scientific Direction, we welcome you to the Puerta de Hierro - Segovia de Arana Research Institute, IDIPHISA.

IDIPHISA aspires to become a reference center in multidisciplinary biomedical research, in the field of clinical and translational research, at national and international level. We also aim for Institute to be recognized as a reference center for teaching in the Community of Madrid. The Institute aims to act as an engine for the generation and dissemination of knowledge, making a commitment to promote innovation, research and the transmission of results in a fast and efficient way, the healthcare practice, so that new and better methods of diagnosis and treatment are developed for the diseases with the highest incidence among the population. Biomedical research in our Institute is present and future. The intense relationship between clinical practice and research is a guarantee of quality in the treatment of patients and the benefit for them is indisputable.

This manual is designed to facilitate your incorporation as a researcher to our Health Research Institute, either as our own staff or as a visiting researcher. In it we have tried to solve all possible doubts that may arise during the first days. If you still have any doubts, please contact us, we are here to help you.

I thank all the professionals for their work and dedication at IDIPHISA.

Dr. Mariano Provencio Pulla
Scientific Director IDIPHISA



INSTITUTO DE INVESTIGACIÓN SANITARIA
PUERTA DE HIERRO - SEGOVIA DE ARANA
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2 BRIEF HISTORY OF THE PUERTA DE HIERRO MAJADAHONDA HOSPITAL AND THE PUERTA DE HIERRO HEALTH RESEARCH INSTITUTE SEGOVIA DE ARANA

The Puerta de Hierro Majadahonda University Hospital is the reference center for a population of around 550,000 inhabitants from the northwestern districts of the Community of Madrid: Majadahonda, Villalba and El Escorial; a population whose growth rate is above average compared to other areas of the Community.

The Puerta de Hierro Hospital was created in 1964 and, since then, has fulfilled a triple function: care, teaching and research. Today, as a public institution dependent on the Ministry of Health of the Community of Madrid, it is a first general hospital, without renouncing the values of its foundation and without ceasing to be that center of excellence that coined the modern concept of hospital and left its mark on Spanish medicine. The hospital celebrated 44 years of history coinciding with the opening of the new headquarters in Majadahonda. This was undoubtedly a key moment in the history of the Center because it marked the beginning of a new stage full of hope and enthusiasm in which, in addition to having especially qualified professionals, we have new, more functional facilities and a more advanced technological environment that responds to the needs of the population and professionals.

At present, the hospital stands out for the number of clinical programs for organ and tissue transplants, for the complexity of its casuistry compared to the average of hospitals in the country, and for being a national reference center in some specialties.

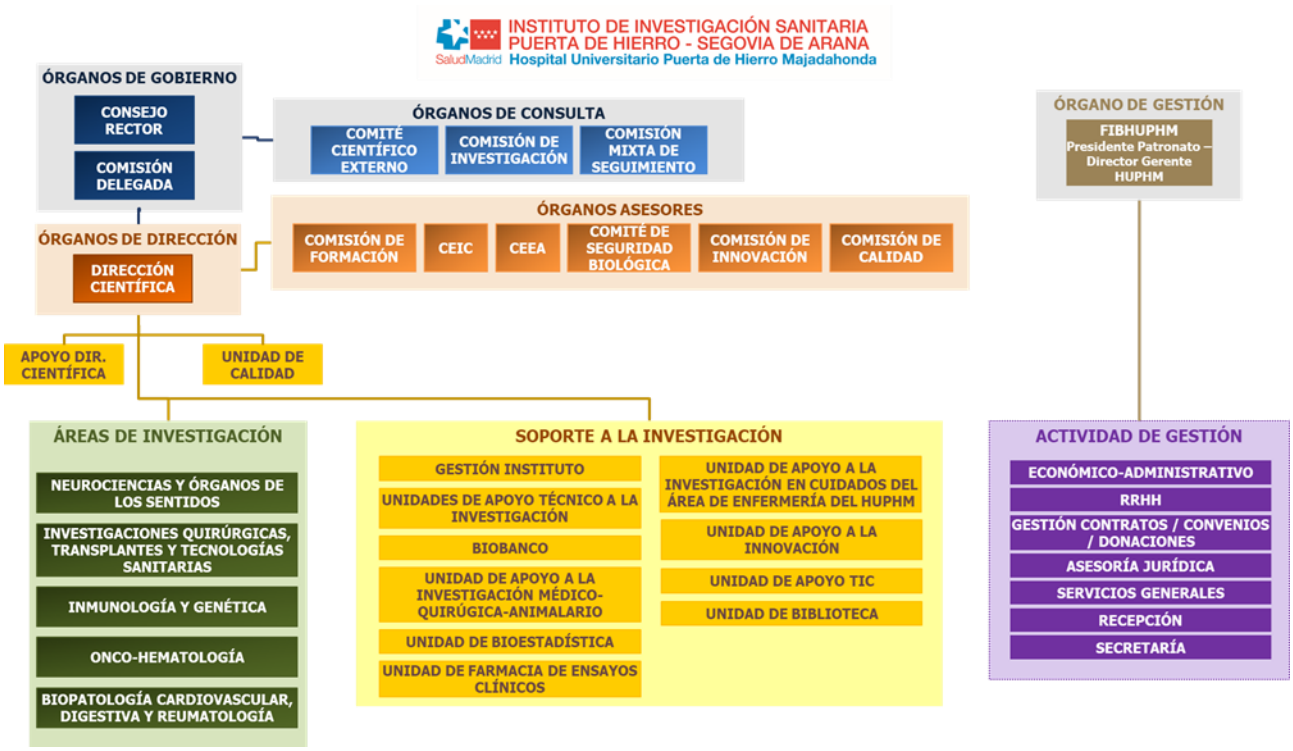
In terms of teaching, the Puerta de Hierro Hospital is a center with a strong university character that is associated with the Faculty of Medicine of the Autonomous University of Madrid. Likewise, it is accredited for the training of Specialists, with about a hundred of residents accessing it every year. On the other hand, this center has had a Health Research Institute since 2012. The creation of IIS Puerta de Hierro contributes to promote joint research activities developed by its staff both at institutional and scientific level.

3 ORGANIZATIONAL STRUCTURE

The Instituto de Investigación Sanitaria Puerta de Hierro - Segovia de Arana, is organized by governing bodies (Governing Council and Delegate Commission), advisory bodies (External Scientific Committee and Research Commission), the executive management that falls on its Scientific Director and by the management body which is the Biomedical Research Foundation of the Hospital Universitario Puerta de Hierro Majadahonda.

In 2019, the Institute, in addition to being made up of the Puerta de Hierro University Hospital, the Autonomous University of Madrid, the General Directorate of Planning, Research and Training of the Ministry of Health, the integration of the Infanta Cristina University Hospital, has added the attachment of the Severo Ochoa University Hospital to the research activities in the prioritized lines, thus enhancing collaboration and cooperation with other centers and research groups.

The Institute currently has 5 research areas and 45 research groups.



4 RESEARCH STRUCTURE

4.1 SCIENTIFIC DIRECTION

Scientific Director: Dr. Mariano Provencio Pulla

Deputy Scientific Director: Dr. José Luis Calleja Panero

Support Staff: Jesús Rey Jiménez

Contact information:

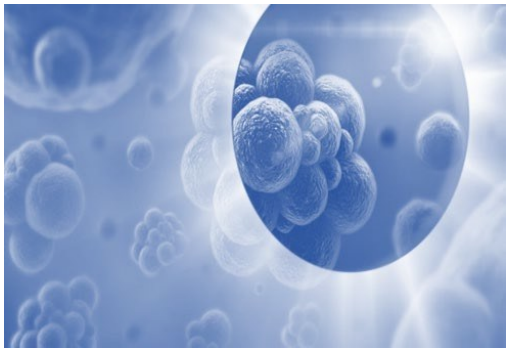
- ventanilla@idiphim.org

4.2 RESEARCH AREAS AND GROUPS

AREA OF RESEARCH	AREA COORDINATOR	NO. OF GROUPS 2023	NUMBER OF RESEARCHERS ASSIGNED IN 2023
ONCOLOGY-HEMATOLOGY	Dr. Mariano Provencio Pulla	7	96
BIOPATHOLOGY CARDIOVASCULAR, DIGESTIVE AND RHEUMATOLOGIC	Dr. José Luis Calleja Panero	15	162
RESEARCH SURGICAL PROCEDURES, TRANSPLANTS AND HEALTHCARE TECHNOLOGIES	Dr. Joaquin Carballido Rodriguez	8	89
NEUROSCIENCES AND SENSE ORGANS	Dr. Gregorio Rodríguez-Boto Amago	10	51
IMMUNOLOGY AND GENETICS	Dr. Carlos Vilches Ruíz	5	15

ONCOLOGY - HEMATOLOGY

- Lung cancer
- Hematology
- Lymphomas
- Molecular Pathology of Cancer
- Therapeutic Targets
- Sarcomas
- Radiation Oncology



CARDIOVASCULAR, DIGESTIVE AND RHEUMATOLOGIC BIOPATHOLOGY

- Hepatology
- Heart Transplantation
- Systemic autoimmune and other autoinflammatory diseases
- Internal medicine
- Metabolism and Nutrition
- Heart Failure and Cardiomyopathies
- Therapeutic endoscopy and oncology
- Renal Diseases
- Inflammatory bowel disease
- Intensive Care Medicine
- Pneumology
- Clinical Pharmacology
- Vaccines
- Microbiology
- Pediatric Research Group

SURGICAL RESEARCH, TRANSPLANTATION AND HEALTHCARE TECHNOLOGY

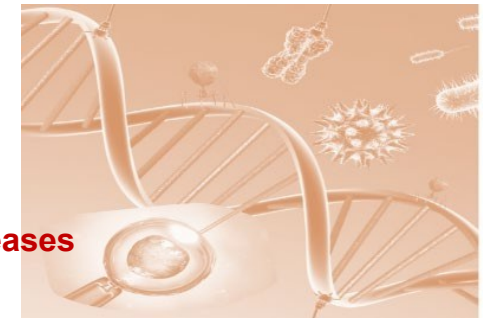
- Urology
- Thoracic Surgery
- Experimental Models
- Anesthesia, Critical Care & Pain
- Gynecology
- Nursing and Health Care
- Primary-Specialized Care
- Advanced Cardiac Surgery

NEUROSCIENCES AND SENSE ORGANS

- Neurosciences
- Otorhinolaryngological Research
- Neuroimmunology
- Neuronal repair and molecular therapy in neurodegeneration
- Neurotransmission
- Neurobiology of Attachment
- Child and adolescent mental health
- Cerebrovascular Disease
- Multimodal Imaging in Ophthalmology
- Immune-mediated Inflammatory Dermatoses and Imaging Techniques

IMMUNOLOGY AND GENETICS

- Immunogenetics and Histocompatibility
- Mito-Cardiology
- Molecular Immunology
- Immunity and lymphoproliferative diseases
- Immune Biomarkers and Immunotherapies



5 RESEARCH SUPPORT

5.1 SINGLE WINDOW

This is the window enabled to contact any area, committee or management of IDIPHISA, or to request information on procedures to make financial contributions or to participate in any of the clinical trials open at H.U. Puerta de Hierro Majadahonda.

Contact information:

- E-mail ventanilla@idiphim.org
- Telephone: 91 191 76 45
- URL: https://investigacionpuertadehierro.com/

5.2 QUALITY UNIT

Unit Coordinators: Jesús Rey Jiménez.

E-mail: jrey@idiphim.org.
Telephone: 91 191 63 64

SERVICES

- Follow-up of the Institute's Strategic Plan.
- Preparation of the annual Scientific Report.
- Maintenance of the Institute's archives.
- Coordination in the collection of indicators for different regulatory bodies such as the Observatory of research and innovation results of the Health Department of the Community of Madrid, ISCIII indicators, SICTI Ministry of Economy, etc.
- Support in the systems certified with quality standards in strategic projects of the Institute.
- Satisfaction and stakeholder surveys. Coordination and follow-up of actions derived from the surveys.
- Support in audits and preparation of reports.
- Communication of results to the Quality and Scientific Management Committee.

CERTIFICATIONS AND ACCREDITATIONS

- Support and coordination in the process of Accreditation of the Health Research Institute of the University Hospital Puerta de Hierro - Segovia de Arana, according to Royal Decree 279/2016, June 24 (article 17), issued by ISCIII.

- Support in the Certification of IDIPHISA's R&D&I Management System. Audits according to UNE 166002 standard. Monitoring of the documentation that makes up the R&D&I management system, actions and verification of the correct implementation and compliance with the internal requirements derived from the R&D&I management system.
- Support in follow-up audits in different research units and laboratories such as: Oncology Early Phase Clinical Trials Unit, the liquid biopsy laboratory ISO 15189 Clinical laboratories - Requirements for quality and competence, and others: ISO 20387 for biobanks, etc.
-

5.3 INSTITUTE MANAGEMENT

Manager: Jesús Rey Jiménez

E-mail:jrey@idiphim.org

Contact Telephone: 91 191 63 64

SERVICES

- Proactive search for financing grants and subsidies (private or public).
- Periodic emailing of calls for proposals.
    - Update of the database of calls for proposals, accessible through the IDIPHISA calls for proposals search engine: *https://convocatorias.idiphim.org/*
- Integrated Management Strategic Health Action:
    - AES Informative Sessions are held every year.
    - Coordination and support in the public and private application process. Thorough review of documentation AES applications.
    - Specific support for AES requests.
    - Follow-up of the status of the applications sent. Management of corrections.
- Communication with financing agents to resolve doubts.
- Support in the preparation of proposals for European projects (mainly H2020 and EIT Health): budget preparation, search for partners, resolution of doubts in the implementation section, ...).
- Support in the management of European projects (mainly H2020 and EIT Health): elaboration of Grant Agreement and Consortium Agreement, support in the economic management of the project, ...).
- Report of scientific activity indicators to ISCiii.

5.4 TECHNICAL SUPPORT UNITS FOR RESEARCH

Scientific Coordinator: **Margarita Sánchez-Beato Gómez**
E-mail: **msbeato@idiphim.org**
Laboratory Phone: **911916095**
Common Areas Laboratory Technician: **Belén Pérez Sacristán.**

The main objective of the Technical Support Units is to provide quality technological support to the Institute's researchers in essential areas of biomedical research that, due to their complexity or cost, cannot be undertaken by individual groups. Thus, in addition to providing technological support by highly qualified personnel, promoting quality research, the performance of the equipment is improved and resources are made profitable by improving their efficiency.

Although the main objective of these units is to provide internal service to the institute's groups, they are also open to collaborations with groups from other public and private institutions.

The **Technical Support Units** are composed of:

- Cytometry and cell separation unit
- Cell culture unit
- Confocal microscopy
- DNA Sequencing and Molecular Biology

These Technical Support Units are integrated in the IDIPHISA R&D&I Management System and certified under the UNE 166002 quality standard since July 24, 2019 and in the process of adaptation to the new version of the standard.

5.4.1 CYTOMETRY AND CELL SEPARATION UNIT

Unit Manager: **Aránzazu García Grande**

E-mail:citometria@idiphim.org

Laboratory Telephone: 91 191 67 56

Nº Registro: 396

Flow cytometry is a quantitative multi-parametric analysis technique that allows sensitive and simultaneous analysis of various physical and chemical characteristics of the cell population of interest. The technological development implemented today in flow cytometers allows this analytical method to have great applicability in basic and clinical research.

OBJECTIVES

The objectives of the Flow Cytometry and Cell Separation Unit are:

A. To provide technical support and scientific advice for the development of projects of the Center's research groups or visiting research groups related to the design of experiments, selection of markers, sample acquisition, analysis of cell populations and elaboration of protocols with application of analytical cytometry.

B. Isolation, enrichment and characterization of cell populations by "Flow Cell Sorting" technology or by immunomagnetic separation.

C. Development of new technologies and equipment evaluation.

D. Continuing education for research personnel.

LABORATORY NETWORK

The Flow Cytometry and Cell Separation Unit is part of the Network of Laboratories and Infrastructures of the Community of Madrid accredited with the **number 396**. The adhesion to this Network of Laboratories makes possible collaborations with other laboratories of the CAM.

ITEMAS: The Flow Cytometry and Cell Separation Unit participates in the Innovation Platform for Medical and Health Technologies (ITEMAS) of the Carlos III Health Institute.

Standard UNE 166002:2021

The Flow Cytometry and Cell Separation Unit has been evaluated and has contributed to obtaining certification under the UNE 166002:2021 standard for the management of clinical research programs and projects and other related activities in the field of Biomedicine. Certificate ES19/86281.

EQUIPMENT

The Flow Cytometry and Cell Separation Unit of IDIPHISA is equipped with first level scientific equipment for research and is suitable for the performance of all its functions as a Support Unit for researchers.

ANALYTICAL FLOW

Digital cytometer MACSQuant® (Miltenyi Biotec) equipped with three solid state lasers (405 nm violet, 488 nm blue and 635 nm red). It allows for the simultaneous detection of 10 parameters and to work with low sample volume. It has 8 optical channels for fluorescence measurements and 2 detectors for physical parameters of cell size (FSC) and cell complexity (SSC).

ANALYTICAL FLOW CYTOMETER FACSYMPHONY A1

The Flow Cytometry and Cell Separation Unit has at its disposal a FACSymphony A1 (BD) flow cytometer with 4 high-performance lasers for the detection of 19 parameters simultaneously (16 fluorescence and 3 light scattering) financed within the State Subprogram of Infrastructures and Scientific-Technical Equipment of the Strategic Action in Health 2021-2023, charged to European funds of the Recovery, Transformation and Resilience Plan (**IFEQ22/00172**).

ANALYTICAL FLOW CYTOMETER FC500

The Flow Cytometry and Cell Separation Unit has an additional cytometer at the disposal of users, on loan from the Immunology Service. It is the FC500 flow cytometer (Beckman Coulter), with an optical configuration of a blue laser (488nm) and 5 fluorescence detectors, which allows the development of cell biology studies.

FACSARIA II CELL SEPARATOR

FACSAria II (BD) high-speed digital cell separator capable of separating up to four phenotypically different cell populations at the same time under both sterile and non-sterile conditions. It consists of 2 lasers of 488nm and 633nm and the possibility of detecting 7 fluorescence parameters in addition to the parameters related to cell size (FSC) and cell complexity (SSC).

AUTOMACS PRO MAGNETIC SEPARATOR

The AUTOMACS PRO (Miltenyi-Biotec) allows the isolation of cell populations from biological samples by immunomagnetic methods. The AUTOMACS PRO system allows the processing of up to 6 samples at the same time with different selection procedures, after programming each one of them with
automated way

DATA ANALYSIS PROGRAMS

- **FACSDiva software (BD):** allows the acquisition of data in the FACSAria II cell separator and its subsequent analysis, diagrams with the possibility of linear, logarithmic and biexponential scales and export of statistical data and templates.
- **MACSQuantify software (Miltenyi Biotec):** under Windows operating system with all functions to represent data with image analysis and statistics with the possibility of data analysis during sample acquisition, data grouping and generation of a single file. Customized analysis templates.
- **FLOWJO (BD) software:** analysis program for data generated by any flow cytometer. It offers a number of different analysis platforms that allow you to perform more specialized analyses.
- **INFINICYT software (BD):** includes tools that allow the analysis, integration and interpretation of the results obtained, such as diagrams based on principal component analysis that provide information on the most significant markers for the separation and identification of the cell populations under study, the possibility of merging and integrating several files into a single file that can be analyzed globally, and the possibility of creating reference images.

5.4.2 CELLULAR CULTURES UNIT Biological Containment Level II

Unit Manager: Silvia Rosado García

E-mail:cultivoscelulares@idiphim.org

Laboratory Telephone: 91 191 67 68

Web: https://investigacionpuertadehierro.com/unidad-de-cultivos-cellular/

Nº Registro: 403

INTRODUCTION

In vitro cell cultures are an essential technological platform for the development of basic and applied research. It is an essential tool in the evaluation of the molecular and cellular mechanisms that occur in all biological processes. In vitro cell culture consists of a system formed by cells from an organ or tissue, normal or tumor, which are maintained in media of defined chemical composition, controlled conditions of: temperature, pH, CO2 concentration and humidity that ensure their survival and expansion, maintaining all their metabolic functions in a similar way to the in vivo situation.

The main objective of the Cell Culture Unit is to support the research groups of the center and other public and private institutions in those activities they wish to carry out within this Unit, as well as to provide services and assistance in this area of work.

The existence of a Cell Culture Unit and its proper functioning allows research groups the possibility of culturing all types of animal cells, both primary cultures and established cell lines, genetically modified organisms and to perform different techniques that allow their molecular and cellular study and characterization.

EQUIPMENT

The Cell Culture Unit is composed of:

- Six type II biological safety laminar flow cabinets (TELSTAR BIOII-A), one of which is exclusively for cell culture with viral vectors.
- Eight ThermoScientific 8000WJ 3429 Series cell incubators with temperature, CO_2 and humidity saturation control; one of the incubators is exclusively for cell culture with viral vectors.

- Nikon Ti-S Eclipse inverted microscope associated with an epifluorescence unit (Intensilight C-HGFI) with image capture and storage capability (Camera: Digital SightCamara Control Unit DS-L2 (DS-Fi1) Nikon.
- Luminometer: Infinite 200 PRO
- Electroporator: Neon Transfection System

Routine equipment consists of:

- Two vortex stirrers: VELP Scientifica ZX3
- Autoclave: Presoclave II (P Selecta)
- Double distiller: Ultramatic Wasserlab
- Three portable suction pumps: Vacusip
- A refrigerated centrifuge: Sorvall Legend XFR
- A Centrifuge: Hermle Z300
- Four combi refrigerators with -20ºC storage possibility
- Liquid nitrogen container: Air Liquide Espace 151 Liquide
- Ice machine: Ice Queen 85C
- Two microcentrifuges: LabnetSpectrafuge 24D
- Inverted microscope: Nikon Eclipse TS100
- Ultrafreezer -80ºC ThermoScientific Forma 900

Both the refrigerators that store the reagents and the CO_2 incubators are equipped with temperature probes that allow remote temperature monitoring at all times. Alarm management is carried out both by the technical manager of the Culture Unit and by Hospital Security and Maintenance.

NETWORK OF LABORATORIES OF THE COMMUNITY OF MADRID

The Cell Culture Unit is integrated into the Network of Laboratories of the Community of Madrid, as a laboratory of assay with the number of registration number 403 (http://www.madrimasd.org/Laboratorios/busquedas/comun/FichLab.asp?Clabo=403).

The objective of this network is to publicize, facilitate and improve the provision of services carried out in the research infrastructures of the Community of Madrid and its member laboratories.

SERVICES RENDERED

The Unit has provided service to:

- The Institute's own research groups that carry out in vitro experimentation, participating in training and in the development and validation of standardized work procedures.
- Instituto de Investigación, Desarrollo e Innovación en Biotecnología Sanitaria de Elche (IDiBE), participating in the determination, analysis and technical advice of different contaminations and work procedures.

rla red de laboratorios Sistema madrid
Nº Registro: 389

5.4.3 CONFOCAL MICROSCOPY

Unit Manager: María José Coronado

E-mail:mjcoronado@idiphim.org

Laboratory Telephone: 91 191 67 56

EQUIPMENT

The Microscopy Unit of IDIPHIM is equipped :

Leica SP5 Confocal Microscope, with three laser lines, is optimized for the acquisition of images from samples, both fixed and *in vivo*, that do not require specific environmental conditions. This system has 3 excitation laser lines:

- Argon laser, which will excite at the following wavelengths; 458, 477, 488, 496 and 514 nm.
- Helium/Neon (He/Ne) laser, which excites at 543 nm.
- Helium/Neon (He/Ne) laser that excites at 633 nm.

LEICA Wide Field Thunder Microscope

- Leica 5 LEDS Microscope
- Inverted microscope with 5x, 20x, 40x, 63x magnification with phase contrast and brightfield.
- Motorized stage, and CO2 incubator, Temperature Control
- sCMOS camera (Leica K5)

The Unit has a CytoSpin centrifuge® (Thermo Shandon) to transfer the cells grown in suspension to slides and there are also 2 transmitted light microscopes in the Unit.

In addition, the Unit has a Leica transmitted light microscope connected to a Leica MC190HD camera and a computer that allows the acquisition of brightfield images such as hematoxylin and other stains.

SERVICES

The services offered at the Unit are:

- Sample Preparation: Cryostat and Microtome Cuts
- Performance of immunofluorescence.
- Technical realization tunnel
- Confocal microscopic visualization.
- Thunder microscope visualization
- Video Microscopy
- Fluorescence signal quantification by image analysis. analysis.
- Hematoxylin staining of both kerosene sections and OCT.
- Secondary antibody aliquots

Rates have been established for all these services to cover laser maintenance and possible breakdowns.

The Confocal Microscopy Unit belongs to the "Spanish Network of Advanced Optical Microscopy" (REMOA), establishing collaborations with other laboratories and facilitating access to knowledge and courses of great interest.

The Unit is part of the Microscopy platform of the Network of Laboratories of the Community of Madrid.

Nº Registro: 389

Standard UNE 166002:2021 The Confocal Microscopy Unit has been evaluated and has contributed to obtaining certification under standard UNE 166002:2021 for the management of clinical research programs and projects and other related activities in the field of biomedicine Certificate ES19/86281

5.4.4 DNA SEQUENCING AND MOLECULAR BIOLOGY

Unit Manager: Elvira Ramil Tojeiro.
Common Areas Laboratory Technician: Belén Pérez Sacristán.
E-mail: secuenciacion@idiphim.org
Laboratory Telephone: 91 191 67 56

Nº Registro: 404

The main objective of the Unit is to provide support to research groups in DNA sequencing techniques. It has an ABI3500Dx capillary electrophoresis genetic analysis equipment and an Illumina MiSeq massive sequencing equipment. The Unit has other large equipment such as a real-time PCR equipment LC480-Roche and a Fluoroskan Ascent FL fluorescence plate reader and also with the small equipment necessary to out the techniques proposed in the Unit: a biomolecule analyzer 2100 Bioanalyzer from Agilent Technologies, thermocyclers, nanospectrophotometer, QUBITv.3 fluorimeter, centrifuges, pipettes and cryopreservation sensors.

The Unit belongs since 2016 to the Madrid+d Laboratories Network of the Autonomous Community of Madrid.

EQUIPMENT

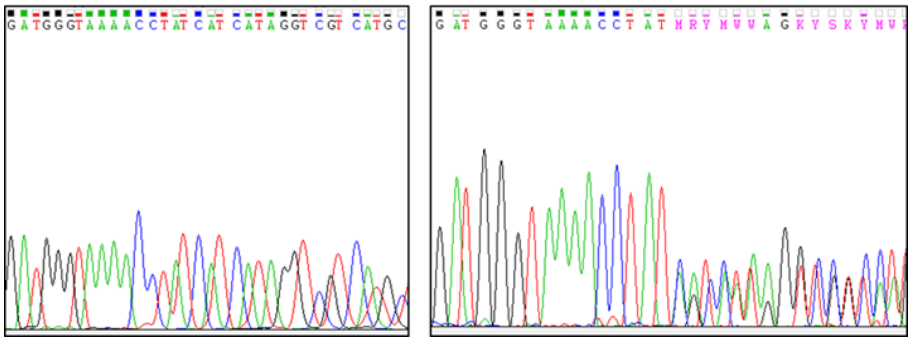
Applications of the Unit's equipment:

SEQUENCING BY CAPILLARY ELECTROPHORESIS AND FRAGMENT ANALYSIS:

The ABI 3500Dx Genetic Analyzer allows automated base assignment of DNA sequences, processed by the Sanger method of fluorochrome-labeled ddNTPs terminators, as well as fragment analysis in microsatellite studies (STRs, LTRs), chimerisms and MLPA-multiplex ligation-dependent probe amplification (MLPA). It is validated for use in two modes: Research Use Only (RUO) or in *vitro* diagnostic mode according to the IVD-CE diagnostic quality standard.

3500 Dx Genetic Analyzer and capillary for analysis of 8 samples.

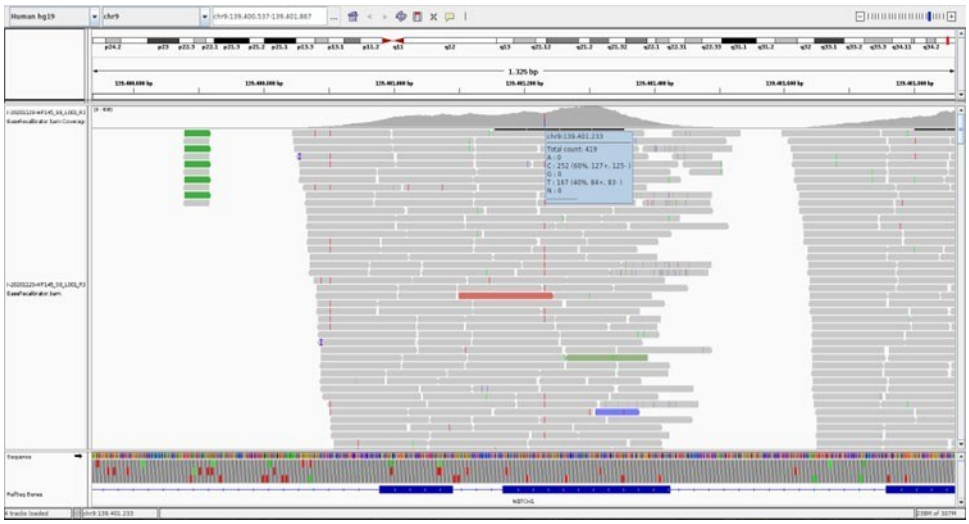
Secuencia original *Secuencia mutada*



Example of a DNA sequencing analysis result.

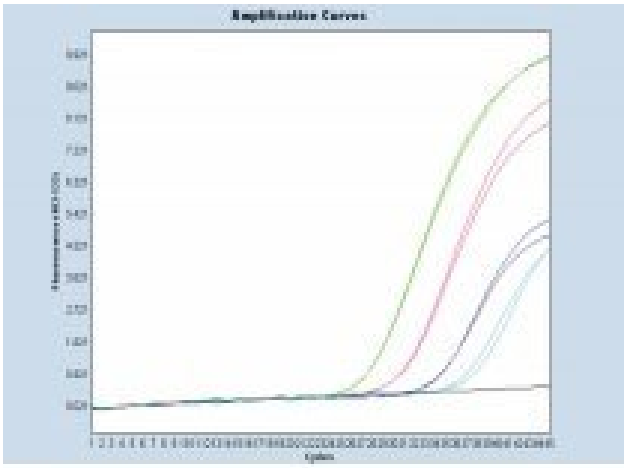
MASSIVELY PARALLEL SEQUENCING OR NEXT GENERATION SEQUENCING (NGS)

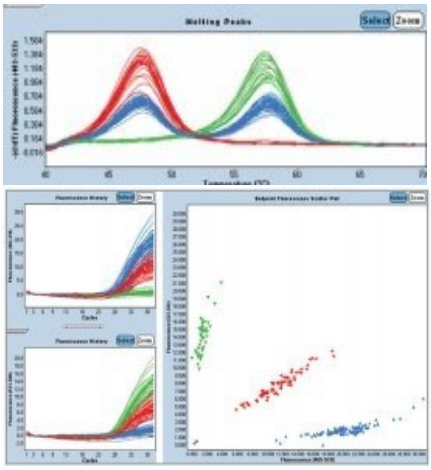
The MiSeq-Illumina sequencer enables a wide range of cost-effective sequencing applications, such as sequencing of multiplexed amplicons, sequencing of hybridization-captured regions (enrichment panels), sequencing of targeted RNA panels, resequencing of small genomes, de novo sequencing, and microbiome studies by sequencing variable regions of ribosomal ribosomal RNA, sequencing of targeted RNA panels, resequencing of small genomes, *de novo* sequencing and microbiome studies by sequencing the prokaryotic 16S ribosomal RNA variable regions and the ITS1 and ITS2 regions of fungi. The throughput range of the kit is between 300 Mbases of DNA and 15 Gbases per run.



Quantitative PCR (qPCR):

Light Cycler 480-Roche (LC480) is a real-time PCR kit in 96-sample plates. Its main applications are the analysis of gene expression variations and genotyping of SNPs and mutations. In microbiological diagnostics, its use allows viral load detection and quantification.





Single cell separator equipment for further studies:

Awarded the State Subprogram for Scientific-Technical Infrastructure and Equipment of the Strategic Action in Health 2021-2023, charged to the European funds of the Recovery, Transformation and Resilience Plan: IFEQ22/00173. In bidding process for its purchase.

SERVICES TO RESEARCH GROUPS

During 2021, the Sequencing and Molecular Biology Unit served the following research groups of the Institute:

- **Oncology and Hematology Area:** Molecular Pathology (Dr. Martín Acosta), Lymphomas (Dr. Sánchez-Beato), Familial Cancer (Dr. Romero) and Hematology group (Dr. Duarte).
- **Area of Surgical Research, Transplants and Health Technologies**: Thoracic Surgery group (Dr. Gómez de Antonio) and Urology group (Dr. Sáenz-Medina).
- **Cardiovascular, Digestive and Rheumatology Biopathology Area:** Internal Medicine group (Dr. de Mendoza, Dr. Citores and Dr.), Heart Failure and Cardiomyopathies group (Dr. García Pavía), Hemodynamics group (Dr. Blasco Lobo) and Rheumatology group (Dr. Sánchez López).
- **Area of Immunology and Genetics:** Immunogenetics group (Dr. Vilches), Immunology and lymphoproliferative diseases (Dr. Gómez Lozano) and Angiogenesis and Immunology group (Dr. Sanz Alcober).
- **Neurosciences Area:** Neuroimmunology Group (Dr. Sánchez López).

External Users:

- Biotech company Emercell (Montpelier, France): genotyping of KIR ligands for immunotherapy research projects (Dr. Henno).
- Alberto Sols Biomedical Research Institute CSIC-UAM. Laboratory of Ion Channels. Project on target proteins in atrial fibrillation (Dr. Valenzuela).
- Private collaborative project of the Thoracic Surgery group (Dr. Gómez de Antonio) of IDIPHISA with the Universities of Okayama (Drs. Tanaka and Okazaki) and Euhime (Dr. Sakaue) of Japan.

5.5 BIOBANK

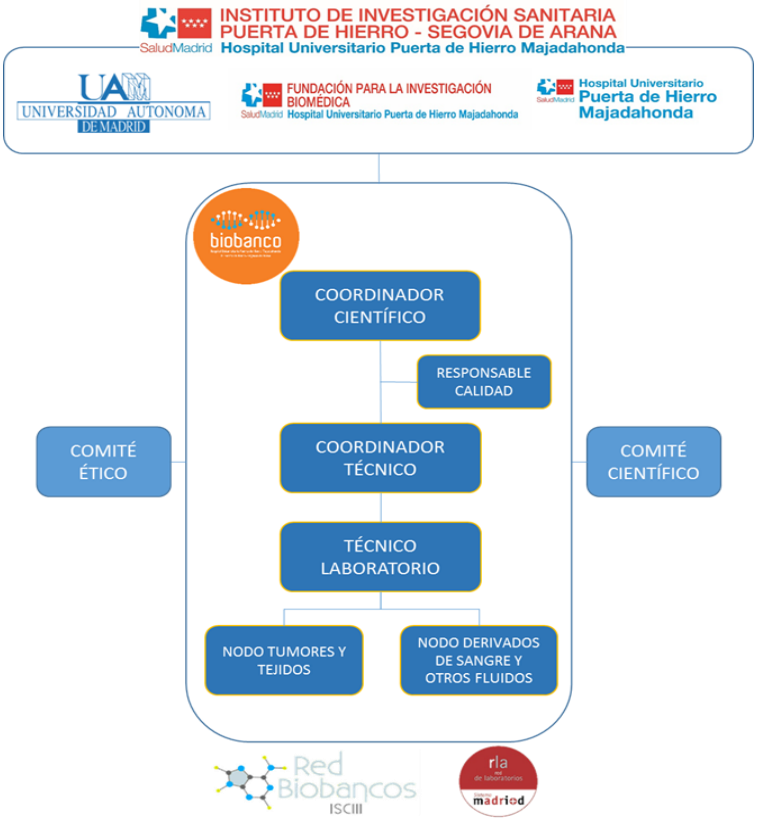
Scientific Coordinator: Antonio J. Sánchez López
Technical Coordinator: Silvia Rosado García
Laboratory Technician: María Gil Ligero
E-mail:biobanco@idiphim.org
Laboratory Phone: 911916758 / 911917711

@Biobanco_PuertadeHierro

Puerta de Hierro Biobank

http://investigacionpuertadehierro.com/biobanco/

STRUCTURE



OBJECTIVES AND LINES OF ACTION

- Obtaining, maintaining and making samples available to the scientific community.

- Management of biological samples and their associated data for biomedical research.
- Processing of biological samples:
  - Collection and cryopreservation peripheral blood mononuclear cells (PBMCs) and leukoreduction cone.
  - Neutrophil Collection and Cryopreservation.
  - Extraction of nucleic acids: DNA and RNA.
  - Determination of concentration and purity by spectrophotometry and fluorometry.
  - Performance of immunoassays.
  - Separation of biological samples: serum, plasma, buffy coat, hematic remains, urine, cerebrospinal fluid.
  - Tissue embedding in kerosene.
  - Tissue freezing: RNAlater, OCT.
- Support and advice offering a complete platform of services to researchers upon request.
- Maintenance of samples participating in clinical trials.

AUTHORIZATION

The Biobank Hospital Universitario Puerta de Hierro Majadahonda (HUPHM) / Instituto de Investigación Sanitaria Puerta de Hierro-Segovia de Arana (IDIPHISA) is authorized to operate by the Dirección General de Ordenación en Inspección de la Consejería de Sanidad de la Comunidad de Madrid with file number: 9516 CS-00036, and is registered in the Red Nacional de Biobancos del Instituto de Salud Carlos III, with code B0000920.

BIOMODELS AND BIOBANKS PLATFORM

In 2023 the Biobank has been integrated into the Biomodels and Biobanks Platform PT23/00015) of the Carlos III Health Institute (ISCIII) (https://www.isciiibiobanksbiomodels.es/) through the Grants of the Platforms of Support for Research in Health Sciences and Technologies of the 2023 Call of the Strategic Action in Health.

LABORATORY NETWORK

In October 2017 after approval by the General Directorate of Universities and Research the Biobank has been registered in the Network of Laboratories and Infrastructures of the Community of Madrid with registration number 420.

ISO20387:2018 Biotechnology -- Biobanking -- General requirements for biobanking.

The Biobank is currently in the ISO20387:2018 implementation phase.

ITEMS

The Biobank participates in the Innovation Platform for Medical and Health Technologies (ITEMAS) of the Carlos III Health Institute.

5 .6 MEDICAL-SURGICAL - ANIMAL FACILITY RESEARCH SUPPORT UNIT

Person in charge and Unit Coordinator: **Martín Santos González.**

E-mail: **martin.santos@salud.madrid.org**
Laboratory Telephone: **91 191 7745 / 91 191 6751**

Located on floor 0 of the research building, the Medical-Surgical-Animal Research Support Unit is authorized to house rats, mice, guinea pigs, rabbits, pigs and sheep, with registration number ES280800000012, in accordance with the provisions of European regulations (European Directive 2010/63/EU of the European Parliament and of the Council of September 2010, on the protection of animals used for scientific purposes) and national regulations (Royal Decree 1201/2005, of October of the Ministry of the Presidency, establishing the basic rules for the protection of animals used for scientific purposes), of 22 September 2010, the protection of animals used for scientific purposes) and national (Royal Decree 1201/2005, of 10 October of the Ministry of the Presidency, establishing the basic rules applicable to the protection of animals used for experimental and other scientific purposes, including teaching).

The Unit has an Animal Experimentation Ethical Committee, authorized as a Qualified body for the evaluation of projects in accordance with RD 53/2013.

The Unit has also been included as part of IDIPHISA's R&D&I Management System, certified under the UNE 166002:2021 standard.

FUNCTIONS

The Medical-Surgical Research Support Unit - Animal Facility is a support unit with animal models that performs the following functions:

1. Training

1.1 Development of medical-surgical teaching models with laboratory animals.

1.2 Organization and development of postgraduate and continuing education courses with laboratory animals and anatomical specimens.

1.3 Surgical complement to the Simulation Unit.

1.7 Training of personnel for the maintenance of training handling experimental animals.

2. Management

2.1 Health and welfare management of animals housed in the animal facility.

2.2 Participation in Committees (Animal Experimentation Ethics Committee, Qualified Body, Biological Safety Committee).

2.3 Management of projects developed with experimental animals.

2.4 Management of the Research Group on Experimental Models (GIME).

2.5 Relationship with other experimentation centers.

2.6 Relationship with the Animal Protection Area of the Community of Madrid for the reporting reports and animals used (Hamellin Program).

2.7 Relationship with the European Union for the reporting of non-technical summaries and animals used (Alures Program).

3. Research

3.1 Guidance and support to the researcher who uses experimental animals.

3.2 Development of experimental models in laboratory animals.

3.2 Development of proprietary (GIME) and third-party projects

3.4 Support for the treatment of the results of projects developed with experimental animals

FACILITIES AND EQUIPMENT

Animalarium:

- A quarantine room with an animal reception room.
- Two housing areas for rodents, guinea pigs and rabbits. They consist of a distribution and work room and different lairage rooms:
    - Two for rats
    - One for rabbits
    - Two for mice

  All housing rooms have light cycle, temperature and relative humidity control. In addition, the rat and mouse housing rooms are equipped with individually ventilated racks, U-TEMP polyetherimide microisolators of different sizes and species (rat, mouse and guinea pig) and a transfer cabinet for handling SPF and immunosuppressed animals.
- A stabling room for large animals.
- A cleaning and disinfection room equipped with two cage washers.

Experimental laboratories and operating rooms:

- An experimental working room for rodents equipped with surgical microscopes.
- Two experimental operating rooms with independent acclimatization and positive pressure, equipped with anesthesia stations, monitoring equipment, laparoscopy towers and electric scalpels.
- A behavioral laboratory.
- A molecular imaging laboratory.

5.7 BIOSTATISTICS UNIT

Head of Unit: **Ana Royuela Vicente**

Members of the Unit: **Enrique Rodríguez Rubio**

E-mail:aroyuela@idiphim.org

Contact telephone: **91 191 75 53**

The Biostatistics Unit supports biomedical research in its multiple areas, improving the procedures to carry it . It provides methodological support to research studies in their design stage, data collection, statistical analysis, interpretation and reporting of results. It also provides service in terms of methodology of systematic reviews and support in critical reading of scientific articles.

The unit has also been included as part of IDIPHISA's R&D&I management system, certified under the UNE 166002:2021 standard.

SERVICES

- Design of research studies. Research methodology in diagnosis, intervention and prognosis.
- File design for data collection.
- Sample size estimation.
- Design and strategy of results analysis.
- Methodology of systematic reviews. Meta-analysis.
- Analysis of results:
    - Descriptive analysis and hypothesis testing. Generation of graphs and tables.
    - Validity and reproducibility of diagnostic tests.
    - Multivariate regression models: linear, logistic, survival.
    - Longitudinal designs: panel data.
    - Advanced analytical techniques: propensity score, multiple imputation of missing data, crossover analysis, joinpoint analysis.
    - Validation of prognostic models.
- Dissemination of results:
    - Scientific article.
    - Final report of research project.
    - Doctoral dissertation.
    - Communication to congress.
- Peer-review process of a scientific paper.
- Training:
    - Critical Reading Skills of scientific articles
    - Statistics applied to Health Sciences
    - Research methodology

5.8 BIOINFORMATICS UNIT

Head of : Rafael Muñoz Viana

E-mail: rmviana @idiphim.org

The mission of the Bioinformatics Unit, created in May 2023, is to provide computational analysis support that enables researchers to access effective solutions when analyzing, visualizing and interpreting their data, encompassing the different technological needs associated with data science.

To achieve these objectives, the unit is involved in advising scientists and researchers on the possibilities and benefits to be gained from the application of bioinformatics and computational biology in their research in today's big data environment.

The unit handles mainly, but not exclusively, genomic data, either of human or model animal origin. So far, pipelines have been implemented to perform the most common analyses related to genomic data. Among the types of data typically processed by this unit are: analysis of DNA variants in exomes of family trios, metagenomics by 16S amplicons, epigenetics (ChIP-seq, ATAC-seq), or transcriptomics by RNA-seq. Pipelines are currently being developed for the analysis of transcriptomics by single-cell RNA-seq and spatial transcriptomics with the company's 10x *single-cell visium* technology.

The unit places special emphasis on the implementation and promotion of current and innovative technologies that allow obtaining high quality results for the development of biomedical research of excellence. In this sense, this year we have started to process data obtained by the novel *visium* spatial transcriptomics technique of the company 10x Genomics.

The unit, recently created, aims to continuously expand and update, improving the services currently offered, as well as incorporating new protocols and services based on the new needs of the ever-expanding field of data science.

This unit belongs to the transbionet network https://inb-elixir.es/transbionet.

INSTALLATION AND INFRASTRUCTURE

Currently, the following equipment is available in the Bioinformatics Unit of the Institute:

- **HARDWARE**
  - The unit has an HP Z8 workstation with 40 cores Intel Xeon Gold 5115 2.40GHz, 125Gb of RAM memory and 12Tb storage capacity.

- **SOFTWARE**

  The Bioinformatics Unit promotes the use of open source programming languages. This policy means an economic cost of zero euros in computer software licenses.

  The workstation runs on linux, and the various pipelines implemented are programmed in R and python, the most widely used open source languages in data science.

SERVICES TO RESEARCH GROUPS

- **Scientific advice:**
  - Experimental design in sequencing projects
- **Data engineering:**
  - Database curation
- **Bioinformatics Analysis:**
  - Microbiome with 16S
  - Whole Exomes (WES)
  - Epigenetics with chromatin immunoprecipitation (ChIP-seq)
  - Epigenetics with ATAC-seq
  - Epigenetics with MNase-seq
  - Transcriptomics (RNA-seq)
  - Single cell transcriptomics (scRNA-seq)
  - Spatial transcriptomics for visiumx10 platform (ST-seq)
- **Functional genomics studies**
  - According to study and objectives
- **Data science**
  - Machine Learning according to study and objectives
- **Training**
  - Introduction to R Programming
  - Human Genetics and Genomics

5 .9 CLINICAL TRIALS UNIT (CTU)

Head of Unit: **Dr. Belén Ruiz Antorán**

E-mail:mariabelen.ruiz@salud.madrid.org ;
farmacologia_clinica@idiphim.org
Phone: **91 191 64 81** **Fax:** **91 191 76 50**

STAFF

- **CTU of Clinical Pharmacology.**
  - Belén Ruiz Antorán (Medical Doctor specialized in Clinical Pharmacology)
  - Gustavo Adolfo Centeno Soto (Specialist in Clinical Pharmacology, Coordinator of the Unit).
  - Rocio Layunta Acero (Research Nurse)
  - Laura Vicente Izquierdo (Research Nurse)
  - Silvia Paloma Rodríguez Araque (Clinical Trials CTA, Data Management)
- **SCReN platform to support clinical trials:**
  - Principal Investigator: Cristina Avendaño Solá (Specialist in Clinical Pharmacology)
  - Ana Velasco Iglesias (Ph.D. Biological Sciences, Project Management, Monitor)
  - Sara Jerónimo Torre (Degree in Biological Sciences, Project Management, Monitor)
  - Cristina Barcelona Soria (Degree in Biological Sciences, Project Management, Monitor)
  - Marta García Martínez-Avial (Degree in Pharmacy. Clinical Trials Assistant)
  - Contact: Tel: 91 191 7867;
  - E mailscren@idiphim.org

The Clinical Trials Unit (CTU) of the Clinical Pharmacology Service provides support for the design, organization and conduct of clinical trials with drugs and medical devices. The objective of the CTU is to collaborate with the hospital's investigators in the ethical, regulatory, methodological and logistical aspects needed for the studies to be carried out in accordance with the required standards.

The CTU works in close coordination with the Spanish Clinical Research Units and Clinical Trials Platform (SCReN) of the ISCIII, whose mission is to support multicenter trials promoted by national research groups and their integration into European projects through the European Clinical Research Infrastructure Network (ECRIN).

The CTU of Puerta de Hierro has participated as coordinator in Spain of publicly promoted clinical trials (FP7, ISCIII, FIS, H2020) and has provided support to a hundred clinical trials carried out in different clinical services of the hospital.

SERVICES

The CTU provides advice to researchers at IIS Puerta de Hierro for the design and implementation of clinical research projects. As an example, it can be requested:

1. Regulatory and ethical-legal support for clinical research projects.

- Cataloguing of the project from the legal point of view, support for processing before the AEMPS, Committees and participating centers.
- Registration of the clinical trial in international databases (EudraCT, clinicaltrials.gov, ISCTR).
- Support to comply with the LOPD and other applicable legislation according to the project.
- Support for compliance with pharmacovigilance or medical device surveillance.

2. Methodological and scientific support

- Support for study design: hypothesis formulation, study design, choice of variables, population selection, sample size calculation, etc.

3. Support for the conduct of the clinical trial

- Trial management and coordination
- Study nursing
- Data collection
- Monitoring
- Pharmacovigilance and reporting of adverse events
- Preparation of periodic or final reports

4. Phase I clinical trials unit. Pharmacokinetics and pharmacodynamics studies.

5. Support for the incorporation of projects into the Spanish Clinical Research Units and Clinical Trials Platform (SCReN) or European Clinical Research Infrastructure Network (ECRIN).

- Essential support services for the design, planning and execution of multicenter, national or European clinical research projects.

5.10 CLINICAL TRIALS UNIT OF THE HOSPITAL PHARMACY SERVICE

Unit Manager: Amelia Sánchez Guerrero
Equipment:
Contact persons Researchers, Promoters, CROs:

- Lucia Armendáriz Patier. FIB Pharmacist
- Inés Gumiel Baena: F.E.A. Hospital Pharmacist

Research Pharmacy Technicians: Management and preparation of clinical research samples:

- Rocío Vizcaya Cortés
- Pablo Ríos Esteban

Head of Pharmacy Service: Amelia Sánchez Guerrero

Telephone: 91 191 64 40
E-mail: eecc.farmacia@idiphim.org

SERVICE PORTFOLIO

The UEC-FH provides support activities to researchers at the Instituto de Investigación Sanitaria Puerta de Hierro- Segovia de Arana for the conduct of clinical trials with drugs in all phases of research.

1. **:** includes the activities required by the developer to initiate CE with drugs in the hospital. They include:
    - **Site pre-selection visit**
    - **Start-up Visit:** Adequacy of the conditions of reception, activation and preparation of the medication according to the promoter's requirements.
2. **Management of the protocol in the hospital information systems to enable prescription and administration in the Medical Day Hospital:**
    - Registration, maintenance and deregistration of the study in all its treatment branches.
3. **Support in the conduct of the clinical trial:**
    - Monitoring / accounting / temperature control
    - Closing of CRD Pharmacy
    - Audits
    - Receipt, placement and activation of periodic medication shipments
    - Dispensing to the PI
    - Electronic filing and maintenance of information
    - Disposal of leftover medication (destruction at the center; return to supplier)
    - Medication management with distributor.
    - Phase I dose titration
4. **Pharmacovigilance of medicines and medical devices:**
    - Adverse event reporting.

5.11 RESEARCH SUPPORT UNIT FOR RESEARCH IN CARE

Unit Manager: **Montserrat Solís Muñoz**

E-mail: **montserrat.solis@salud.madrid.org**

Contact phone: **91 191 74 57**

STAFF

Montserrat Solís Muñoz. Supervisor of the Research, Development and Innovation in Care Unit. PhD from the Complutense University. Master in Health Care Research, Universidad Complutense de Madrid.

Nuria de Argila Fernández-Durán. Nurse of the Research, Development and Innovation in Care Unit until October 11, 2023. Master in Nursing Sciences, University of Alicante. Nurse Specialist in Family and Community Nursing.

E-mailnuria.argila@salud.madrid.org

DESCRIPTION

The Care Research Unit of the Hospital Universitario Puerta de Hierro Majadahonda (HUPHM) promotes research among professionals under the Nursing Department and provides support in the development of research studies in all phases to nurses, midwives, physiotherapists, EIR of different specialties, Master and PhD students, from the HUPHM and the Infanta Cristina, Severo Ochoa and Guadarrama Hospitals, among other professionals.

This was one of the first Nursing Research Support Units to be set up in Spain and the first in the Community of Madrid. The challenges set from the beginning were aimed at promoting Nursing Research, innovating in the management of research in care, motivating a greater number of professionals to lead research in care, promoting research training for nursing professionals, promoting evidence-based practice, promoting multicenter studies, establishing synergies with research support units within the center itself and with other centers at regional and national level.

The Care Research Unit provides scientific-technical support to the Nursing Management, Quality Unit, and other Services or Units that require it. It also collaborates with the Nursing Management in different working groups to provide scientific-technical support in all initiatives of interest to the hospital. Likewise, she collaborates with the Nursing Management, Continuing Education and Quality Unit in the organization of scientific events and/or scientific-technical management.

Collaborates with Continuing Education in the design of an annual Research Training for professionals under the Nursing Department. The training offer in this area can be seen in the HUPHM Continuing Education App.

The HUPHM Care Research Unit has participated as a consultant and/or collaborator in studies funded by ISCIII competitive calls (PI20/00431, PI19/00168, PI17/01788, PI17/01049, PI15/00897, PII2/02787, PI11/00766, PI10/01063, PI10/01980, PI09/90431, PI07/90359, PI06/1535, PI06/90274, PI05/2455, PI05/2501, PI01/0477, PI97/1050),
among many other projects.

MAIN OBJECTIVES

- To develop activities of Research in Care oriented to the resolution of health problems of the population.
- To promote the generation and application of new scientific evidence oriented towards excellence in care, in a context of humanization of care and safe practices.

- Promote and participate in the organization of activities aimed at improving training and skills in research and evidence-based practice: courses, workshops, seminars, conferences.
- Contribute from digital transformation of care processes for the optimization of professional/patient-user results.
- Promote ideas and projects in innovation in care for the improvement of clinical practice.

SERVICES

- Design of Care Research projects: epidemiological studies, systematic reviews and meta-analysis, instrument validation, qualitative research.
- Preparation of research protocols and scientific writing.
- Advice on Bibliographic Search and management of documentary sources, with the collaboration of the Library Unit.
- Statistical advice (with the collaboration of the Biostatistics Unit, in some cases), in the preparation of tables and figures, in the interpretation of the analyses and their scientific writing.
- Preparation of documentation for the CEIm.
- Preparation of documents to participate in public and private funding calls, as well as awards.
- Advice on scientific dissemination: scientific publications (selecting the most appropriate journal in each case), oral communications or posters, papers.
- Design of questionnaires, online forms, data collection notebooks, databases.
- Promotion of the translation of research results into clinical practice.
- Promoting innovation and excellence in care, contributing to the development of technical documents to support evidence-based clinical decision making.
- Participation in the organization of activities aimed at improving the training and research skills of other professionals.
- Promotion of alliances at regional and national level with Hospitals, Primary Care Centers, Universities, Scientific Societies and Associations, Nursing Associations, etc., facilitating synergies between professionals and intra- and inter-center teams, which allow for the expansion of collaboration opportunities in multicenter studies.
- Improve work procedures to optimize results in the activities in which the Unit participates.

5.12 INNOVATION SUPPORT UNIT

Principal Investigator: **Mariano Provencio Pulla.**
Members of the Unit: **Luz Pérez Gómez de Cadiñanos and Jesús Rey Jiménez.**
E-mail: **lperez@idiphim.org; jrey@idiphim.org.**
Telephone numbers: **91 191 69 37 y 91 191 63 64**

SERVICES

- Channeling of IDIPHISA's innovative ideas or projects.
- Advice and protection of research results.
- Management with industrial and intellectual property protection agencies.
- Technical management in innovation processes.
- Promotion of innovative culture.

DISCLOSURES

Disseminations: OEPM Technology Watch bulletins, public and private calls, calls for research or innovation awards.

5.13 ICT SUPPORT UNIT

Manager: **Jesús Rey Jiménez**

E-mail:jrey@idiphim.org

Contact Telephone: **91 191 63 64**

SERVICES

- Support in the purchase of computer equipment and other ICT equipment (servers, workstations, ...)
- Interlocution with the IT Service for ICT incidents.
- ICT Consulting Scientific Management and FIB Management
- ICT Project Coordination:
    - IDIPHISA web management and maintenance. Maintenance and management of backups and security copies.
    - Managementy maintenance Intranet IDIPHISA with access restricted a researchers.
    - Hosting management of the website and resolution of reported incidents.
    - IDIPHISA domain management.
    - IDIPHISA mail platform management.
    - IT support to projects and research groups
    - Management and maintenance of the search tool for funding calls accessible from the IDIPHISA website.
    - Design, development, evolution and maintenance of *Investig@*, the platform for the management and reporting of researchers' scientific output.

5.14 LIBRARY UNIT

Unit Manager: **Cristina Escudero Gómez**
E-mail: **biblio.hpth@salud.madrid.org;cescuderog@salud.madrid.org**
Telephones: **91.191.78.73/74**

OBJECTIVES

To provide healthcare professionals with the scientific information necessary for the development of their research and teaching activities and clinical decision-making to be of the highest quality, resulting in improved care for the public.

ACCESS

The Virtual Library has a web page, integrated in the institutional page of the Hospitalwww.madrid.org/hospitalpuertadehierro/biblioteca where the user, once identified, will be able to make use of them.

It also has a large room with study capacity for 60 people. It has 10 computers with Internet access in the room located on the upper floor.

SERVICES OFFERED

- Bibliographic information
- Bibliographic searches
- Help in consulting the main bibliometric indicators (journal impact factors, quartiles, number of citations, h-index).
- Document Retrieval Service
- User training
- Support in the elaboration of the CVN (Standardized *Curriculum Vitae*) of the FECYT.
- Creation of scientific production profiles (Researcher ID, ORCID, Google Scholar)
- Information on Open Access, European mandates for the deposit of publications
- Assists in the development of research data management plans and their subsequent deposit in the institutional repository to meet open science mandates
- Information on tools to know where and how to publish
- Curriculum evaluation for teacher accreditation

AVAILABLE RESOURCES

- Health sciences e-journals: 5,256/Different platforms
- Health Sciences e-books_ 14,572/Different specialties and platforms
- Discovery Platforms: ClinicalKey
- Databases: Pubmed, Embase, CINAHL, Cochrane, WoS, Joanna Briggs, Fisterra.

In addition, off-platform journal subscriptions are available: Radiology, Radiographics, Annals of Pharmacotherapy, Journal of Rheumatology, Pediatrics, American Journal of Respiratory and Critical Care Medicine, European Respiratory Journal, Journal of Neurosurgery.

HUMAN RESOURCES

- 1 librarian, 1 support staff

5.15 CELL THERAPY LINES

5.15.1 CELL THERAPY UNIT OF THE NEUROSURGERY DEPARTMENT

Responsible for the Unit and Technical Direction: **Mercedes Zurita Castillo**

E-mail: **mercedes.zurita@salud.madrid.org**

Unit Secretary: **María Nieves González del Castillo**
E-mail:nc.terapiacelular@salud.madrid.org
Phone: **911916600**

The Cell Therapy Unit of the HUPHM is located in the research area of the Hospital (Blood Bank/Laboratories Building). It was specifically designed to perform cell therapy treatments in patients with neurological disabilities, within the strategic lines developed by the Unit.

It currently has an organization chart approved by the AEMPS, which includes the following researchers:

- Dr. Mercedes Zurita Castillo (Technical Direction)
- Ms. Paula Martínez Rial (Head of Quality Control)
- Ms. Concepción Aguayo Ferrer (Production Manager)
- Mrs. Marta Victoria Fernández Cuellar (Quality Assurance Manager)
- Ms. Maria Nieves Repolles Garcia (Quality Control Technician)
- Ms. Ester Moñivas Gallego (Production Technician)
- Ms. Silvia de la Calle (Production Technician)
- Ms. Celia Bonilla Horcajo (Quality Assurance Technician)

The HUPHM Cell Therapy Unit currently has the first Non-Industrially Manufactured Advanced Therapy drug with registration No. 83796 authorized by the Spanish Medicines Agency (AEMPS) under the framework of Royal Decree 477/2014 in January 2019 and that same year the Interterritorial Council of the National Health System approved its administration under the Social Security framework.

The drug NC1, whose active ingredient is "autologous adult stem mesenchymal cells from expanded bone marrow" is currently indicated for the treatment of chronic spinal cord injuries of traumatic origin, but the Unit, due to its long history of research, continues to work on extending the indications of this drug to other neurological pathologies.

5.15.2 CELL PRODUCTION UNIT (UPC-HUPHM). HEMATOLOGY AND HEMOTHERAPY .

Technical Manager and Qualified Person: **Rafael Duarte Palomino**
Quality Assurance Manager and Alternate Technical Manager: **Rocío Zafra Pizarro**
Production Manager: **Rocío Sánchez**
Responsible for Quality Control: **Trinidad Martín Donaire**
Responsible for Cryobiology Area: **María Esther Martínez Muñoz**
Cryobiology Production Technicians: **Miguel García Berciano and Nuria Panadero**
Phones: **+34-91-191-6303; +34-91-191-7767.**
E-mail:rduarte.work@gmail.comrocio.zafra@salud.madrid.org

INTRODUCTION

The Cell Production Unit of the Hospital Universitario Puerta de Hierro Majadahonda (UPC-HUPHM) is located on the second floor of the Laboratories building, within the Hematology Laboratory (comb 7) and is part of the Hematopoietic Transplant, Cryobiology and Cell Culture Laboratory of the Hematology Department. Since 2004, in the old hospital headquarters, there was already a clean room for cell culture for cell therapy procedures. Since the move to Majadahonda, the new UPC-HUPHM continues to produce stromal mesenchymal cells (MSCs) and other cell cultures for therapeutic purposes under GMP (*Good Manufacturing Practice*) conditions, in compliance with the current regulations for Advanced Therapies (RD 1394/2007). For this, it is essential to have an adequate infrastructure, a strict quality system in accordance with GMP standards and to be accredited by the Spanish Agency of Medicines and Health Products (AEMPS). The UPC-HUPHM was initially accredited by the AEMPS in 2010, re-accredited in 2013, 2016 and 2019, and is in the process of new re-accreditation in 2022, so that it is fully authorized to work with investigational medicinal products for human use, for the manufacture of biological drugs and Cell Therapy.

STRATEGIC LINES and CLINICAL TRIALS

- Cell therapy with ESCs for the treatment acute graft-versus-host disease (GVHD). Following the initial development of a phase I-II clinical trial for the treatment of refractory acute GVHD (EudraCT: 2010-022316-39), UPC-HUPHM has treated more than 50 allogeneic transplant recipients with refractory GVHD as compassionate use treatment for drugs in special situations (R. Alonso Trillo, et al. EBMT 2022, P125), and is currently developing an application for AEMPS approval of CME as a treatment for patients with refractory acute GVHD through a Hospital Use Exception.
- Cell Therapy with ESC for other complications of allogeneic transplantation, including hemorrhagic cystitis and refractory cytopenias.
- Bone Regeneration Cell Therapy with ESCs. Two clinical trials have recently been conducted in this field in which UPC-HUPHM is the cell production room for all participating Spanish centers:
  a. Title: "ORTHOpedic Randomized Clinical Trial with Expanded Bone Marrow MSC and Bioceramics versus Autograft in Long Bone NonUNIONs" (ORTHOUNION). EudraCT No.: 2015-000431-32. Sponsor: UAM (Spain). Coordinator: Prof. E. Gómez Barrena.
  b. Title: "Evaluation of the safety, feasibility and preliminary efficacy of donor MSCs, in the treatment of patients with osteronecrosis of the femoral head after allogeneic stem cell transplantation" (ALOFEM). EudraCT No.: 2018-000886-35. Sponsor: UAM (Spain). PI: Prof. E. Gómez Barrena.
- Cell Therapy with ESC for Acute Respiratory Distress. During the COVID pandemic, a randomized, double-blind clinical trial has been conducted in these patients: "Double-Blind, randomized, controlled, Clinical Trial to Assess the efficacy of allogenic mesenchymal stromal cells in patients with acute respiratory distress syndrome due to COVID-19" (COVID-AT). EudraCT: 2020-002193-27. Sponsor: Dr. Cristina Avendaño Solà. PI: Dr. Rafael Duarte Palomino.
- Cell Therapy with ESC for Chronic Lung Transplant Rejection. The clinical trial: "An Open Label, Randomised, Controlled Clinical Trial to Assess the Safety of Endobronchial Administration of Allogeneic Mesenchymal Stromal Cells in Patients With Lung Transplant Chronic Rejection: Study Endosc-Clad" is pending approval by the AEMPS. EudraCT: 2022-000279-38. Sponsor: Fundación para la Investigación Biomédica del Hospital Universitario Puerta de Hierro Majadahonda. PI: Dr. David Gómez de Antonio and Dr. Piedad Ussetti. This trial is funded by the Carlos III Institute in the 2021 call within the modality of Independent Clinical Research Projects (ICI21/00122).
- Development of ESCs from new cell sources, including placenta and endometrium.

SERVICE PORTFOLIO

Cell Therapy products prepared since 2004:

- CD34+ and CD133+ Hematopoietic Progenitors
- HLA-identical or haploidentical donor lymphocytes
- Anti-CMV Specific T Lymphocytes
- Anti EBV Specific T Lymphocytes
- Autologous MO MSCs
- Allogeneic MO MSCs
- NK cells

6 HUPHM BIOMEDICAL RESEARCH FOUNDATION

Foundation Director: **Fernando Neira Álvarez**

Contact information:

- VAT ID: G-83726968
- Address: C/ Joaquín Rodrigo, 2 (Edificio Laboratorios)
  28222 Majadahonda - Madrid
- E-mailsecretaria@idiphim.org
- Telephone: 91 191 76 45

Reception

- E-mailrecepcion@idiphim.org
- Telephone: 91 191 77 60

Secretariat, General Services

- Contact information: María Jesús Propios
- E-mailsecretaria@idiphim.org
- Telephone: 91 191 76 45

Purchases

- Contact information: Olaitz Berástegui Lizarraga
- E-mail:pedidos@idiphim.org ; oberastegui@idiphim.org
- Telephone: 91 191 69 65

Contract Management Clinical Trials

- Contact information: Carlos Jiménez and Elena Olalla
- E-mailcontratos.eecc@idiphim.org
- Telephone: 91 191 69 17

Agreement Management

- Contact information: Carmen Muñoz Sánchez and Almudena Ferreras
- E-mailconvenios@idiphim.org
- Telephone: 91 191 69 14

Invoicing Clinical trials

- Contact Information: María del Carmen Gutiérrez del Val
- E-mailmgutierrezdelval@idiphim.org
- Telephone: 91 191 66 63

Human Resources

- Contact information: Begoña Sáenz de Tejada Madina
- E-mail:bsaenz@idiphim.orgrrhh@idiphim.org
- Telephone: 91 191 67 45

Accounting and Donations

- details: Mercedes Fernández Otero and Patricia Castillo Herrero
- E-mail: ;contabilidad@idiphim.org
- Telephone: 91 191 67 55

National Competitive Projects

- Contact information: Elena Lérida de Tejada
- E-mail elerida@idiphim.org
- Telephone: 91 191 67 45

European Projects

- Contact Information: Jesús Rey Jiménez and Mercedes Fernández Otero
- E-mail proyectos.europeos@idiphim.org
- Telephone numbers: 91 191 63 64 / 91 191 67 55

Funding Calls

- Contact information: Jesús Rey Jiménez
- E-mail oficinaproyectos@idiphim.org
- Telephone: 91 191 63 64

Research Ethics Committee and Medicines Research Ethics Committee (CEIm)

- Contact information: Patricia Gómez Torres
- E-mail secreceic.hpth@salud.madrid.org
- Telephone: 91 191 76 62

Innovation Support Unit

- Contact information: Luz Pérez Gómez de Cadiñanos
- E-mail unidadinnovacion@idiphim.org
- Telephone: 91 191 69 37

Quality Unit

- Contact information: Jesús Rey Jiménez
- E-mail jrey@idiphim.org
- Telephone: 91 191 63 64

7 HOW TO GET TO IDIPHISA - FIB HUPHM

Access to the center

The Hospital Universitario Puerta de Hierro Majadahonda is one of the reference hospitals in the Community of Madrid, located at Calle Joaquín Rodrigo, No. 2 in the municipality of Majadahonda 28222 in Madrid. It has several entrances to its buildings.

- Main access: Joaquín Rodrigo Street (south area of the building).
- Emergency room: Manuel de Falla street (north area of the building).
- Consultations: access from the north and south areas (Consultations building).
- Admission and Hospitalization: access from the north area and south area (Consultation building).
- Segovia de Arana Biomedical Research Institute: east area of the building.

Public transportation

Buses

The bus lines that stop in the vicinity of the Hospital are the following:

- Line 567. Majadahonda Hospital-Villaviciosa de Odón.
- Line 633. Majadahonda Hospital-Galapagar-Galapagar-Colmenarejo.
- Line 653. Majadahonda Hospital (by FF.CC. station)-Madrid (Moncloa-Dársena 38).
- Line 655. Majadahonda Hospital-Madrid (Moncloa-Dársena 38).
- Line 650A. Circular Line Hospital-Majadahonda-Pozuelo-Hospital.
- Line 650B. Circular Line. Hospital-Pozuelo-Majadahonda-Hospital.
- Line 626. Villanueva de la Cañada-Majadahonda Hospital-Las Rozas.
- Line 667. San Lorenzo del Escorial-Majadahonda Hospital (through Galapagar).
- Line 685. Majadahonda Hospital-Las Rozas-Guadarrama-Navacerrada.
- Line 626. Las Rozas- Majadahonda (Urgencias Hospital)-Villanueva de la Cañada - Line 580. Majadahonda Hospital-Brunete.

Likewise, from all those municipalities that have rail service, there is the possibility of transferring from the different lines at the Majadahonda station to the urban service:

- Line L1 Circular (Hospital - Station FF.CC.).
- Line L2 Circular. Hospital - Station FF.CC.

Cab.

Stops at the main door and at the outpatient door.

Contact telephone numbers

Puerta de Hierro University Hospital

- Calls from outside to the hospital: 91-191 60 00
- Calls to switchboard: 416000

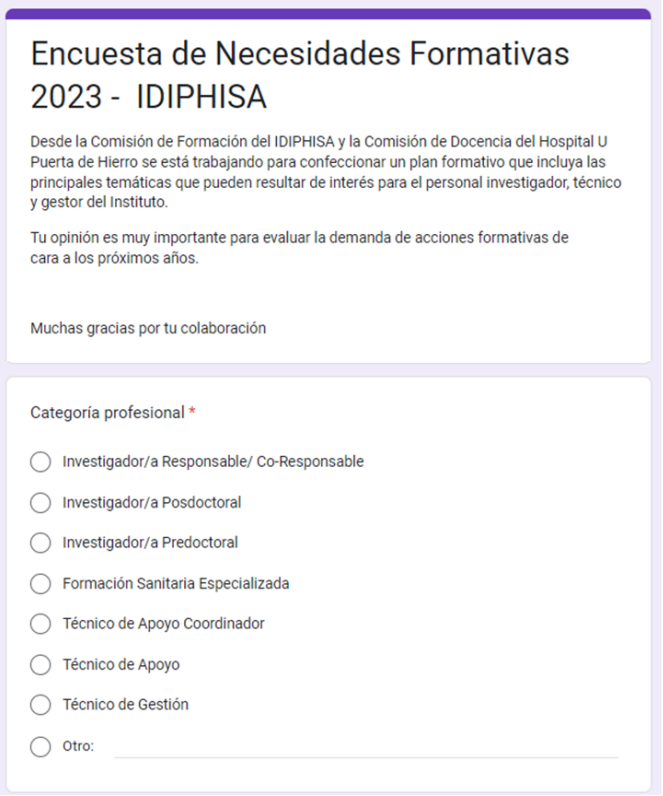
Biomedical Research Foundation

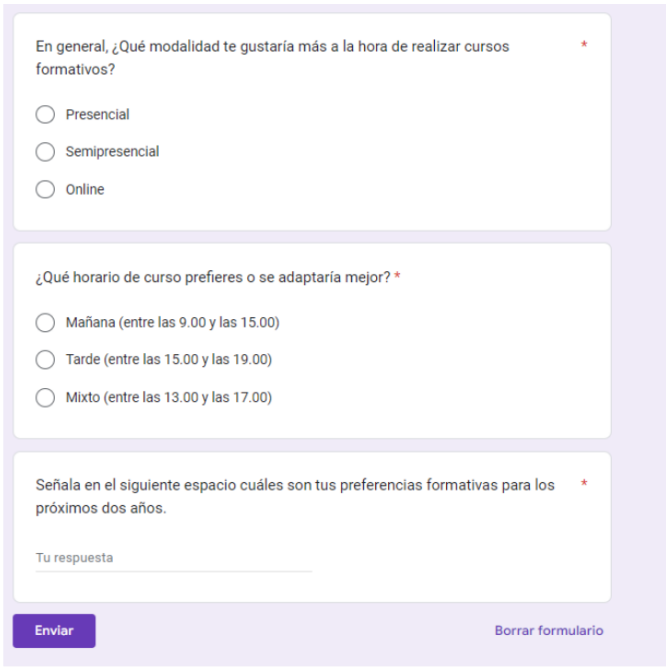
- Secretary's Office: 91 191 76 45

8 TRAINING

IDIPHISA has **its own Training Plan** that includes the different training activities offered by the hospital centers that comprise it and the UAM, to which have been added those training activities developed by IDIPHISA focused on satisfying the training needs not covered by the existing training offer from each of the entities.

A **survey** is launched annually **to find out the training needs of all IDIPHISA members** and to be able to prioritize actions for the following year. The survey is disseminated by the Research Institute itself and by the HUPHM Teaching Commission.

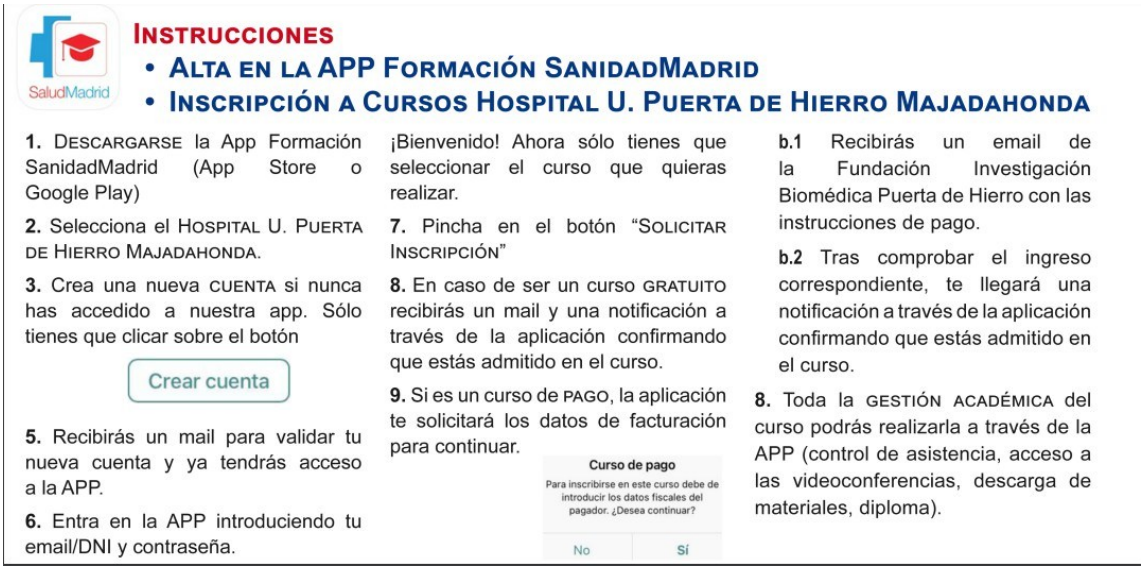




The Training Plan as well as the calendar of research sessions can be consulted at the following URL:

https://investigacionpuertadehierro.com/formacion/

In order to keep up to date with training, register for courses, control attendance and download evaluation documents and certificates, it **is essential to install and register in the SaludMadrid Training APP**, managed by the Hospital's Continuing Education Department.



INSTRUCCIONES

- **ALTA EN LA APP FORMACIÓN SANIDADMADRID**
- **INSCRIPCIÓN A CURSOS HOSPITAL U. PUERTA DE HIERRO MAJADAHONDA**

1. DESCARGARSE la App Formación SanidadMadrid (App Store o Google Play)

2. Selecciona el HOSPITAL U. PUERTA DE HIERRO MAJADAHONDA.

3. Crea una nueva CUENTA si nunca has accedido a nuestra app. Sólo tienes que clicar sobre el botón

Crear cuenta

5. Recibirás un mail para validar tu nueva cuenta y ya tendrás acceso a la APP.

6. Entra en la APP introduciendo tu email/DNI y contraseña.

¡Bienvenido! Ahora sólo tienes que seleccionar el curso que quieras realizar.

7. Pincha en el botón "SOLICITAR INSCRIPCIÓN"

8. En caso de ser un curso GRATUITO recibirás un mail y una notificación a través de la aplicación confirmando que estás admitido en el curso.

9. Si es un curso de PAGO, la aplicación te solicitará los datos de facturación para continuar.

Curso de pago

Para inscribirse en este curso debe de introducir los datos fiscales del pagador. ¿Desea continuar?

No Sí

b.1 Recibirás un email de la Fundación Investigación Biomédica Puerta de Hierro con las instrucciones de pago.

b.2 Tras comprobar el ingreso correspondiente, te llegará una notificación a través de la aplicación confirmando que estás admitido en el curso.

8. Toda la GESTIÓN ACADÉMICA del curso podrás realizarla a través de la APP (control de asistencia, acceso a las videoconferencias, descarga de materiales, diploma).

RESEARCH SESSIONS

They take place weekly on Thursdays at 1:30 p.m. exclusively in PRESENT format.

The **venue is Classroom 15 located in area D2 of TEACHING** (second floor, entrance next to the chapel). To get there, it is recommended to **enter the Hospital through the main entrance and continue along the corridor** to the teaching area as shown in the following map:

9 COMMUNICATION

IDIPHISA's management has the following channels for the transmission of information to its researchers:

1. **The corporate website:**

   https://www.investigacionpuertadehierro.com/

2. **IDIPHISA Intranet**

   IDIPHISA's intranet is the place to find information of general knowledge, which, due to its confidential nature, cannot be published on the Institute's website. It can be accessed through the following URL:

   https://intranet.idiphim.org/

3. **E-mail** through the following addresses
   - Communications from the foundation's management:
     - secretaria@idiphim.org
   - Communications from the scientific direction and information about research sessions:
     - informacion@idiphim.org
   - Dissemination and promotion of calls for public or private funding:
     - oficinaproyectos@idiphim.org

4. **INVESTIG@ quarterly newsletter.** You can access it through the following URL:

   https://investigacionpuertadehierro.com/category/boletin-investiga/

   To propose new news to be included in the next edition of the newsletter:

   - boletin.idiphisa@idiphim.org

To request to be added to the subscription list **send a request to** .ventanilla@idiphim.org

10 R&D&I POLICY

The R&D&I Management Unit has defined a Policy that expresses the commitment to comply with the requirements of the UNE-166002 Standard, provides a reference framework for establishing and reviewing R&D&I objectives and makes it suitable for the organization's purpose.

It is oriented to improve the health of citizens, focusing therefore on the development translational research that implies a constant improvement of the healthcare activity and therefore improves the quality of life of the population:

We ensure that R&D&I projects meet the necessary requirements and focus on priority areas. The system has a set of procedures that should help the achievement of objectives and the correct allocation of the resources involved.

The R&D&I policy also assumes, through the "principal investigators (PI)", the challenge of motivating and leading the entire human team that conforms it, encouraging in turn the emergence of leaders within the development of all the processes and activities that are carried out. In order to promote the development of the personnel and their skills, so that it results in a more effective and efficient performance, the training actions considered necessary will be planned and developed, taking into account the existing economic availability. In addition, continuous improvement is a permanent objective for everyone and refers to all the activities developed.

The FIBHUPHM, as the body in charge of administration and financial management, undertakes to comply with the legal and regulatory requirements applicable to it.

The policy is documented and has been disseminated so that it is understood and applied, ensuring that everyone is aware of the importance of the activities and how they contribute to the achievement of the Objectives. Its content is reviewed during the System Review Meeting to adapt it to possible changes.

The R&D&I policy is available on the INSTITUTO's website:

- https://investigacionpuertadehierro.com/politica-de-idi/

The Instituto de Investigación Sanitaria Puerta de Hierro - Segovia de Arana is certified in UNE 166002:2021. This certification is for the activities: "**Management of clinical research programs and projects and other related activities in the field of biomedicine**".

You can access the certificate through the following URL:

IDIPHISA Certificate UNE 166002:2021

This recognition makes Research, Development and Innovation management a consistent system in our center.

IDIPHISA is the first accredited Health Research Institute in the Community of Madrid to achieve certification in accordance with the requirements of the UNE 166002:2021 standard.

The UNE 166002 Standard provides a framework for systematizing R&D&I activities.

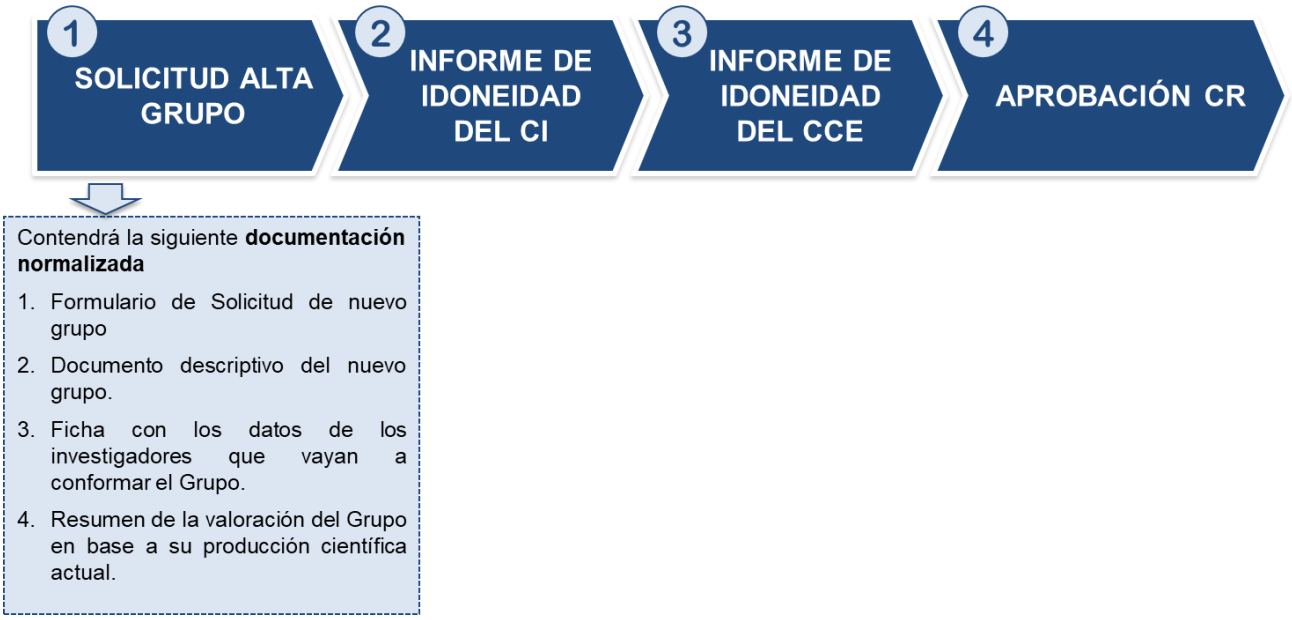
11 DECALOGUE OF GOOD PRACTICES IN INFORMATION SECURITY

1) Access only to the information necessary for the development of the functions corresponding to the job position and observe the duty of professional secrecy with respect to personal data.
2) Keep the password to access information systems secret, avoiding lending it or writing it down on paper or computer media whose security may be compromised.
3) Use only the corporate e-mail account for business purposes, encrypting in any case the sensitive data sent.
4) Permanently delete any work file or temporary file, whether on computer or paper, containing sensitive data and do not store sensitive or valuable data on local equipment.
5) Ensure that all data are backed up
6) Lock computers that display or have access to sensitive data when they are not being attended and collect paper documents with sensitive data that may remain on printers or meeting tables. Documents with personal data should be securely destroyed, and never thrown directly into the trash.
7) The extraction of information from corporate systems to portable devices is prohibited. In case of need and prior authorization to perform the extraction, they must always be stored in a safe place (under lock and key). In addition, whenever possible, they should be encrypted and anonymized (if they are personal data).
8) Prevent virus and malware infections that compromise information by avoiding the use of key rings and USB disks without prior analysis, opening suspicious e-mails, installing unapproved software or accessing insecure websites.
9) Communicate any incident regarding information security or any related need through the channels defined in the Hospital and the Foundation.
10) To be familiar with the applicable legislation and regulations on information security, in particular Order 1943/2005, of the Regional Minister of Health and Consumer Affairs, approving the code of good practice for users of computer systems of the Regional Ministry of Health and Consumer Affairs, as well as Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) and Organic Law 3/2018, of 5 December, on Personal Data Protection and guarantee of digital rights.

12 CREATION OF NEW GROUPS OF RESEARCH

Any IDIPHISA researcher can request the creation of a new group. The steps for the decision making and elaboration of the opinion are the following:

1. Elaboration of a suitability report by the research committee: It will be based on the activity data and scientific production of the group in the last five years and must define, based on such data, a proposal to classify the group as: emerging, consolidated, clinical or associated based on the official IDIPHISA classification.
2. Referral of this report to the External Scientific Committee for evaluation.
3. Approval by the Governing Council
4. Once approved, the Scientific Directorate will communicate the opinion to the area coordinator and the Principal Investigator and he/she will become a member of the Institute under the same conditions as the rest of the members.



To start the process and obtain the templates, please ask for more information at the following e-mail address:

- ventanilla@idiphim.org

13 SIGNATURE POLICY FOR PUBLICATIONS SCIENTIFIC

POLÍTICA DE FIRMAS PARA LAS PUBLICACIONES CIENTÍFICAS IDIPHISA

INVESTIGADORES CONTRATADOS POR EL HOSPITAL* O POR LA FUNDACIÓN DE INVESTIGACIÓN (FIBHUPHM):	**[Servicio o Unidad/ Nombre del grupo/ Laboratorio/ Plataforma], Hospital Universitario Puerta de Hierro Majadahonda, IDIPHISA. Madrid, España o Spain.** Ej. 1: Servicio de Nefrología. Hospital Universitario Puerta de Hierro Majadahonda, IDIPHISA. Madrid, Spain. Ej.2: Servicio de Oncología Médica. Hospital Universitario Infanta Cristina, IDIPHISA. Madrid, España. ***HOSPITAL**: se refiere al H.U. Puerta de Hierro o a los Hospitales adscritos al Instituto.
INVESTIGADORES DEL HOSPITAL* VINCULADOS A LA UNIVERSIDAD:	**Servicio o Unidad, Hospital Universitario Puerta de Hierro Majadahonda. Departamento, Facultad, Universidad, IDIPHISA. Madrid, España o Spain.** Ej.: Servicio de Gastroenterología y Hepatología, Hospital Universitario Puerta de Hierro Majadahonda. Departamento de Medicina, Facultad de Medicina, Universidad Autónoma de Madrid, IDIPHISA. Madrid, Spain.
INVESTIGADORES CONTRATADOS POR LA UNIVERSIDAD DEL IDIPHISA (UAM):	**Departamento, Facultad, Universidad, IDIPHISA. Madrid, España o Spain.** Ej. 1:, Departamento de Biología Molecular. Facultad de Ciencias, Universidad Autónoma de Madrid, IDIPHISA. Madrid, Spain.
INVESTIGADORES PERTENECIENTES A REDES O CONSORCIOS:	**Incluir el acrónimo y/o nombre completo de la Red o Consorcio conforme a la política que estas estructuras establezcan.** Ej.: Servicio de Neurología, Hospital Universitario Puerta de Hierro Majadahonda, IDIPHISA. Madrid, Spain. CIBER Enfermedades Raras (CIBERER).

RECOMENDACIONES:

- Emplear siempre la misma firma y nombre
- Si el apellido es compuesto utilizar un guion medio
- Consultar propuesta de normalización de los autores en: https://www.recursoscientificos.fecyt.es/recomendaciones-de-uso
- No traducir los nombres de las entidades al inglés
- En caso de haber obtenido cofinanciación no olvide revisar las medidas obligatorias de comunicación y publicidad

14 OWNERSHIP OF INVENTIONS

The management of the ownership of the inventions made by the IDIPHISA research personnel assigned to the Hospital Universitario Puerta de Hierro Majadahonda and the FIBHUPHM's own personnel in the exercise of the activities that have been entrusted to them and/or making substantial use of the infrastructures and/or resources of the Institute, will correspond to the FIBHUPHM, with the exception of the existence of another ownership and/or processing regime subscribed to a validly granted legal instrument.

In the case of intellectual property rights, and regardless of the type of protection adopted, the following shall be indicated on the work: "© IDIPHISA, year (...). All rights reserved".

If entities other than the FIBHUPHM participate in the invention, a co-ownership will be drawn up establishing the terms and obligations of the parties.

The Foundation may manage the transfer of the ownership of the rights over the Results to the personnel, author of the same, reserving in this case for the original owner (transferor) a non-exclusive, non-transferable and free license of use for teaching, research or assistance purposes. When the researcher obtains benefits on the exploitation of the aforementioned assigned inventions, the distribution of the same ones will be in accordance with the distribution of benefits provided for the public research organizations, that is to say, if the ownership of the invention and/or work belongs to the FIBHUPHM the benefits of the exploitation will be distributed in the following way:

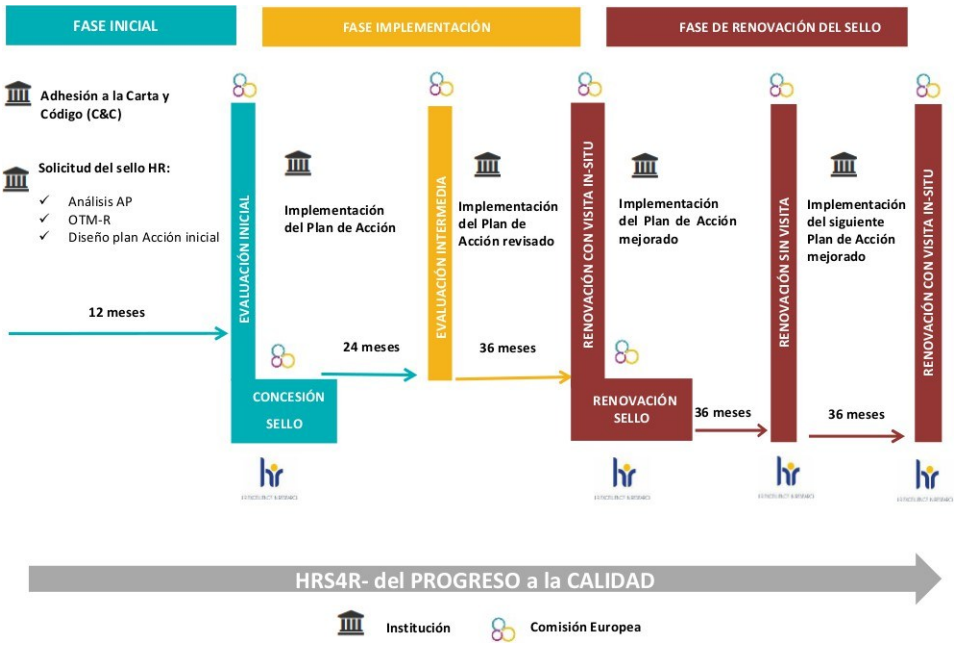
- 1/3 FIBHUPHM
- 1/3 Research group or department to which the inventors belong
- 1/3 Inventor/s

In the case of inventions that are the result of an activity unrelated to that of the IDIPHISA researcher and/or the Foundation, and this is carried out with the researcher's own means and outside the time dedicated to his professional activity, the ownership of the rights, as well as the benefits, obligations and liabilities therefrom, shall correspond entirely to the author or inventor.

15 HUMAN RESOURCES STRATEGY FOR RESEARCHERS (HRS4R)

The Instituto de Investigación Sanitaria Puerta de Hierro - Segovia de Arana signed and sent to the European Commission in March 2018 the declaration of commitment to the principles of the "***Charter for European Researchers***" and the "***Code of Conduct for the Recruitment of Researchers***".

What are the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers?	The Charter and the Code of Conduct **are recommendations from the EC to the Member States** and they are invited to apply them voluntarily: · **The European Charter for Researchers** is a set of general principles and requirements that define **the roles, responsibilities and rights of researchers and employers** and funders. · **The Code of Conduct for the Recruitment** of Researchers consists of a set of general principles and requirements to be followed by employers and funders when appointing or recruiting researchers. It stresses the importance of open and transparent recruitment procedures and diverse and experienced selection committees.
What is the HR Strategy for Researchers (HRS4R)?	It is a **process of self-assessment and evaluation** that culminates in the recognition of institutions that present an appropriate action plan to improve their HR policies and align them with the charter and the code. It is a recognition of the continuous improvement of the Institution.
Why is it important?	· The grant contracts in **Horizon Europe state that the beneficiaries must take the necessary measures to implement the principles** of the Charter for Researchers and the Code of Conduct for the Recruitment of Researchers. · The **ISCiii accreditation guide** includes the need for IIS to have a defined HRS4R strategy.

What is the procedure to obtain recognition?	
HRS4R strategy at IDIPHISA	PDF **Human Resources Strategy for Researchers - HRS4R at IDIPHISA**
More Information	**https://hrs4r.investigacionpuertadehierro.com/**
Informative Session	On September 29th, an Information Session was held within the framework of the IDIPHISA Research Sessions of the HRS4R strategy. You can access it through the following link: Video Briefing
Related links	• https://euraxess.ec.europa.eu/ • https://euraxess.ec.europa.eu/jobs/hrs4r • https://www.youtube.com/watch?v=Hu12ivHZV4I • https://investigacionpuertadehierro.com/acciones-hrs4r-idiphisa/

16 CAREER OPTIONS

Regulatory Framework	The professional career at IDIPHISA is regulated by the Resolution December 3, 2020, of the Directorate General of Labor of the Ministry of Economy, Employment and Competitiveness, on registration, deposit and publication of the Collective Agreement of the Group of Companies of the Biomedical Research Foundations of the Health Institutions attached to the Madrid Health Service (SERMAS). This agreement includes, among other aspects, the classification of the personnel working in the center with a detailed description of each of the categories and their professional profiles. It also includes aspects related to remuneration and mobility, training, rights and duties and other issues that are also directly related and aligned with the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers (HRS4R). This document establishes professional categories assigned to the following functional areas: • Area 1. Research. • Area 2. Scientific-technical. • Area 3. Administration and management
EURAXESS Research Professional Development Scheme	In EURAXESS, four main professional profiles have been established for researchers, known as R1, R2, R3 and R4. These profiles describe different stages of the research career, from initial training to research leadership. Each profile has its own characteristics and requirements, but all contribute to the advancement of knowledge and innovation in their respective fields. **R1 - Researcher in training** The R1 profile is designed for researchers in training, including PhD students and postdocs in the early stages of their careers. R1 researchers are gaining experience in their field and may be working under direct supervision. Their responsibilities may include conducting experiments, analyzing data, and contributing to the scientific literature by writing papers and communications. **R2 - Recognized researcher** The R2 profile is aimed at experienced researchers who have demonstrated competence in their field. These professionals may have a PhD or a significant amount of relevant work experience. R2 researchers can lead research projects, supervise younger researchers and begin to establish themselves as experts in their subject area. **R3 - Experienced researcher** The R3 profile refers to researchers with an established track record and considerable experience in their field. These professionals have demonstrated a significant impact in their area of expertise, often through publishing influential papers, obtaining research funds

	and active participation in the scientific community. R3 researchers can lead research teams, collaborate in international projects and contribute to science policy development. **R4 - Research Leader** The R4 profile is reserved for leading researchers in their fields, internationally recognized for their significant contributions. These professionals are leaders in knowledge generation, innovation and the management of large-scale research projects. R4 researchers often hold high-level positions in academic institutions, research organizations or industries, and play a leading role in the formulation of scientific agendas and research strategies at the global level. **More information:** • **Euraxess:** Brief summary of each profile (R1 to R4) and link for more information. https://euraxess.ec.europa.eu/europe/career-development/training-researchers/research-profiles-descriptors • **FECYT: Researcher Career path in Spain at a glance! (6th edition)** https://www.fecyt.es/es/publicacion/researcher-career-path-spain-glance-6th-edition
More information	• https://investigacionpuertadehierro.com/mapa-de-carrera-professional/

17 EQUALITY PLAN

The Fundación para la Investigación Biomédica del Hospital Universitario Puerta de Hierro de Majadahonda (FIBHUPHM), in its quest for excellence, has among its principles the promotion of actions that provide technical and scientific training to its entire staff, recognizing the value of diversity and promoting the professional development of all its personnel through values of respect, equality, diversity, inclusion and equity, without discrimination of any kind for reasons of gender, age, race, religion, opinion or any other personal or social condition.

The following plans are currently in effect:

Equality Plan (22/03/2021)	
Anti-Harassment Protocol (22/03/2021)	
Conciliation Plan (13/06/2024)	

18 IDIPHISA RESEARCHER'S OMBUDSMAN

Mission	**To mediate in the appeals of researchers at any stage of their career, in order to improve the quality of research in all its fields and of the working environment.**
Competencies	• Act ex officio, or at the request of a party, in relation to complaints, claims and appeals and irregularities or deficiencies observed in relation to respect for the rights, duties and freedoms that are formulated by any member of IDIPHISA. • To obtain from the various authorities and agencies all information it deems appropriate for the fulfillment of its purposes. • To attend the sessions of IDIPHISA's bodies that deal with any related matter or are of interest to him/her • Resolution proposals and conciliation formulas that facilitate a quick and efficient resolution. • Issue reports in relation to its actions. • Annual report of activities
Composition	• Dr. Carmen de Mendoza • Dr. Raquel Gutiérrez González • Dr. Silvia Rosado
Contact	• defensordelinvestigador@idiphim.org
IDIPHISA Research Defender Bases	

19 POLICY FOR FINANCING SCIENTIFIC PUBLICATIONS AND THESES DOCTORAL STUDENTS 2024

This policy is supported by the nominative subsidy from the Consejería de Sanidad de la Comunidad de Madrid in favor of the Fundación para la Investigación Biomédica del Hospital Universitario Puerta de Hierro de Majadahonda under program 312D "Fundaciones de Investigación Biomédica" of the Comunidad de Madrid Expenditure budget for 2024.

Funding policy for scientific publications 2024

The guidelines for the Scientific Publications Funding Policy for the year 2024 are as follows:

- The applicant must be the main author (first, last or corresponding signatory) of the publication and be a member of IDIPHISA.
- Publications must be indexed according to JCR 2022 in Open Access journals in Q1 and Q2.
- Publications should not have alternative financing.
- The expense must be incurred and paid in 2024.
- The invoice must be issued in the name of the Fundación para la Investigación Biomédica del Hospital Universitario Puerta de Hierro de Majadahonda in the year 2024. The following fiscal data must be included in the invoice:
    - Tax ID Number: G83726968
    - Company Name: Fundación de Investigación Biomédica del Hospital Puerta de Hierro de Majadahonda
    - Address: C/Joaquín Rodrigo 2, Edif Laboratorios, planta 0, 28222 Majadahonda, Madrid

Doctoral Thesis Funding Policy 2024

In addition, an extra allocation has been approved to partially defray the cost associated with the publications of the doctoral theses read during the year 2024 by members of IDIPHISA. The characteristics of these grants are as follows:

- Maximum grant of 500€ per applicant.
- The doctoral student must prove that he/she has been a member of IDIPHISA during the completion of the doctoral thesis.
- Proof of publication expenses must be provided.
- The invoice must be issued in the name of the Fundación para la Investigación Biomédica del Hospital Universitario Puerta de Hierro de Majadahonda in the year 2024.


SaludMadrid
INSTITUTO DE INVESTIGACIÓN SANITARIA
PUERTA DE HIERRO - SEGOVIA DE ARANA
Hospital Universitario Puerta de Hierro Majadahonda