INCLIVA | VLC
Biomedical Research Institute

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WELCOME MANUAL

INCLIVA

This document has been drafted and prepared by the Training Unit and approved by the INCLIVA Board of Governors by way of the minutes dated 9 June 2025.

CONTENTS

1. INTRODUCTION

First of all, we would like to welcome you to INCLIVA. Throughout this handbook, you will find information about our facilities, available resources, policies and procedures, as well as details on how you can settle into your role. Whether you are a researcher or a member of the management team, we encourage you to explore, ask questions and make the most of your time here.

2. THE INCLIVA BIOMEDICAL RESEARCH INSTITUTE

What is INCLIVA?

The Hospital Clínico Universitario de València Foundation was established in 2000 under the patronage of the Valencian Regional Government, making it the first foundation in the Valencian Community to be affiliated with a public hospital. It was founded with the aim of driving, promoting and fostering scientific and technical research within the Valencia Clínico-Malvarrosa Health Department.

In September 2011, it was accredited as a Health Research Institute by the Ministry of Science and Innovation; its accreditation has been renewed ever since and remains in force today.

The current INCLIVA Biomedical Research Institute is the result of the joint efforts of three institutions: the Regional Ministry of Health, through the Hospital Clínico Universitario de València; the University of Valencia, which has affiliated the institute with the centres of excellence within its Faculty of Medicine and Dentistry; and the Carlos Simón Foundation.

The four main areas of research at the IIS INCLIVA are: **Cardiovascular, Oncology, Reproductive Medicine, and Metabolism and Organ Damage.** In addition, it runs seven cross-cutting research programmes: Translational Oncology; Overweight, Obesity and Metabolic, Vascular and Renal Risk; Neurological Degeneration; Ageing and Associated Diseases; Reproductive Medicine; Rare Diseases; and Detection and Management of Ventricular Dysfunction.

Currently, the IIS INCLIVA comprises **59 R&D&I groups** (established, emerging and associated clinical groups) and 15 emerging researchers on Joan Rodés, Miguel Servet or Ramón y Cajal research grants. The 59 R&D&I groups comprise more than 700 researchers with multidisciplinary profiles.

During the **2024 financial year**, the Foundation has secured and/or managed:

- 55 new competitive public and private projects at national level, totalling €9,941,936.
- 14 active international projects. The funds raised for R&D&I for the international projects currently underway amounted to €5 million.
- 15 registered patents (4 of which have been licensed), 1 utility model, 8 software registrations, 1 trade secret and 4 spin-offs.
- 623 articles in indexed journals, with 34% in the top decile and an average impact factor per article of 7.8.
- 450 active clinical trials and 144 contracts signed to launch new clinical trials.

With regard to this last point, it is worth highlighting the pioneering 'First-in-human' studies in oncology and **Phase I clinical trials,** which demonstrate the institution's strength in translational research.

Furthermore, IIS INCLIVA participates in 10 **CIBER** research groups, 2 national platforms initiated by the ISCIII (the National Biobank Platform and Support for Clinical Research – SCReN ISCIII–) and 8 European networks or platforms (Big Data Value Association –BDVA–, European Advanced Translational Research Infrastructure –EATRIS–, EU-OPENSCREEN, Worldwide Innovative Networking –WIN–, European Clinical Research Infrastructure Network –ECRIN-SCREN–, European Health Data and Evidence Network –EHDEN–, Reference Site Collaborative Network –RSCN– and **GAIA-X** at its Spanish node). It is also a member of the board of directors of the Network of Hospital and Bio-health Clinical Research Management Entities (**REGIC**), where it holds the presidency, and of the board of directors of the Valencian Community business cluster, **BIOVAL**, the Valencian Biobank Network (**RVB**), the multi-sectoral open innovation initiative promoted by the Valencian Network of Science Parks (**INNOTRANSFER**) and the Alliance for Translational Research into Rare Diseases in the Valencian Community (**AITER**).

Furthermore, the institute has a number of scientific and technological research and innovation platforms available to all its staff: Biobank, Precision Medicine Unit, Biomarker Analysis Unit, Molecular, Cellular and In Vivo Analysis Unit, Biostatistics Unit, Bioinformatics Unit, Body Composition Unit, Analytical Liquid Chromatography Unit, Mass Spectrometry Unit, Data Science Unit, Multigene Analysis Unit, Biomedical Imaging and Metabolomics Section, Flow Cytometry and Cell Culture Unit, Microscopy Unit, Personal Autonomy, Disabilities and Severe Mental Disorders Unit, Animal Housing and Experimental Operating Theatres Unit, and Medical Genetics and Genomics Section.

In 2019, the IIS INCLIVA was awarded the **HR Excellence in Research (HRS4R)** quality mark, which recognises its ability to attract talent, create a favourable working environment, promote research and innovation, and advance the careers of researchers within the European framework.

Collective Agreement

INCLIVA is a signatory to the Collective Agreement for public foundations and health research institutes in the Valencian Community (DOGV 9924 / 28 August 2024). This agreement sets out the rights and obligations of staff employed by INCLIVA under an employment contract.

Link: https://dogv.gva.es/datos/2024/08/28/pdf/2024_8637_es.pdf

Where are we?

The IIS INCLIVA comprises various facilities located close to one another, as well as to the Hospital Clínico Universitario de València and the Faculty of Medicine at the University of Valencia. This proximity facilitates the creation of shared support services to promote research.

Headquarters, a care facility for cancer and heart disease patients, and the location of our own laboratories (Precision Medicine and Biobank). Avda. Menéndez Pelayo, 4 acc; 46010 – Valencia

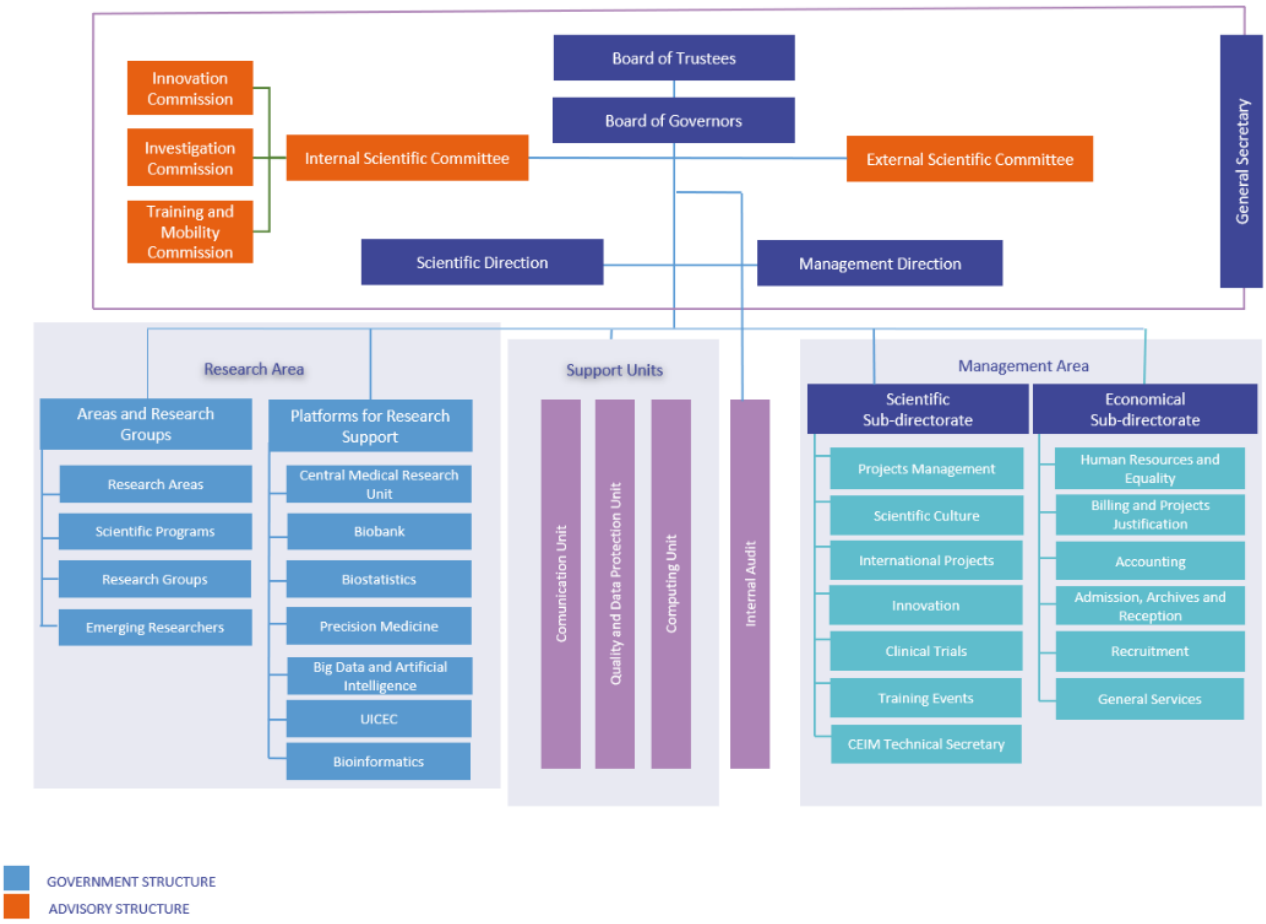
Technical Secretariat, where the administrative staff supporting the research team can be found. Pasaje Luz, Álvaro de Bazán, 10; 46010 – Valencia

Ancillary building. INCLIVA also has offices at Avenida Menéndez y Pelayo number 3, where various research support units are located (e.g. the Bioinformatics Unit or the Biostatistics Unit)

Laboratories: most of the laboratories are located in the UCIM (Central Medical Research Unit) of the Faculty of Medicine. Avda. Blasco Ibáñez, 15; 46010 – Valencia.

How are we organised?

The organisational structure of IIS INCLIVA is shown in the figure below. However, the latest information can be found at the following link: https://www.incliva.es/organigrama/



With regard to the Management and Support Units, the following sections provide information on the INCLIVA Management Office and the purpose of each unit, as well as general information on the services offered by the Scientific Platforms in support of R&D+

3. MANAGEMENT SERVICES FOR RESEARCH STAFF

The technical secretariat of the IIS INCLIVA provides a range of services to research staff with the aim of facilitating and supporting their research activities. The management team consists of the following individuals:

- Scientific Director: Dr Andrés Cervantes
- Deputy to the Scientific Director: Patricia Fernández

- Managing Director: Vicente de Juan
- General Secretary: Maite Sáenz
- Deputy Head of Finance: Consuelo López

It comprises the following units. Further information is available on the website section for each of them:

UNIT	DESCRIPTION
General Secretariat	Coordinates INCLIVA's governing bodies, acts as the organisation's legal representative, and manages contracts, agreements and arrangements between research staff and industry and other organisations. It acts as the liaison with patient associations and civil society for joint initiatives and/or donations. **Contact:** Maite Sáenz msaenz@incliva.es
National Projects Unit	It actively seeks out competitive regional and national calls for proposals, both public and private. It also supports research staff throughout the application process. It compiles calls for proposals published by various organisations and bodies and distributes them to research staff via a weekly newsletter. **Contact:** Raquel Llorens proyectosnacionales@incliva.es
International Projects Unit	It actively searches for competitive calls for proposals at international level. It provides information and training to research staff on participating in consortia and preparing proposals. It attends national and international events related to European calls for proposals. It supports research staff in participating in European and international R&D&I funding programmes and manages the awarded projects from start to finish. It carries out financial monitoring and accounts for international R&D&I projects. **Contact:** Ana Ferrer proyectoseuropeos@incliva.es
Innovation Support Unit	It promotes and manages innovation and knowledge transfer at INCLIVA: identifying ideas and analysing their feasibility, developing innovation projects, and protecting and exploiting results. **Contact:** Elena Carrió innovacion@incliva.es
Clinical Trials Unit	Manages the entire process for conducting a clinical trial at the centre when we act as a participating centre, with an external institution acting as the sponsor: processing facility suitability assessments, negotiating and signing the contract with the sponsor, and financial monitoring. **Contact:** Miguel Roig and Mayca Román ensayosclinicos@incliva.es
Clinical Research and Clinical Trials Unit (UICEC)	Provides support to research staff interested in initiating independent clinical studies, managing their development and providing monitoring services. It acts when INCLIVA or a researcher affiliated with the centre is the sponsor of the study. **Contact:** Sofía Galant uicec@incliva.es
Training and Mobility Unit	It organises the organisation's training activities and events. It manages internal and external R&D&I placements and work placements for vocational training programmes, specialised vocational training courses, bachelor's degrees and master's degrees. **Contact:** Natividad Paz and Cristina García formacion@incliva.es
Scientific Output Unit	Monitors INCLIVA's scientific output, maintaining an up-to-date record of publications and information on research groups. Prepares reports on scientific output and indicators, coordinates the Scientific Report, manages the Integration Plan and supports *Open Science* initiatives. **Contact:** María Revengamemoria@incliva.es , mrevenga@incliva.es
CEIM Support Unit	Provides administrative support to the Committee on Ethics in Research Involving Medicinal Products (CEIm) at the Hospital Clínico Universitario de València. This Committee evaluates clinical trials involving medicinal products or medical devices,

	observational studies involving medicinal products, research projects and studies for academic purposes. **Contact:** Maialen Llopis and Ester Penadés ceic_hcv@gva.es
Quality and Data Protection Unit	Manages quality and data protection matters at INCLIVA and advises and supports research staff with their needs in relation to these two areas. It also ensures that actions relating to INCLIVA's Open Science Policy are carried out correctly. **Contact:** Rafael Barajas calidad@incliva.es
Billing and Accounting Unit	It is responsible for the financial monitoring and accounting of competitive regional and national R&D&I projects. It also manages the invoicing of clinical trials and service provision contracts. **Contact:** Vera Marín gestioneconomica@incliva.es
Accounting Unit	This unit is responsible for recording incoming invoices and their payments, as well as staff payroll and grants from various funding sources. It also prepares tax returns and records donations received. **Contact:** Mª José Rosalén contabilidad@incliva.es
Procurement and Contracting Unit	It initiates and manages all matters relating to the organisation's procurement of equipment, supplies and services: notices, open or ongoing tenders and contract awards. **Contact:** Isabel Gomis contratacion@incliva.es
IT Unit	It is responsible for maintaining all IT, audiovisual and telecommunications infrastructure located at INCLIVA's premises. Its services include providing access to high-performance computing (HPC Cluster) and the development and hosting of data collection forms (RedCap and OpenClinica). It also provides technical support and advice to the organisation's staff. **Contact:** Miguel Herreros informatica@incliva.es
Scientific and Technological Platforms Management	This unit centralises the request and comprehensive management of the scientific and technological services offered by INCLIVA. It supports research staff in the implementation of new services and the maintenance of existing ones. **Contact:** Irene Cañigral plataformas@incliva.es
Communications Unit	It raises the profile of INCLIVA's work through news and content related to the organisation, covering clinical developments, advances in R&D&I and other events, as well as organising outreach activities. **Contact:** Arantxa Martín prensa@incliva.es
General Affairs	Among other tasks, this unit manages access control to INCLIVA's facilities and coordinates with maintenance, cleaning and security companies. **Contact:** Cristina García asuntosgenerales@incliva.es
Incoming/Outgoing Registry	Receipt and dispatch of general documentation **Contact:** Alicia Gumiel and Inma Montalt, recepcion@incliva.es

4. DOCUMENTS OF INTEREST TO RESEARCH AND ADMINISTRATIVE STAFF

INCLIVA has a series of plans, projects, policies and institutional guidelines that are essential for understanding the organisation, as detailed in the following subsections. This documentation is kept up to date on the institution's website via the following link, under the section 'Documents of interest to research and administrative staff':

Intranet – INCLIVA – Biomedical Research Institute

This same section contains an up-to-date description of INCLIVA, in both Spanish and English, as well as a brief PowerPoint presentation with basic information about the organisation.

In addition, the institution has a Transparency Portal on its website which includes all the latest institutional information (governing bodies, statutes, annual accounts, etc.), as well as the organisation's internal regulations:

https://www.incliva.es/portal-de-transparencia/

Legal Information – INCLIVA – Institute for Health Research

Scientific Report

INCLIVA's Annual Scientific Report presents an overview of scientific activity and a compilation of projects and scientific publications produced by the research groups affiliated with INCLIVA. It also contains detailed information on finance, human resources, communications, platforms and associated networks.

If you require further information on this matter, please contact:memoria@incliva.es

Strategic Plan

INCLIVA has a Strategic Plan for 2025–2029 based on the achievement of six major strategic objectives: (1) to promote research by strengthening multidisciplinary translational R&D and consolidating new disciplines and emerging fields; (2) to provide research groups with the resources, platforms and facilities appropriate to their needs; (3) to optimise institutional management and governance processes in order to provide a responsive service and foster a sense of belonging to the organisation; (4) to ensure the sustainability and strengthening of INCLIVA's critical mass of researchers in the medium and long term, by promoting scientific leadership and the professional development of its staff; (5) to stimulate research activity at local, national and international levels, building a network of collaborators and strategic partners to increase its international presence and standing; and (6) to consolidate areas of activity complementary to research that reinforce its distinctiveness and specialisation, focusing on innovation, impact and a patient- and society-centred approach.

If you require further information on this matter, please contact:patricia.fernandez@incliva.es

Affiliation and Author Attribution Guide

The aim of the affiliation guide is to ensure that the scientific output resulting from research carried out at INCLIVA is visible, recognisable and quantifiable. Compliance with this guide is essential in order to properly identify and assess the Institute's overall scientific output and its evolution over time, as well as to meet the standards set by the Carlos III Health Institute.

If you need further information on this matter, please contact:mrevenga@incliva.es

Integration Plan

INCLIVA's Integration Plan sets out the procedure for incorporating new research groups and modifying existing ones from the institute's affiliated bodies (the Department of Health, the University of Valencia and the Carlos Simón Foundation). It also details the requirements and documentation needed to progress within a research career. This document is periodically reviewed and updated by INCLIVA's management office, reviewed by its Internal Scientific Committee and approved by the institution's Governing Board.

If you require further information on this matter, please contact:mrevenga@incliva.es or patricia.fernandez@incliva.es

Cooperative Scientific Project (PCC)

INCLIVA's research groups are responsible for developing this project, the aim of which is to foster or maintain collaboration between INCLIVA-affiliated groups working in different subject areas. The PCC is divided into Cross-cutting Programmes, each led by at least one coordinator. Each Cross-cutting Programme has a specific theme and defined objectives. Furthermore, it includes the contribution of the R&D&I carried out by the groups within the framework of this plan to the National Health System, the planned innovations and the gender perspective in research. The groups affiliated with each Programme must carry out the projects defined in the plan and meet the proposed interrelation indicators. The results of this project's implementation are presented annually in the organisation's Scientific Report.

If you require further information on this matter, please contact:patricia.fernandez@incliva.es

Training Plan

The IIS INCLIVA has a biennial Training Plan which provides for the training of research and management staff affiliated with the institution. The objectives of the 2025–2026 Training Plan are as follows: (1) to promote the training of basic, clinical and translational research staff in the Institute's R&D&I areas; (2) to foster the training of technical research staff and support staff; (3) to promote the participation of training specialists in research activities through their gradual integration from their original departments; (4) to increase R&D&I training for primary care and nursing staff; (5) to maintain and improve the training of staff involved in the Institute's management in general and in its specific development units; (6) to promote training for research or technical staff from outside the Institute, through specific workshops or courses; (7) to encourage training placements at prestigious centres to facilitate access to new knowledge and supplementary training in innovative techniques or procedures; (8) to encourage the mobility of staff attached to INCLIVA and the creation of new collaborations and synergies; (9) to cooperate in other training programmes outside the institution (e.g. REGIC, Regional Ministry of Health); (10) to encourage the organisation of meetings between the Institute's staff and expert researchers or managers at regional, national and international levels through meetings, seminars or conferences related to INCLIVA's strategic or priority areas; (11) to foster a culture of innovation and entrepreneurship amongst research, technical and management staff within the institution's sphere of activity; and (12) to promote leadership amongst the institution's female researchers through the INCLIVA Leadership Programme. Via this link on the website, you can find further information on the planned training activities and download the full text: https://www.incliva.es/servicios/servicios-al-personal-investigador/gestion-cientifica/formacion-y-movilidad/formacion/.

If you require further information on this matter, please contact: formacion@incliva.es

Translation, Innovation and Transfer Plan

This plan addresses the translation or transfer of the IIS's scientific results into clinical practice and the productive sector, both within the Institute's own environment and globally. This strategy includes measures to involve key non-scientific stakeholders. This plan sets out a clear, transparent and coherent vision for technology transfer, with strategic objectives and priorities, a policy on the protection of research results, and a policy on the creation of spin-offs, including a policy on equity participation by researchers and the IIS. It also includes initiatives amongst researchers to promote: 1) An increase in the number of patents registered and licensed. 2) The transfer of knowledge to the private sector. 3) The development of new marketable healthcare products or devices. 4) The implementation of new clinical processes. 5) The creation of spin-offs and start-ups. 6) Academic clinical trials or studies.

If you require further information on this matter, please contact: innovación@incliva.es

Open Science Policy

IIS INCLIVA's open science policy reflects its strategic commitment to transparency, accessibility and collaboration in the scientific process. Inspired by the principles set out in the UNESCO Recommendation on Open Science (2021) and the guidelines of the OECD (Organisation for Economic Co-operation and Development), this policy promotes free and open access to research outputs, including publications, data, software and methodologies. The aim is to ensure that the knowledge generated by the Institute is available to the entire scientific community and society at large, thereby promoting reproducibility, the efficient use of resources and the generation of social impact. UNESCO defines open science as an inclusive approach that facilitates the circulation of knowledge beyond institutional and geographical boundaries, and which opens up scientific processes to social actors beyond the traditional academic community. The OECD, for its part, highlights the economic and social value of open data policies, emphasising their potential to boost competitiveness, innovation and evidence-based decision-making. In this regard, the Institute's institutional adoption of these principles places it in a position of leadership and responsibility within the international biomedical research system. At national level, this policy is in line with the provisions of Article 37 of the Law on Science, Technology and Innovation (amended by Law 17/2022), which requires that the results of publicly funded research be made openly accessible. It also complies with the principles of the Carlos III Health Institute (ISCIII), which requires the implementation of data management plans and open access to scientific publications in its competitive calls for proposals. Furthermore, this approach responds to the growing requirements of other public and private funders—both national and international—who regard open science as a criterion of quality, impact and social responsibility. If you require further information on this matter, please contact: calidad@incliva.es

5. SUPPORT PLATFORMS AND BIBLIOGRAPHIC RESOURCES FOR R&D&I

The INCLIVA Health Research Institute operates a number of research platforms that provide specialised scientific, technological and infrastructure support to the Institute's research groups, as well as to external

organisations and companies upon request. Details of each platform's features, along with the various services and fee structures they offer, can be found at https://www.incliva.es/servicios/plataformas/.

The science and technology platforms play a vital role in structuring INCLIVA's research groups and aim to facilitate research and provide added value by offering high-quality services at very competitive rates.

Furthermore, under agreements established with the Faculty of Medicine at the University of Valencia and the Carlos Simón Foundation, INCLIVA has access to laboratories and equipment associated with these institutions.

The resources of the Central Medical Research Unit (UCIM) at the University of Valencia can be viewed on its website (https://www.uv.es/unidad-central-investigacion-medicina/es/unidad-central-investigacion-medicina-ucim.html).

Furthermore, INCLIVA prioritises ensuring that all research staff have access to bibliographic resources. Access is currently available to the following virtual libraries:

- Virtual Library of the Valencian School of Health Studies (EVES): https://eves.san.gva.es/es/biblioteca/colleccions-subscrites
- University of Valencia Virtual Library: http://biblioteca.uv.es. Access is available from any computer connected to the University of Valencia's internal network or from any computer by configuring access via a Virtual Private Network (VPN).
- Web of Science: https://www.webofscience.com . Staff affiliated with INCLIVA can access this service from any computer connected to its internal network.
- Additional resources: Any other bibliographic resource or information service will be managed through the procurement procedure and must be requested by the department or unit requiring it.

6. PRACTICAL INFORMATION

The INCLIVA website features the comprehensive management application **Intranet** (https://www.incliva.es/intranet/), which is accessible to contracted staff. This will enable you to consult institutional, personal and research-related information (projects and clinical trials in progress). From this page, you can also access:

- Fund@net: a comprehensive management application where you can view personal information (contractual documentation, payslips, information on occupational health and safety, submit requests for holidays and leave, etc.) and information on the management of projects and clinical trials in which researchers participate as coordinators or collaborators. Such participation must be reported to the relevant unit so that all staff can be included in the project or clinical trial (Clinical Trials Unit, CEIM Support Unit or National/International Projects Unit).
- Forms: financial management forms, mobility forms, and documentation relating to services for research staff.
- Corporate Identity: files containing INCLIVA logos in various formats and versions, templates, email footers, screensavers, posters, conference materials and scientific posters.
- Suggestions box.
- Time and attendance records.

- General and strategic documentation relating to the institution.
- Access to the INCLIVA corporate email portal.

We've also answered some of the general questions you might have:

- Employment contract: this is governed by the Collective Agreement for Public Foundations and Health Research Institutes in the Valencian Community. You can find the full text of this Agreement in the Human Resources section – Documents of Interest – of your Fundanet account.
- Access to your Fundanet account: staff will receive an email in their INCLIVA account, where they can register their account. A user manual will be provided.
- Time recording: Please note that it is compulsory to clock in and out using the Woffu app (https://incliva.woffu.com/#/login). Staff will receive an email at their INCLIVA account, where they can register their user account. A user manual will be provided.
- Working hours: the full-time weekly working hours are 37.50 hours.
- You can download all documentation relating to regulations and employment matters via the 'Human Resources – Documents of Interest' section of your Fundanet account.
- Holiday and other leave requests: via the 'Human Resources – Request Leave' section of your Fundanet account.

Finally, INCLIVA provides research and management staff with a number of **meeting rooms** that can be booked via the Outlook calendar by creating an event in the relevant room. You can view the detailed room booking guide via this link. There are two types of rooms: moderated and unmoderated.
In moderated rooms, users create the meeting and a request is automatically sent, which must be accepted or rejected by the moderator. In non-moderated rooms, the booking is automatically recorded. To check room availability, simply consult that room's calendar in Outlook. The guide also explains how to add room calendars so that you can view them. These are the rooms available at INCLIVA and their types:

- 2nd Floor Meeting Room located in the Main Building (Moderated)
- Meeting Room on the 5th Floor of the Main Building (Moderated)
- Auditorium located in the Main Building (Moderated)
- Classroom located in the Technical Office (Moderated)
- Large Room B, located in the Technical Office (Unmoderated)
- Room C, located in the Technical Office (Unmoderated)
- Room D, located in the Technical Office (Unmoderated)

7. DATA PROTECTION IN RESEARCH PROJECTS AND CLINICAL TRIALS

The protection of personal data is a fundamental right and is the subject of particular attention when it comes to genetic, biometric or health-related data. Consequently, the processing of such data requires special security measures and express consent, except in the cases provided for under EU law.

Any processing of personal data, within the framework of a research project or clinical trial, must comply with the following requirements, in accordance with current legislation:

Informed consent must **be obtained from each participant, or another lawful basis must be established**, in order to **process the data**, to enable them to take part in the study or project, and to allow the research team access to medical records. Current legislation includes specific cases in which personal data may be used without the

relevant consent. For further information, please consult the Research Ethics Committee and the Data Protection Unit.

It must be possible to **demonstrate that each participant** in the study/project **has been informed** that their personal data will be used, the type of data to be processed, and their rights, including the right to object to its use in the study/project. This requirement is met by providing the project/study's Patient Information Sheet or by providing information via other media, which may vary depending on the characteristics of each project.

The review, collection, storage, disclosure, access, use or any other processing of personal data without the patient's express consent[1] and/or without having provided them with information about the project/study in which it will be used, directly contravenes the provisions of REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (GDPR) in Articles 6, 12, 13 and 14, as well as the provisions of Organic Law 3/2018 on the Protection of Personal Data and the Guarantee of Digital Rights.

If, as part of the research process, it becomes necessary to create a file (database or similar) containing any personal data relating to the patient, even if encrypted, this file must be managed as follows:

- Personal data must be used in an encrypted (or pseudonymised) form, ensuring that no personally identifiable data is present in the working files. It is prohibited to include first names, surnames, medical record numbers or SIP numbers in the research data file.
- Depending on the scope and/or sensitivity of the data being processed, the use of files and equipment with encryption methods should be considered.
- The file generated for the project must contain only the project data; no additional data must be included.
- Sufficient safeguards must be put in place to ensure the confidentiality, integrity, availability and resilience of the information in the file. To this end, the measures set out in Section 10, *'IT Security*', which are applicable to each specific case, must be implemented.

It is important to bear in mind that during a project or study verification or audit, the traceability of all actions carried out over time will always be verified. Actions such as signing a consent form or using a Patient Information Sheet (PIS) prior to its approval, or using data without consent or without having previously informed patients of this, are easily detectable and may call into question the integrity and/or legality of the data and, consequently, of the research carried out using them.

Should there be a need, as part of a research project, to share personal data with external entities, whether national or international, a preliminary analysis must be carried out before the project begins. This must be reported to the Quality and Data Protection Unit.

Should there be a need, as part of a research project, to engage a service provider who is expected to have direct or indirect contact with the personal data covered by the project, a review must be carried out prior to engaging them. This must be reported to the Quality and Data Protection Unit in order to receive guidance.

Authorisation for the use of data in a research project does not, under any circumstances, constitute authorisation for the data to be removed from the premises of the INCLIVA Health Research Institute, nor for its transfer to any person who is not a member of the research team.

[1] Or another duly identified legal basis that permits such processing.

The patient's signing of the consent form only authorises the use of the data for the specific project or study to which it relates. The carrying out of any other activity or the disclosure of such data falls outside the permitted legal framework.

8. BASIC IT SECURITY PRACTICES

INCLIVA has an Information Security Policy in place to ensure the protection, integrity and availability of the foundation's data. It can be viewed at:

https://www.incliva.es/wp-content/uploads/2025/05/org_1_-1_ENS_POL_001_Politica_de_Seguridad_de_la_Informacion_v1.pdf

Based on this policy, appropriate measures and controls are defined and implemented to prevent risks and ensure compliance with current regulations. Some of these measures are outlined below by way of summary:

- Corporate equipment and resources. Provided by the foundation to carry out the institutional duties associated with the post. This equipment is connected to the network and contains important, often sensitive, information; therefore, its use for non-work-related activities must be avoided. This equipment is protected by measures that guarantee the confidentiality and security of the data it contains. For this reason, it is not recommended to extract information from it or to work with other devices not belonging to the foundation, unless strictly necessary and explicitly authorised.
- Use of genuine software and system and antivirus updates. Only properly licensed software from secure sources must be used. It is vital to keep software up to date to prevent threats.
- Secure passwords. Passwords must not be easy to guess and must include capital letters, symbols and numbers. They must be changed frequently, particularly if there is any suspicion that they may have been compromised. It is much safer to use a password manager, such as KeePass for example, than to write them down on post-it notes in visible places or in notebooks. Where possible, two-factor authentication must be enabled *(something you know,* such as a password, and *something you have,* such as a certificate, a PIN sent by mobile phone or email).
- Backups. Ideally, backups should be made on at least two different media, and a designated person should be responsible for ensuring that important information is backed up, checking that the backups are viable, and that they are being stored correctly.
- Network/Cloud Folders vs USB Devices and the Importance of Encryption. The use of portable storage devices, such as USB sticks or USB drives, is strictly restricted due to the high risk of malware and data loss they pose. Should their use be unavoidable: (1) It must be authorised, and it must be possible to trace who has used them, for what purpose and when. (2) Any data stored on them must be protected by security measures such as full-disk encryption or, at the very least, password-protected compression.
- It is preferable to prioritise the use of secure servers by storing files in network-shared folders or corporate cloud storage, such as the OneDrive linked to your email account (the use of free services, such as personal *Google*, *Dropbox or WeTransfer* accounts, etc., is prohibited). It is also highly recommended to apply encryption measures to files shared via the cloud or email when the information they contain is deemed to require special protection.
- Use of corporate email. The use of personal email addresses for corporate communications is prohibited. Instead, one of the following email addresses must be used: (1) the Foundation's own

address @incliva.es; (2) the University of Valencia's address @uv.es; (3) the Carlos Simón Foundation's address @carlossimonfoundation.com / @fundacioncarlossimon.com; (4) the Valencian Regional Government's address @gva.es. When communicating with external parties, such as companies, they should preferably be asked to use their corporate email accounts.

- Protection against suspicious emails: particular care must be taken with external senders or recipients of emails when they use non-corporate accounts, especially free ones (Gmail, Hotmail, etc.), as threats often originate from such accounts. In the event of even the slightest suspicion, an attempt should be made to verify the person's identity by other means, such as a telephone call. Before opening attachments or clicking on links, the sender must be verified, taking particular care with files that appear harmless but may contain dual file extensions or hidden spaces. Do not forward suspicious emails so that their risk level can be assessed. Instead, send a photo or a screenshot to avoid inadvertently spreading threats.

  https://www.incliva.es/wp-content/uploads/2025/05/org_1_-1_ENS_POL_001_Politica_de_Seguridad_de_la_Informacion_v1.pdfhttps://www.incliva.es/wp-content/uploads/2025/05/org_1_-1_ENS_POL_001_Information_Security_Policy_v1.pdf

  For further information, additional documents are available on the ifundanet intranet (in the 'Documents of Interest' section) or by contacting the Technical Security Committee (ens@incliva.es).

9. OCCUPATIONAL RISK PREVENTION

All activities carried out at the Institute shall be conducted in such a way as to minimise any risks that may arise, taking the following aspects into account:

- The company regards the health and safety of its staff as one of its main objectives, on a par with productivity, service quality and profitability.
- Every effort will be made to reduce the likelihood of accidents and occupational illnesses, as well as to improve working conditions.
- The company intends to comply with current legislation on the prevention of workplace accidents and occupational illnesses and the improvement of working conditions.
- Anyone who has staff under their supervision is responsible for their health and safety at work and must therefore be familiar with and ensure compliance with all prevention rules relevant to the work carried out.
- The first step in prevention will always be to avoid risks and tackle them at source.
- Every effort will be made at all times to adapt the work to the individual.
- Every effort shall be made to minimise risks as far as possible. Collective protection shall always take precedence over individual protection, but the latter shall never be replaced. Employees and/or their representatives shall be duly informed and instructed on the current preventive rules and measures applicable to their work. With regard to working conditions relating to psychosocial aspects, the company's management shall take the necessary steps to contribute to the development of a positive psychosocial climate. With regard to working conditions relating to ergonomic aspects, the company, with specialist support from the Health and Safety Service, will implement measures aimed at analysing tasks, tools and working procedures at all times, with the aim of preventing accidents and work-related illnesses, whilst increasing the level of satisfaction and performance of contracted staff.

INCLIVA adopts a participatory prevention model, based on the right of staff to participate actively in all matters that may affect their health at work, so that the necessary actions can be taken to protect them. To this end, use will be made of the legally established representative channels and any others created for this purpose.

Staff recruited through INCLIVA receive, upon signing their contract, all information relating to the workplace risk assessment, the prevention policy, what to do in the event of an accident, and the institution's Emergency Plan (the latter depending on the location of their workplace), together with the names of the members of the emergency response teams.

Administrative and research staff carrying out their duties at the University of Valencia's facilities can access the Induction Manual on occupational risk prevention via the following link: https://www.uv.es/sgeneral/Reglamentacio/Doc/Pas/G17_sp.pdf
In the case of the Hospital Clínico Universitario de València, its Induction Manual can be consulted at: https://www.san.gva.es/documents/d/recursos-humans/manual-acogida-prl_cast-1

Research and administrative staff working at the Carlos Simón Foundation can access the Induction Manual via their "Employee Portal".

What should you do in the event of an accident if you are employed by INCLIVA?

The employee must report the incident to the Human Resources Unit and the Health and Safety Department. The Health and Safety Department will provide you with a medical certificate for a work-related accident so that you can receive treatment from the mutual insurance company. With this certificate, you must go to INCLIVA's mutual insurance company (Unión de Mutuas) located at C/ Artes Gráficas nº2. Once treatment has been provided, the mutual insurance company will issue the relevant certificate electronically (certificate of sick leave or certificate of no sick leave).

10. EQUALITY PLAN, LGTBI PLAN AND PREVENTION AND ACTION PLAN AGAINST HARASSMENT

INCLIVA has an Equality Plan for Women and Men in place, which sets out a series of fundamental principles based on values and commitments that enable us to achieve equality between women and men.
Furthermore, to ensure effective equality of rights for LGBTI people at INCLIVA, the Foundation has drawn up the First LGBTI Diversity Plan. This plan aims to establish a 'Zero Tolerance' policy towards discrimination and harassment, promote respectful working environments, raise awareness of rights and equal opportunities, and increase the visibility of LGBTI people. With the approval of this plan, INCLIVA declares its commitment to diversity. Furthermore, a Protocol for the prevention of and response to harassment on the grounds of sexual orientation, gender identity and/or gender expression has been drawn up with the aim of fostering a culture of prevention, demonstrating zero tolerance, facilitating the identification of harassing behaviour, establishing an accessible procedure for confidential complaints, investigating allegations internally in a swift and confidential manner, as well as taking action against the person responsible for the harassment and providing redress to the affected victim.

11. ETHICAL CODES AND POLICIES

INCLIVA Code of Ethics and Conduct

The Code sets out the principles and standards of conduct that must govern the actions of all those associated with the INCLIVA Health Research Institute, with the aim of ensuring ethical and responsible behaviour in the course of their work. It applies to the governing and management bodies and to all INCLIVA professionals, regardless of their position in the hierarchy, their functional role or their legal status.

Link: https://www.incliva.es/wp-content/uploads/2022/12/2022-Codigo-Etico-INCLIVA.pdf

Code of Good Scientific Practice

The Code of Good Research Practice (CBPI) sets out the ethical and quality criteria that must guide the research activities carried out by research staff within INCLIVA. This code is consistent with the principles of Responsible Research and Innovation (RRI) promulgated by the European Commission, which emphasise the importance of implementing measures that enable society – which is generally less familiar with science – to recognise and understand the usefulness of the resources managed by INCLIVA and the social benefits derived from the advances made through the research carried out. Furthermore, INCLIVA's CBPI takes the European Code of Conduct for Integrity in Research[2] as its benchmark, with the aim of serving as a tool for the self-regulation of research activity that takes into account the four key ethical principles: Reliability, Honesty, Respect and Responsibility.

If you require further information on this matter, please contact:icanigral@incliva.es

Link to the code: Intranet – INCLIVA – Institute for Health Research (under 'documents of interest to research staff and managers').

Whistleblowing Channel

This is a secure and confidential tool on the INCLIVA website, available to the entire INCLIVA community, through which concerns, suspicions or reports regarding actions that contravene the law can be submitted, as well as any information regarding behaviour that may pose a criminal risk or contravene the law.

Link: https://www.incliva.es/canal-de-denuncias/

[2] The European Code of Conduct for Research Integrity. ALLEA – All European Academies, Berlin 2018

12. APPROVAL AND ENTRY INTO FORCE

The review of this edition of the document has been coordinated by INCLIVA's Training Unit, with the participation of all the units referred to in its content. It was approved by the Governing Board of IIS INCLIVA on 9 June 2025 and ratified by the Board of Trustees of IIS INCLIVA on 17 June 2025.

This approval was granted within the framework of the powers conferred on each of these bodies, and in accordance with the procedures laid down in the organisation's internal regulations.