



**GROUP
INCORPORATION
AND
MONITORING
MANUAL**

Ref.: MA-GNR-08



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As a health research institute, IDIVAL carries out research and innovation activities aimed at improving the health of patients and society as a whole.

In accordance with international standards, the staff who carry out research tasks are organized into functional structures, known as research groups, which focus their activities on specific lines of research and necessarily work collaboratively.

IDIVAL carries out translational research that is designed to be applied and is nourished by continuous interaction between researchers and clinicians, with the Marqués de Valdecilla University Hospital at the epicenter of its activity.

1. WHO ARE WE?

The Marqués de Valdecilla Research Institute Foundation (IDIVAL) is a private foundation belonging to the public foundation sector. IDIVAL promotes and develops biomedical research and innovation in the biosanitary environment of Cantabria, with the Marqués de Valdecilla University Hospital as its epicenter. IDIVAL was created with the aim of seeking solutions to health problems and contributing to scientific, educational, social, and economic development.

In March 2015, IDIVAL was accredited by the Carlos III Health Institute (ISCIII) as a Health Research Institute.

Mission

To be a cutting-edge research center with a strong translational component that makes valuable innovations in the prevention, diagnosis, and personalized treatment of diseases available to society.

Vision

To act as the backbone of health research and innovation in Cantabria, promoting the economic development of the region and the creation of highly skilled jobs through collaboration with local agents, positioning itself as an international center of excellence in research in its priority areas.

Values

At IDIVAL, we are committed to the following values and want the people who work at this institution to consider them their own:

- Scientific excellence.
- Attracting talent.
- Transparency and proactive communication.
- Sustainability.
- Social responsibility.
- Specialization.

Headquarters

IDIVAL has its own facilities located in the Valdecilla hospital complex. This building has approximately 3,000 m² of research space dedicated to laboratories and general services. The ground floor houses the Technology Services, the first and second floors contain laboratories and offices for researchers, and the third floor is home to the Central Support Unit, the Testing Unit, and the CEIC.

The IDIVAL research groups are housed in the IDIVAL building, the Marqués de Valdecilla University Hospital, and the University of Cantabria.



Valdecilla Instituto de Investigación Sanitaria IDIVAL	
PLANTA 3	
301-	Administración y Gestión (I+D+I)
307-	Plan Nacional
316-	Ensayos Clínicos/CEIC
318-	Sala de Usos Múltiples
319-	Dirección Científica
320-	Dirección de Gestión
321-	Personal
PLANTA 2	
201-	Laboratorios
202-	Despachos
205-	Despachos
206-	Laboratorios
PLANTA 1	
106-	Laboratorios de Genética Molecular
107-	Coordinador Unidad de Genética
123-	Laboratorios
124-	Laboratorios
125-	Despachos
PLANTA 0	
003-	Biobanco - Nodo de ADN y Fluidos
009-	Coordinadora Servicios Tecnológicos
010-	Unidad de Microscopía Láser
011-	Despachos
019-	Unidad de Microscopía Electrónica
023-	Unidad de Citometría de Flujo / Laboratorio

Staff

In accordance with its statutes and its Organization and Operating Regulations, the staff of the IDIVAL Groups belong to the institutions that comprise them: IDIVAL itself, the Cantabria Public Health System, centered at the Marqués de Valdecilla University Hospital, and the University of Cantabria.

IDIVAL is a member of the Human Resources Strategy for Researchers (**HRS4R**), which seeks excellence in human resources management.

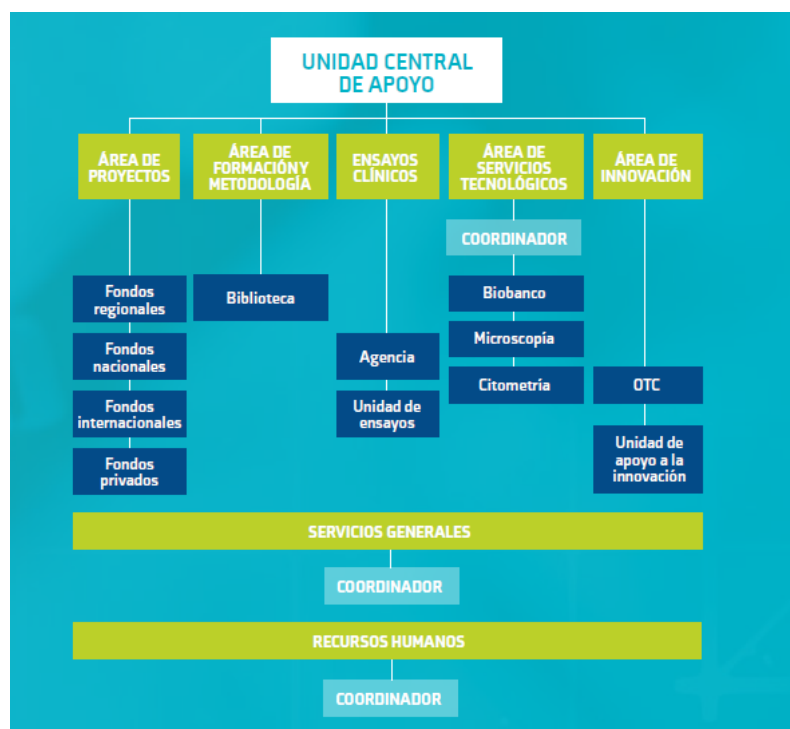


IDIVAL organizational chart

HR EXCELLENCE IN RESEARCH

IDIVAL has a governance structure defined in its statutes. The highest governing body is the Board of Trustees, whose president is the Regional Minister of Health and vice-president is the Rector of the University of Cantabria, who delegates some of his functions to the Delegate Commission. IDIVAL has two departments, a Management

Department and a Scientific Department, appointed by its Board of Trustees and headed by respectively the Central Support Unit and the Research Groups.



2. IDIVAL RESEARCH AREAS AND GROUPS

The IDIVAL Research Groups are the basic units of IDIVAL's research structure and are made up of staff from the Institute itself or attached to the Foundation who, regardless of the institution or entity to which they belong, have scientific affinity and carry out their activities under the direction, supervision, or parameters set by the group's Principal Investigator.

The group must be defined by its research topic and not necessarily by its healthcare or departmental affiliation. Groups must operate within an IDIVAL Research Area.

Research Areas are groupings of scientific activity that encompass a series of IDIVAL groups, which have been recognized on the basis of a strategic analysis.

1.1. Types of groups. IDIVAL Research Groups are classified as:

- Consolidated. Groups with their own stable scientific output, projects with stable competitive external funding for at least the last five years, and technical or research staff who work exclusively on research tasks.
- Emerging. Groups with recently established research activity that have been operating for less than three years. An IDIVAL group cannot be emerging for more than three years, as after this period it must be classified as either Associated or Consolidated following the corresponding evaluation by the External Scientific Council. Exceptionally, the External Council may maintain an Emerging Group in this status for a further two years after the three-year evaluation.
- Associate. Research groups with more than three years of experience that, in the opinion of the External Scientific Council, do not meet the criteria to be classified as a Consolidated Group.
- Cross-disciplinary. These will exist without the need for classification and without the need to fall within a specific area of research. Cross-disciplinary research groups are characterized by the fact that their research activity is considered fundamental for other groups and has a cross-disciplinary theme.
- Recently created. Groups that have been in existence for more than three years and therefore cannot be considered Emerging, but which are integrated into the Novo Institute without reaching the thresholds for Consolidated groups. An IDIVAL group cannot be Emerging for more than three years, as after this period it must be classified

as Associated or Consolidated following the corresponding evaluation by the External Scientific Council.

1.2. **Map of IDIVAL Groups.** The current structure of IDIVAL research areas and groups is shown in the attached chart.



Cáncer / Cancer	
Señalización celular y dianas terapéuticas en cáncer Cell Signaling and Therapeutic Targets	IP: José Luis Fernández Luna
Ciclo celular, células madre y cáncer Cell Cycle, Stem Cells and Cancer	IP: Alberto Gandarillas Solinis
Apoptosis Apoptosis	IP: Juan M. Hurlé González
Neoplasias hematológicas y trasplante de progenitores hematopoyéticos Hematological Neoplasms and Bone Marrow Transplantation	IP: Enrique M. Ocio San Miguel
Oncología médica Clinical Oncology	IP: Fernando Rivera Herrero
Melatonina y cáncer mamario Melatonin and Breast Cancer	IP: Samuel Cos Corral
Anatomía patológica y patología molecular Pathology and molecular pathology	IP: Javier Gómez Román
Hematopatología Traslacional: Translational Hematopathology	IP: Santiago Montes Moreno
Neurociencias / Neurosciences	
Enfermedades Neurodegenerativas Neurodegenerative Diseases	IP: Jon Infante Ceberio CO-IP: Eloy Rodríguez Rodríguez
Clinica y genética de las cefaleas Clinical and Genomics Research in Headache	IP: Julio Pascual Gómez
Biología Celular del Núcleo Nuclear Cell Biology	IP: Nazely Diban-Ibrahim Gómez
Investigación en enfermedades mentales Research in mental illness	IP: María Rosa Ayesa Arriola
Psiquiatría y Salud Mental Psychiatry and mental health	IP: Javier Vázquez Bourgon
Neurofisiología en epilepsia y neurointensivos Epilepsy Neurophysiology and Brain Intensive Care	IP: José Luis Fernández Torre

● Transversal / Transversal	
Epidemiología y Salud Pública Epidemiology and Public Health	IP: Trinidad Dierssen Sotos
Ingeniería Fotónica Photonic Engineering	IP: José Miguel López Higuera
Derecho Sanitario y Bioética Health Law and Bioethics	IP: Joaquín Cayón de las Cuevas
Economía de la Salud Health Economics and Health Services Management	IP: David Cantarero Prieto
Investigación en enfermería Nursing Research	IP: Carmen Sarabia Cobo
Salud Comunitaria Community Health	IP: Pedro Muñoz Cacho
● Patología de Sistemas / Systems Pathology	
Citocinas y factores de crecimiento en los fenómenos de plasticidad tisular patológica Cytokines, Growth Factors and Pathological Tissue Plasticity	IP: Juan Francisco Nistal Herrera
Enfermedades infecciosas y microbiología clínica Infectious Diseases and Clinical Microbiology	IP: M ^a del Carmen Fariñas Álvarez
Investigación clínica y traslacional en enfermedades digestivas Clinical and Translational Research in Digestive Diseases	IP: Javier Crespo Garcia
Investigación cardiovascular Cardiovascular Research	IP: José M ^a de la Torre Hernández CO-IP: José Antonio Vázquez De Prada Tiffe
Enfermedades esqueléticas, metabólicas y ambientales (IESQUEMA) Skeletal, metabolic and environmental diseases (IESQUEMA)*	IP: José Antonio Riancho Moral
Inmunopatología Immunopathology	IP: Marcos López Hoyos CO-IP: Ricardo Blanco Alonso
● Medios Diagnósticos y Terapéuticos / Diagnostic and Therapeutic Means	
Nanomedicina Nanomedicine	IP: Mónica López Fanarraga
Investigación e Innovación en cirugía Research and Innovation in Surgery	IP: Marcos Gómez Ruiz
Imagen Molecular Molecular Imaging	IP: M ^a Isabel Martínez Rodríguez
Diagnóstico y tratamiento por imagen Imaging Diagnosis and Therapeutics	IP: José Antonio Parra Blanco

3. IDIVAL GROUP STAFF

Membership of an IDIVAL group is independent of the nature of the link with the entity or institution of origin linked to IDIVAL.

The staff of the groups is normally composed of a manager, researchers, collaborators, nursing staff, residents, and technical staff. It may also have a co-manager or other categories deemed relevant.

2.1. Requirements for IDIVAL Group staff

Research group staff must meet the following requirements:

1. Be IDIVAL Foundation staff, or be assigned from other public or private institutions that make up the Institute.
2. Be integrated into an IDIVAL Research Group through a voluntary assignment process, except for IDIVAL staff researchers, who must be incorporated into a Group.
3. There must be a notification of incorporation by completing the specific form, which must be signed by the interested party and by the Group leader.

The incorporation or departure of group members must be communicated by the group leader to the Scientific Director of IDIVAL by updating the composition of the group in the annual Activity Report, or by specific communication at any time. In both cases, new members must complete the specific form (Annex I) endorsing their membership, signed by the head of the group and the member joining. This incorporation will be reviewed and validated, where appropriate, by the Scientific Director, who may request additional information in this regard.

2.2. Categories of IDIVAL Group personnel

The types of personnel in IDIVAL groups are as follows:

- **Principal Investigator.** The IDIVAL group leader is considered to be the member of the IDIVAL group who assumes the scientific direction of the group, as well as the liaison and mediation with the Area Coordinators and the Scientific Director of IDIVAL. He or she is responsible for ensuring compliance with the research commitments made by his or her group and for communicating IDIVAL's scientific guidelines to the members of the group he or she leads, as well as providing the information required by the Institute's Management at any time, particularly the group's annual report.

The Principal Investigators of the IDIVAL groups will be appointed by the Scientific Director, after evaluation by the relevant advisory bodies.

- **Co-Principal Investigator.** A Co-Principal Investigator is considered to be a member of an IDIVAL group who shares the scientific leadership of the group with the Principal Investigator in all their duties. IDIVAL considers the existence

of this figure to be particularly advisable in groups where the Principal Investigator is in the last five years of their professional career, in order to facilitate the handover of the duties of Principal Investigator.

The Co-Principal Investigators of IDIVAL groups will be appointed by the Scientific Director, after consulting the advisory bodies assigned this advisory function to the Board of Trustees.

- **IDIVAL Researcher.** An IDIVAL Researcher is considered to be a member of an IDIVAL group who has had a competitive national or international project in the last 5 years.
- **Collaborator.** Collaborating staff are considered to be all healthcare or teaching staff with higher education qualifications who do not hold the rank of researcher.
- **Group technicians.** Group technical staff are considered to be those who perform technical research tasks, other than healthcare and teaching, regardless of their qualifications and affiliation.

4. PROCEDURE FOR ACQUIRING IDIVAL GROUP STATUS

The process for acquiring this status will begin at the request of a researcher from a founding institution who assumes responsibility for the group, addressed to the Scientific Director, and will have the following requirements for access to the corresponding external evaluation:

1. It must be signed by the head or leader and the other members of the group, who will also recognize him or her as the head.
 2. The request must be made by completing a specific form that will be requested from the IDIVAL Management. The request shall include at least the following information on the research activity of the Research Group:
 - 2.1. Identification details of the Group Leader;
 - 2.2. The composition of the research groups, with the identification details of each of the members.
-

- 2.3. The most relevant scientific publications of the last five years, indicating their impact factor;
 - 2.4. Projects obtained through competitive calls for proposals in the last five years, specifying the principal investigator, the amount received, and the duration of the projects;
 - 2.5. Participation in research networks and consortia;
 - 2.6. Patents promoted;
 - 2.7. Participation in clinical practice guidelines;
 - 2.8. Brief description of the group's current research activity;
 - 2.9. Five-year development plan.
3. It must be endorsed by the head of the relevant institution in each case.
 4. The Scientific Directorate will conduct an initial evaluation, after which it may propose changes to the composition of potential groups based on strategic considerations and the achievement of a balanced approach to the Institute's various lines of research.
 5. The application must be reviewed by the Internal Scientific Council.
 6. The group will be evaluated by the External Scientific Council, which, in the event of a positive evaluation, will consider the group for one of the IDIVAL categories and areas.
 7. IDIVAL group status will be acquired upon acceptance as such by the IDIVAL Board of Trustees and will be communicated by the IDIVAL Scientific Directorate.

5. RIGHTS AND DUTIES

Membership of an IDIVAL group implies acceptance of the IDIVAL Regulations and the rights and obligations arising therefrom, as well as the guidelines established in the Strategic Plan. It also implies compliance with commonly accepted ethical principles and methodological criteria, as reflected in IDIVAL's Code of Quality, Ethics, and Good Scientific Practice, as well as respect and consideration for colleagues and the institution's management bodies.

The status of IDIVAL Research Group will allow the public use of this designation and access to its facilities, institutional and organizational support, and the IDIVAL promotion and support measures that are appropriate in each case.

The identification of the Research Groups and their members will be public and will be permanently updated on the website.

Research Groups must submit all projects presented to competitive calls for proposals under the National Plan and European calls for proposals, regardless of the Group's affiliation (University, Hospital, or the Institute itself).

All IDIVAL group staff will have access to the IDIVAL intranet and will be provided with IDIVAL corporate email upon request. IDIVAL staff must use IDIVAL corporate email for professional communication.

They must also follow the Institute's own regulations, the main documents of which are available on the website and intranet and are as follows:

1. Statutes
2. Organization and Operating Regulations
3. Regulations for Use of Facilities
4. Organization and Operating Rules for Technological Services
5. Emergency response protocol
6. Laboratory biosafety manual
7. Project management instructions
8. Expense reimbursement form
9. Guide to Quality, Ethics, and Good Scientific Practice in Research
10. Protocol for prevention and action against discriminatory harassment, moral harassment, sexual harassment, and harassment based on gender.

6. MONITORING OF IDIVAL GROUPS

6.1. Annual report

IDIVAL groups must submit the group's annual report at the beginning of each year, indicating the main milestones in the field of research for the year, changes in its composition, and changes in its lines of research. The submission methods will be those communicated each year (expected to be via the IDIVAL grant platform and using the existing forms). The submission of the annual report will be linked, budget permitting, to funding for each group based on its activity.

6.2. Periodic evaluation of the groups

Consolidated IDIVAL groups will be evaluated periodically on their scientific track record, ideally every five years. These evaluations may require a public presentation by the head of each group on its composition, lines of research, scientific output, applicability of results, and any other information deemed relevant by the Scientific Management and the External Scientific Council.

The required documentation shall be submitted to the Scientific Director for evaluation, who, once examined, shall forward it to the External Scientific Council. In the event of any document or information be , the group leader shall be required to provide it within a maximum period of one month.

Any group may request an evaluation by the External Scientific Council in order to confirm its status or modify its classification.

The evaluation may result in a change in the classification of the group if the Scientific Management and the External Scientific Council deem it appropriate.

Any Research Group may request an evaluation by the External Scientific Council in order to confirm its status or modify its rating.

6.3. Change of Group Leader

Changes in group leadership must be communicated at least six months before the effective date and will be submitted for evaluation by the External Council, which may

propose changes in the group's classification. The proposed new leader must submit an application to form a group as if it were a new group.

6.4. Group co-leader

Groups may have a co-leader at the proposal of the Group leader and the interested party. The distribution of Group coordination tasks will be agreed upon by the Group leader and the co-leader.

This position is recommended for all groups where the leader is expected to leave within two years.

6.5. Periodic evaluation of in-house researchers

IDIVAL's own research staff belonging to the IDIVAL Research Groups, i.e., those who have an employment relationship with IDIVAL, will be periodically evaluated in terms of their scientific performance. The External Scientific Council will participate in this evaluation and will mainly take the following aspects into consideration:

- Translational and collaborative nature of the lines of research.
- Active national and international projects with competitive funding, differentiating between those carried out as principal investigator and as collaborator.
- Published works, differentiating between national and international, with an impact factor in the first quartile, and as first or last author in the first quartile of impact.
- Membership of collaborative networks and written collaboration agreements, whether regional, national, or international, and those that involve funding and those that do not.

7. LOSS OF GROUP STATUS

IDIVAL Research Group status will be lost:

1. By written resignation of the group leader, supported by the signatures of at least 30% of the group members.

2. Due to loss of such status decided by the Board of Trustees at the proposal of the Scientific Director of IDIVAL and following a process ruled on by the External Scientific Council.

3. Due to non-renewal of IDIVAL Group status in periodic evaluations.

8. ORGANIZATIONAL STRUCTURE: GOVERNING BODIES, ADVISORS, AND AREA COORDINATORS

The governing bodies of IDIVAL are the Board of Trustees, the Executive Committee, the Scientific Director, and the Director of Management, and its advisory bodies are the Internal Scientific Council and the External Scientific Council. Their organization and functioning are defined in the statutes and in the Organization and Functioning Regulations.

8.1. Internal Scientific Council

In accordance with Article 38 of IDIVAL's Statutes, the Internal Scientific Council is an advisory body responsible for advising the Management in the performance of its duties. It is made up of a minimum of three researchers from the Foundation's Research Groups (), appointed by the IDIVAL Board of Trustees, at the proposal of the Scientific Director, who will act as its President, and who will hold the position in a personal capacity.

The composition of the Internal Scientific Council shall, whenever possible, represent the different Research Areas of the Institute, through the participation of their Coordinators. It may also be supported by a management technician, without voting rights.

The Internal Scientific Council may include members invited by the Scientific Director who have specific knowledge that is useful in the Council's advisory work.

- **Functions.** The Internal Scientific Council is an advisory body responsible for advising the Management in the performance of its functions. Under no circumstances does this body have any management or representation functions at IDIVAL. The Board of Trustees, its President, the Scientific Director, and the Management Director of the

Foundation may also request individual advice from the members of the Internal Scientific Council. The Internal Scientific Council has at least the following functions:

1. To advise and support IDIVAL's Management in the preparation of the Strategic Plan, the annual operational programs, and the Institute's annual activity reports. In this regard, the Internal Scientific Council will play a particularly important role in advising on the preparation, dissemination, and updating of at least the following plans: Scientific Plan, Training Plan, Integration Plan, Communication Plan, and Guardianship Plan for Emerging Groups.
2. To act as a two-way channel of communication, transmitting the needs raised by the heads of the Research Groups to the Management, and the various plans emanating from the Strategic Plan and the guidelines of the Institute's Management to the heads of the Research Groups.
3. Participate in the development and updating of the criteria for evaluating the scientific quality of the activity carried out by researchers and Research Groups and in the overall evaluation of the Institute's research activity and trajectory.
4. Collaborate in the development, updating, and dissemination of the Code of Quality, Ethics, and Good Scientific Practices, and in its updates, prior to its submission by the Scientific Director to the External Scientific Council, and ensure compliance with it.
5. Report on the incorporation of new IDIVAL researchers into the IDIVAL staff and new IDIVAL Research Groups as a preliminary step to their evaluation by the External Scientific Council.
6. Report on the allocation of IDIVAL's material resources to the Research Groups and, in particular, on the allocation of space in the IDIVAL building.
7. Evaluate the quality of projects or programs submitted to competitive calls for proposals that require it or are deemed appropriate by IDIVAL management, and advise on the evaluation for the recognition of beneficiaries of the promotion measures approved by IDIVAL.

8. Advise and inform the Institute's management in the review of complaints, conflicts, and situations of scientific malpractice.
9. Advise management on proposals to amend these Regulations.
10. Advise IDIVAL management on all matters it deems necessary.

8.2. Area Coordinators.

Each Area will be headed by a Coordinator appointed by the Scientific Director of IDIVAL for a maximum period of four years, renewable once, after consultation with the research group leaders responsible for each Research Area. The Area Coordinators will perform the following functions:

1. Coordinate the smooth running and ensure the scientific productivity of the Research Groups that make up the Area, within the general policy defined in the Strategic Plan.
2. Keep IDIVAL management permanently informed of the work of the area and the programs established, proposing the adoption of measures that may improve functioning and provide relevant information for the preparation of the Activity Report.
3. To convey to the group leaders of the area they coordinate information regarding the meetings of the Internal Scientific Council, the decisions of IDIVAL's management, and IDIVAL's organizational structure.
4. Represent the groups in the areas they coordinate before the Internal Scientific Council.
5. Advise the Scientific Management and the Management Department, especially on matters related to the functioning of the area they coordinate.