Organisational and Operating Regulations

RE-GNR-01

Valdecilla
Instituto de Investigación Sanitaria
IDIVAL

ORGANISATIONAL AND OPERATING REGULATIONS

Reference: RE-GNR-01

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	Created by	Revised by	Approved by
Head	Managing Director	Managing Director	Board
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Signature			

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0	Document approval	16/02/2011
1	Update based on new Institute activities and organisation. Update of the corporate image	27/05/2014
2	Modification of Article 2 regarding scope of action	19/09/2014
3	Update of the procedure for creating Groups, Research Areas, and appointing Group heads, joint Group heads and Area coordinators (under the Science Department). Establishment of substitutes for the Scientific Director and Managing Director if not appointed. Update to the definition of associated Research Group. Update of corporate image colours in the document	16/12/2016

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The Marqués de Valdecilla Research Institute (**IDIVAL**) is the successor entity of the Marqués de Valdecilla Training and Research Institute, thanks to the desire of the Government of Cantabria and the University of Cantabria to contribute decisively to fostering biomedical research at the Marqués de Valdecilla University Hospital.

As indicated in Article 1 of its Articles of Association, IDIVAL is a private non-profit foundation working in the founding public sector, whose assets have long been allocated to the Institution's work in the public interest.

IDIVAL follows the Healthcare Research Institute model developed in Royal Decree 339/2004, of 27 February, on accrediting such institutes. Their purpose is to conduct and harmoniously integrate basic, clinical and public health research, fostering translational research with better transfer of the scientific advances achieved in the prevention and treatment of the most common health problems in Spain. This is pursued in association with the University of Cantabria, with a focus on creating ties with public research bodies and other public or private research centres.

IDIVAL is internally regulated by these Regulations, which were approved by its Board, pursuant to Article 23n of its Articles of Association, as detailed below. These Regulations are public and will be permanently available on the IDIVAL website.

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CHAPTER 1. PURPOSE AND SCOPE

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Article 1. Purpose of the Regulations

The purpose of these Regulations is to govern the organisation and operation of IDIVAL, pursuant to the provisions of its Articles of Association.

Specifically, these Regulations include the purposes and principles of action, regulatory framework for its activity, organisational structure and operating guidelines, strictly subject to applicable legal provisions and to its Articles of Association.

In addition to regulating aspects related to its own resources, i.e. the IDIVAL Foundation, the IDIVAL Regulations consider the resources of its member entities insofar as they are available to IDIVAL, always considering that these resources will maintain the legal regime applicable in each case according to the entity they depend on.

These Regulations will be complemented by IDIVAL internal regulations regarding specific aspects of the Institute's operations, such as the IDIVAL Building Facility Regulation and the Technology Support Services Regulation, among others.

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Article 2. Scope

IDIVAL's scope of action is the Marqués de Valdecilla University Hospital. However, it may establish relationships with other regional, national and international bodies or institutions to comply with its purposes.

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CHAPTER 2. PRINCIPLES, PURPOSES AND AREAS OF ACTION

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Article 3. IDIVAL's Principles of Action

IDIVAL's basic principles of action will be as follows:

3.1 **Alignment with local needs.** IDIVAL seeks to benefit patients and society through its activity in translational research, innovation and knowledge transfer. This activity must be coordinated with the various local agents in terms of both research and management. IDIVAL will also promote the clear, accurate identification of the most relevant research lines for the Marqués de Valdecilla University Hospital. These research lines will be reflected in the promotional measures detailed in a strategic plan.

3.2 Scientific excellence. IDIVAL directs its efforts towards promoting and conducting clinical research and generating top-quality knowledge.

3.3 **Focus on international competitiveness.** An ongoing search for internationalisation requires being willing to collaborate and share internationally; this must lead to greater quality and visibility of the Institute's activity.

3.4 Sense of belonging to the institution. By promoting the capacities of its teams and rigorous work, IDIVAL seeks recognition for its activity and how the institution values its members.

3.5 **Focus on attracting talent.** IDIVAL is committed to talent as an essential means of continuously improving its activity. To develop and attract talent IDIVAL will foster activities that favour the national and international exchange of knowledge in order to achieve greater scientific and clinical relevance for the Marqués de Valdecilla University Hospital and the staff who work there.

3.6 Transparency and equality in personnel recruitment. By respecting researchers and their working conditions, and by requiring professional responsibility.

3.7 Focus on innovation and on social return on investment. IDIVAL's activity not only seeks to generate knowledge but, above all, to generate social wealth and benefits. This entails ongoing interaction with society, which must be informed of its activities.

3.8 Independent external assessment. IDIVAL will undergo independent external assessment as an essential part of the search for excellence.

3.9 Sustainability. IDIVAL seeks to make its activity sustainable from an economic and environmental perspective.

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Article 4. IDIVAL's Purposes

In line with Article 6 of its Articles of Association, IDIVAL has the following purposes and will implement the following activities to achieve them:

4.1. Purposes applicable to Healthcare Research Institutes. IDIVAL is founded to achieve the purposes established by the regulations on the accreditation of Healthcare Research Institutes:

a) Bringing basic, clinical and healthcare service research closer together.
b) Creating a high-quality healthcare, teaching and research environment for degree students, trainee specialists and healthcare professionals.
c) Becoming the ideal place for attracting talent and for the location of major scientific and technological facilities.

4.2. Actions to achieve its purposes. To achieve its purposes, the Foundation may, using its own or third-party resources, conduct any activities directly or indirectly geared towards this mission. These include:

a) Fostering excellent research projects in biomedicine and innovation, integrating them with medical assistance and technology transfer.

b) Promoting researchers' capture of resources from bodies that provide funding for national and international research, as well as from companies or sponsors, in order to meet the foundation's objectives.

c) Designing, conducting and managing research and innovation projects, units and centres, and allocating material resources, providing administrative support for professional selection and recruitment processes and the procurement of assets or equipment awarded to the Institute's projects.

d) Safeguarding the quality, ethics and deontological principles of research.

e) Developing research and innovation units for shared use by multiple research groups, acquiring the necessary equipment and recruiting researchers and/or technicians.

f) Developing and favouring the development of research training programmes, focusing particularly on scientific training for young researchers, training in research methodology, and needs in the field of primary care.

g) Fostering an excellent and innovative culture of healthcare research, facilitating relationships and collaboration between research professionals at regional, national and international level with lines and interests similar to those of the Institute, and promoting the participation of Foundation Research Groups in stable cooperative research structures and collaboration with the private sector.

h) Promoting the transfer of results:
   - To society and the healthcare system, transferring the knowledge generated by its activity to clinical practice.

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- To the scientific world, disseminating its activity through publications and the Institute's scientific reports.
- To the economic system, fostering innovation and the transfer of results.

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Article 5. IDIVAL's Areas of Action

IDIVAL will develop at least the following Areas of Action to achieve its purposes:

5.1. Central Research Support Unit IDIVAL will offer Marqués de Valdecilla University Hospital researchers and the University of Cantabria research groups assigned to it the services of its Central Research Support Unit, which will work on the following lines:

a) **Support in research management.** To optimise R&D management, IDIVAL will be responsible for the comprehensive management of the research projects of all the Institute's groups applied for via IDIVAL. This is regardless of the original association of the groups and whether the funding entity belongs to the Government of the Autonomous Region of Cantabria or whether it is a national or international, public or private entity. Comprehensive project management will include providing advice on administrative, legal, economic and technical aspects during the application, execution, justification and closure phases; acting as a liaison with other bodies and institutions; and formalising any related contracts or agreements.

b) **Support in innovation.** IDIVAL will have human and material resources to encourage a culture of innovation, and to protect research results and their transfer, in direct collaboration with the Carlos III Health Institute Itemas Network. It will also collaborate in the promotion and management of public-private cooperation in clinical research, development and technology innovation, and transfer of R&D results to healthcare activity and the productive sector. IDIVAL assumes the responsibility for offering researchers with the services of the Research Results Transfer Office (OTRI), which manages the identification, protection and use of knowledge arising from healthcare, research and training activities.

c) **Technology support.** IDIVAL will offer researchers support services including Technology Services and the Marquesa de Pelayo Library. In this regard, IDIVAL will manage the Marquesa de Pelayo Virtual Library at the regional level and in permanent collaboration with the Marqués de Valdecilla University Hospital, where the library is based.

d) **Training and methodological support.** IDIVAL will offer a permanent line of training and methodological support for research; this may fund specific training activities.

e) **Support for Clinical Trials.** IDIVAL will have resources to support the management and development of Clinical Trials.

   i. **Trial management.** Through the Clinical Trial Agency, IDIVAL assumes the status of exclusive cooperation agent at the Marqués de Valdecilla University Hospital, and supports the development of clinical trials and post-authorisation studies, taking on supervisory and control duties.

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Under the terms regulated by the State Government, the Government of Cantabria and the Ministry of Health, the Agency will provide support to a Research Ethics Committee accredited pursuant to Article 12 of Law 14/2007, while maintaining the current Clinical Research Ethics Committee under the terms of Additional Provision Three of that Law.

ii. **Clinical Trials.** IDIVAL will support the Clinical Trial Unit based at the Marqués de Valdecilla University Hospital and working under its Clinical Pharmacology Service. This Unit will support intervention studies on patients and healthy individuals, particularly trials of highly complex medication.

5.2. Fostering research. Each year IDIVAL will approve, if the budgetary context permits, a research promotion programme with lines to support training and recruit human resources, support for research and innovation projects, dissemination of results, and support for IDIVAL groups based on their activity.

5.3. Strategies to promote research activity in healthcare. IDIVAL will collaborate in the design of strategies to promote, recognise and integrate research in the care and teaching activities of the Marqués de Valdecilla University Hospital and the University of Cantabria.

5.4. Dissemination, record of activities and Activity Report. IDIVAL will have a line of action aimed at disseminating its actions and results to the Scientific Community and to Society. It will also facilitate access to data on scientific activity through its website and by IDIVAL Management preparing an Annual Activity Report, and it will participate in the preparation of statistics, assessments and monitoring the research activity of its research teams.

5.5. Assessment of scientific activity. IDIVAL will continuously assess its scientific activity, its translational results and their transfer, and it will collaborate in the development of scientific quality assessment criteria to be applied to its research teams.

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CHAPTER 3. IDIVAL's LEGAL FRAMEWORK

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Article 6. General Legal Framework of IDIVAL's Activity, Registered Address and Headquarters

6.1 **Legal framework.** IDIVAL is governed by its Articles of Association, by any rules and provisions established by the Board to interpret and develop them, and in any case by current legal provisions.

6.2 **Under its founding agents.** In compliance with Article 3 of its Articles of Association, as an instrument of its founding bodies, IDIVAL may receive commissions from the Government of the Autonomous Region of Cantabria and the University of Cantabria to implement any action related to its purposes. IDIVAL may not take part in any public procurement tender called by these entities, but if no bid is submitted, it may be assigned to provide the required services.

6.3 **Registered address.** Pursuant to Article 4 of its Articles of Association, IDIVAL's registered address is established in Santander, Edificio IDIVAL, Avenida de Cardenal Herrera s/n, 39011.

6.4 **Procurement.** Procurement of goods and services, building work and investments will follow the regulations applicable in each case, and the institution's procurement rules. In all cases, these procedures will identify the source of the procurement funding and its allocation to an in-house inventory, donation or transfer for use to another entity under relevant agreements.

6.5 **Personnel selection**. IDIVAL will select personnel in accordance with the principles of transparency, equality, merit and capacity.

6.6 **Financial and accounting system.** In compliance with Article 16 of its Articles of Association, this system will be governed by the following principles:

a) The financial year will coincide with the calendar year, from 1 January to 31 December. Exceptionally, the first year will comprise the period from the date of creation of the Foundation to 31 December following that date.

b) The Foundation will provide orderly, appropriate accounts of its activities so as to follow a chronological order of the operations carried out, according to applicable current regulations. This will require a Ledger, an Inventory Log and Annual Accounts.

c) In terms of economic and financial management, the Foundation will be governed according to the general principles and criteria set forth in current regulations.

d) Annual accounts will be drawn up according to current regulations, approved by the Foundation's Board within a maximum of six months from year end, and submitted to the Protectorate of Foundations within 10 working days following approval.

6.7 **Budget and Action Plan.** In compliance with Article 17 of its Articles of Association, IDIVAL will be governed by the following principles:

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a) The Foundation's budget will jointly and systematically include a provision of expenditure for the Foundation for the period in question, and the expected income to fund the Foundation's programmes, projects and other expenses.

b) The budget will comply with the provisions in the adaptation of the General Accounting Plan for non-profit entities, and to the budget reporting rules of these entities.

c) The Board will prepare and submit to the Protectorate, in the last three months of each year, a Plan of Action indicating its expected objectives and activities over the following year.

6.8. Ethical Principles and Confidentiality. IDIVAL research and support personnel will comply with the ethical principles of research, as well as respect and consideration for colleagues and IDIVAL management bodies.

They will also be subject to the obligation of maintaining activities secret if required, for which they will sign the relevant confidentiality commitments. In this regard, personnel from its governing bodies, the Central Research Support Unit and advisory bodies, and all personnel deemed pertinent by Management, will sign the relevant confidentiality agreements.

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Article 7. IDIVAL's Relational Framework with other Institutions

IDIVAL will maintain a relational framework according to its purposes, and always in accordance with the interests of its member institutions.

7.1. Relations with the Healthcare Administration of the Autonomous Region of Cantabria. IDIVAL will establish its relationship with the Healthcare Administration of the Autonomous Region of Cantabria in a specific agreement so as to enable the Institute to act as an R&D agent, especially in managing research funds and the transfer of R&D.

In any aspects of this agreement not updated, the Convention dated 16 February 2011 (Official Gazette of Cantabria no. 96, of 20 May 2011) and any addenda will apply to Healthcare Administration professionals.

For the purposes of this provision, the Healthcare Administration of the Autonomous Region of Cantabria is understood to comprise the Ministry of Health and the Cantabrian Health Service.

7.2. Relations with other institutions. IDIVAL will promote collaboration between its teams and other R&D Institutions and their professionals, from both the Cantabrian Health Service and at regional, national and international levels, processing the relevant legal documents to enable this collaboration. At the regional level, IDIVAL will develop suitable coordination channels with other R&D structures in the Autonomous Region of Cantabria, and especially with the Institute of Biomedicine and Biotechnology of Cantabria and its member entities, the University of Cantabria and the Spanish National Research Council.

7.3. Documentary support. The processing of legal documents will include any documents or information necessary to identify the Institution, accredit that the collaboration meets the principles and purposes of IDIVAL, and define the objectives of the collaboration.

7.4. Board approval. Defining IDIVAL's collaboration with other institutions by means of collaboration agreements must be approved by the IDIVAL Board according to point 23 of its Articles of Association, notwithstanding that the Board may delegate this duty to one of the IDIVAL Governing bodies.

7.5. Acceptance of relationships previously established by the Marqués de Valdecilla Foundation. IDIVAL accepts the continuity of the relationships established by the former IFIMAV Unit of the Marqués de Valdecilla Foundation, as well as the obligations and rights established provided they are not expressly interrupted.

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CHAPTER 4. IDIVAL'S ORGANISATION

SECTION 1. GENERAL DESCRIPTION

Article 8. IDIVAL's Governing Bodies and Structure

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Article 8. IDIVAL's Governing Bodies and Structure

The composition, duties and operating rules of Governing Bodies, management and structure are stated in the IDIVAL Articles of Association; they are public and will be kept updated on the website.

8.1. IDIVAL has the following joint and individual **governing bodies.** Their composition, duties and renewal mechanisms are stated in the Articles of Association:

8.1.1. Board.

8.1.2. Board Executive Committee.

8.1.3. Managing Director and Scientific Director.

8.2. IDIVAL has the following **advisory bodies.** Their composition, duties, and appointment and termination mechanisms are stated in the Articles of Association:

8.2.1. External Scientific Council.

8.2.2. Internal Scientific Council.

8.2.3. Business Council.

8.2.4. Other Committees.

8.3. IDIVAL may have other **external advisory bodies** with their own organisation rules, such as:

8.3.1. Clinical Research Ethics Committee.

8.3.2. Animal Experimentation Research Committee.

8.4 IDIVAL conducts its activity according to the following **hierarchical functional structure**:

8.4.1. Research Areas.

8.4.2. Research Groups.

8.4.3. IDIVAL Research Group personnel.

8.4.4. Committees.

8.4.5. Working Groups.

8.5. IDIVAL has a **Central Research Support Group** to support its researchers.

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SECTION 2. IDIVAL'S GOVERNING BODIES

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Article 9. Board

The framework regarding its composition, duties, powers and operating regime is stated in Chapter I, Section I of the IDIVAL Articles of Association.

As indicated in Article 19 of its Articles of Association, the Board is the Foundation's governing and representation body. It will exercise its duties subject to the provisions of the Law and its Articles of Association.

9.1. Composition. According to Article 20 of the Articles of Association, the IDIVAL Board comprises:

9.1.1 **Ex officio member** of the Foundation Board are the individuals holding the following positions:

a) Minister for Health of the Government of Cantabria, who will act as Chairperson.
b) Rector of the University of Cantabria.
c) Managing Director of the Cantabrian Health Service.
d) Vice Rector for Research and Knowledge Transfer at the University of Cantabria.
e) Managing Director of the Marqués de Valdecilla University Hospital.

9.1.2. The Board will also comprise the following nine elective members:

a) Two members appointed by the Minister for Health of the Government of Cantabria.
b) Two members appointed by the Rector of the University of Cantabria.
c) Three members appointed by the Managing Director of the Marqués de Valdecilla University Hospital.
d) Two researchers of renowned competence, appointed by agreement by the Minister for Health of the Government of Cantabria and the Rector of the University of Cantabria.

9.1.3. The composition of the board may increase due to the subsequent incorporation of new members, after amending the Articles of Association pursuant to legal provisions These appointments and replacements will be agreed by the Board.

Ex officio members will maintain their status while they hold the positions leading to their appointment. Elective members will hold their position for a period of three years, which may be extended for periods of the same term if agreed by the Board.

9.2. Duties of the Board. In accordance with Article 23 of the Articles of Association, in addition to those established in applicable state or regional legislation, the responsibilities and powers entrusted to the Board include but are not limited to:

a) Board governance and representation, and approving management plans and regular programmes of action.
b) Interpreting and implementing these Articles of Association and, where appropriate, agreeing to modify them whenever convenient for the interests of the Foundation and better achieving its purposes.
c) Appointing and terminating Executive Committee members
d) Appointing and terminating the Scientific Director and the Managing Director
e) Appointing and terminating External and Internal Scientific Council members, and establishing their composition and duties.
f) Appointing and terminating the Chairperson of the External Scientific Council.
g) Appointing and terminating the Board Secretary.

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h) Approving regulations on Business Council entity participation and collaboration, and agreements to be signed with entities joining the Council.
i) Establishing the economic and employment conditions of executives and other personnel, as well as approving calls for personnel selection processes.
j) Granting and withdrawing general and specific powers of attorney.
k) Approving budgets, credit transactions and annual account to be submitted to the Protectorate.
l) Drafting the action plan.
m) Deciding on the distribution of income, notwithstanding the provisions of current legislation.
n) Approving the Foundation's Internal Operating Regulation.
o) Approving the collaboration agreements signed with other public or private institutions.
p) Approving the transfer of the Foundation registered address.
q) Adopting resolutions on the termination or merger of the Foundation if it cannot comply with its purpose.
r) Any other powers set forth in these Articles of Association or in current legislation.

The Board may delegate its powers to one or more of its members, the Executive Committee or IDIVAL Directors. In any case, the following Board powers may not be delegated:

a) Approval of accounts and the Action Plan.
b) Modification of Articles of Association.
c) Merger and liquidation of the Foundation.
d) Disposal of assets amounting to over one million euros.
d) Actions that require authorisation from the Protectorate.

Article 10. Executive Committee

The Executive Committee acts as a Governing body by delegation from the Board, and is governed by Articles 32 and 33 of the IDIVAL Articles of Association.

10.1. Composition. The Board will appoint, from among its members, an Executive Committee formed by six Board members, who will be:

a) Managing Director of the Marqués de Valdecilla University Hospital, who will act as Chairperson.
b) Three representatives of the Healthcare Administration.
c) Two representatives of the University of Cantabria.

2. Board members appointed as members of the Executive Committee will carry out these duties for periods of three years, renewable for the same period.

3. The Secretary of the Board will be Secretary of the Executive Committee.

10.2. Duties. The Executive Committee will carry out the following duties pursuant to applicable legal regulations and to the provisions of the IDIVAL Articles of Association.

a) As entrusted by the Board, enforce resolutions adopted by that body.
b) Conduct regular follow-up on centre management duties.
c) Review the proposed agenda for Board meetings and review any documentation to be submitted.
d) Propose the adoption of resolutions to the Board.

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e) Follow-up agreements signed by the Foundation.
f) Facilitate Foundation management duties, especially regarding relations with the founding entities.

Article 11. Scientific Director

According to Article 34 of the Articles of Association, the Board will use the system of unrestricted designation to appoint the Scientific Director for a maximum initial period of four years; they may be renewed for subsequent periods of the same term.

The Scientific Director will be any specialist from the Marqués de Valdecilla University Hospital. Scientific Management and General Management may lie with the same person. In the event of illness, the Scientific Director will be replaced in their duties by the Managing Director.

11.1. Duties. According to Article 35 of the Articles of Association, the Scientific Director is responsible for planning and managing scientific policy and research plans: The duties of the Scientific Director are:

a) Acting as the maximum representative and spokesperson for the Foundation on scientific matters.
b) Managing, planning and leading the scientific policy of the Foundation.
c) Drafting the scientific plan of the Institute, and coordinating its implementation.
d) Ensuring the quality of research conducted at the Institute and that it follows ethical principles of conduct.
e) Fostering translational research and cooperation between Institute groups, and the transfer of research outcomes to the industrial and commercial fields.
f) Coordinating the scientific assessment of research lines, groups and projects.
g) Promoting the assessment of the Institute researcher's scientific activity in terms of excellence and translation.
h) Chairing the Internal Scientific Council.
i) Proposing the creation, modification or elimination of Institute research areas and groups.
j) Reporting on public and private calls for research projects and other activities related to research.
k) Coordinating relations with the External Scientific Council.
m) Any other duties expressly entrusted by the Board.

Article 11.2. Replacement system. Except in the case set forth in Article 34.3 of the Articles of Association, in the event of vacancy, absence or illness of the Scientific Director or Managing Director, they shall replace each other reciprocally.

The above provisions is excepting replacing the Managing Director regarding withdrawals from the Foundation's bank accounts, which will lie with the Management Coordinator.

Article 12. Managing Director

According to Article 34 of the Articles of Association, the Board will use the system of unrestricted designation to appoint the Managing Director for a maximum initial period of four years; they may be renewed for subsequent periods of the same term. Scientific Management and General Management may lie with

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the same person. In the event of illness, the Managing Director will be replaced in their duties by the Scientific Director.

12.1 Duties. As described in Article 36 of the IDIVAL Articles of Association, the Managing Director is responsible for:

a) Directing, organising, coordinating and conducting Institute activities, enforcing guidelines from the Board and the Executive Committee.
b) Managing the internal organisation of the Institute and its research infrastructure.
c) Proposing to the Board activities specified in the lines of research, their cost, planned sources of funding and the annual budget of the Foundation.
d) Coordinating actions designed to obtain the resources necessary to meet the objectives of the Foundation.
e) Informing and reporting to the Board on the Foundation's research activities and programmes.
f) Managing material and human resources to achieve maximum efficiency of research support resources.
g) Proposing services necessary for the Foundation to carry out its activities and duties.
h) Proposing internal operating regulations to the Board for approval.
i) Formalising collaboration agreements with public and private institutions for less than the maximum amount expressly established by the Board.
j) Acting as representative and spokesperson for the Board before institutions regarding management activities.
k) Drafting and preparing annual operating programmes and approving the Institute's annual research report.
l) Preparing the Foundation's annual accounts.
m) Proposing the Foundation's Action Plan and Budget.
n) Economic, budget, financial, asset and accounting management of the Foundation.
o) Acting as the Foundation's procurement body, notwithstanding the prior authorisations required according to the internal operating regulations that may be approved.
p) Any other duties expressly entrusted by the Board.

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SECTION 3. ADVISORY BODIES

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IDIVAL will have internal and external advisory bodies Internal advisory bodies are governed by the rules established by IDIVAL and will specifically advise the Institute. External advisory bodies have their own operating rules and provide advice according to current regulations and as required by IDIVAL.

The **internal advisory bodies** are the External Scientific Council and the Internal Scientific Council. Other internal committees may be created with specific objectives.

The external advisory bodies are the Clinical Research Ethics Committee of Cantabria and the University of Cantabria Bioethics Committee.

Article 13. External Scientific Council

According to the provisions of Article 37 of the IDIVAL Articles of Association, the External Scientific Council is an advisory body providing advice on the Foundation's scientific activities and ensuring scientific quality.

13.1. Composition. According to the provisions of Article 37 of the IDIVAL Articles of Association, this body will comprise at least three members freely appointed and withdrawn by the Board from relevant figures in the scope of action of the Foundation who have stood out for their professional and scientific career.

The Chairperson, Secretary and remaining members of the External Scientific Council will be freely appointed and withdrawn by the Board. Their appointment will last a maximum of four years, renewable for subsequent periods of the same term from relevant figures in the scope of action of the Foundation who have stood out for their professional and scientific career.

The External Scientific Council will act with independent criteria and scientific autonomy from IDIVAL.

13.2. Duties. The External Scientific Council is an advisory body and in no case does it assume Foundation management or representation duties. External Scientific Council duties include but are not limited to:

1. Issuing opinions at the request of the IDIVAL Board or Management.
2. Reviewing and reporting on annual reports and action plans.
3. Advising IDIVAL Management on the identification of priority Research Areas in the Cantabrian Health Service.
4. Assessment during the IDIVAL Research Group association process.
5. Assessing the career of the Institute's research personnel.
6. In general, all scientific advice the IDIVAL Board or Management deem necessary to comply with the purposes of IDIVAL regarding research and training in research.

13.3. Operating Regime. Based on the provisions of the Articles of Association, the External Scientific Council is governed by the rules established in Articles 29 and 30 regarding calls, debates and adopting resolution, as applicable due to its nature.

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Article 14. Internal Scientific Council

According to Article 38 of the IDIVAL Articles of Association, the Internal Scientific Council is an advisory body responsible for advising Management on the performance of its duties.

14.1. Composition. It is formed by at least three researchers from the Foundation's Research Groups, appointed by the IDIVAL Board at the proposal of the Scientific Director, who will act as Chairperson, and member positions are personal.

The composition of the Internal Scientific Council will represent, whenever possible, the Institute's different Research Areas with the participation of their Coordinators. It may also receive support from a management technician with no voting rights.

The Internal Scientific Council may have guest members invited by the Scientific Director with specific knowledge that is of use to the Council's advisory duties.

14.2. Duties. The Internal Scientific Council is an advisory body responsible for advising Management on the performance of its duties. In no case does this body assume IDIVAL management or representation duties. The Board, its Chairperson, the Scientific Director and Managing Director of the Foundation may also request individual advice from Internal Scientific Council members. Internal Scientific Council duties include at least:

1. Advising and supporting IDIVAL Management in drafting the Strategic Plan, annual operating programmes and annual activity reports of the Institute. In this regard, the Internal Scientific Council will have a particularly relevant role in providing advice for the preparation, dissemination and updating of at least the following plans: Scientific Plan, Training Plan, Integration Plan, Communication Plan and Tutoring Plan for Emerging Groups.

2. Being a two-way communication channel, conveying needs proposed by Research Group leaders to Management, and the different plans arising from the Strategic Plan and Institute Management guidelines to Research Group leaders.

3. Participating in the preparation and updating of criteria to assess the scientific quality of the activity carried out by researchers and Research Groups, and the overall assessment of the Institute's activity and research history.

4. Collaborating in the preparation, update and dissemination of the Quality, Ethics and Good Practice Codes, and in their updates, prior to the Scientific Director submitting them to the External Scientific Council, and ensuring their enforcement.

5. Reporting on the incorporation of new researchers to IDIVAL staff, and of new IDIVAL Research Groups prior to their assessment by the External Scientific Council.

6. Reporting on the assignment of IDIVAL material resources to Research Groups, and particularly the assignment of spaces in the IDIVAL building.

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7. Assessing the quality of projects and programmes submitted to competitive calls when required or deemed convenient by IDIVAL management, and advising on assessments for the recognition of beneficiaries of promotion measures approved by IDIVAL.

8. Advising and reporting to Institute management on reviewing claims, conflicts and cases of scientific malpractice.

9. Advising Management to propose modifications to these Regulations.

10. Advising IDIVAL management on all issues it deems necessary.

14.3. Operating Regime. The Internal Scientific Council is governed by the following operating rules:

1. The Internal Scientific Council will meet at least four times a year.

2. Meetings will be called by the Chairperson, their own initiative or when requested by a third of its members indicating, where appropriate, the issues to be included in the agenda in the call request addressed to the Chairperson.

3. The Internal Scientific Council may be supported by a technician with no voting rights acting as Secretary.

4. The Secretary will issue the relevant Minutes of Internal Scientific Council meetings, these must be signed and approved by all members present. They will be transcribed into the Minutes Log and signed by the Chairperson. The Minutes will include those present at the session, the agenda, details of the location and time the meeting is held, the literal text of resolutions adopted, and a summary of member interventions.

5. In the event of a conflict of interests or rights between the Foundation and any of its members, the affected parties will not take part in the decision that must be adopted by the Internal Scientific Council, which will be the competent body to determine, by simple majority of attendees, if this conflict exists or not.

Article 15. Other Internal Committees

IDIVAL may have other stable advisory structures comprising personnel for its member institutions acting on issues of specific interest to IDIVAL.

15.1. Composition. They will comprise teams of professionals agreed by the Board who, either because they are within the scope of IDIVAL organisation or management, by mandate or order of its own organisations, or voluntarily, are called to join the teams based on their technical knowledge and responsibilities.

15.2. Themes. The creation of internal committees, including but not limited to the following, will be considered with special attention:

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1. Business Council. According to Article 39 of the IDIVAL Articles of Association, the Board may create a Business Council, which will be the advisory body responsible for coordinating Foundation collaboration with the business sector. Its composition, duties and operating system will be determined by a Board resolution.

2. Infrastructure Committee. Committee to analyse the condition of existing research support infrastructure in our environment, which studies the use, future needs, possible improvements to efficiency and, particularly, coordination use of equipment in Cantabria dedicated to supporting biomedical research.

3. Training Committee. Committee which, in coordination with the University of Cantabria, collaborates in analysing research training needs, improvements to existing programmes, particularly seeking to train new researchers and fostering research in Primary Care and Nursing.

4. Innovation Committee. Centralised advisory committee on local innovation, especially with regard to aspects regarding development, industrial property, transfer, and public-private collaboration in the biohealth environment, in close collaboration with other innovation agents in Cantabria.

Article 16. External Advisory Bodies

IDIVAL may have other stable advisory structures basically comprising personnel external to its member institutions, regardless of whether nay IDIVAL member may participate in them, to provide advice on issues of specific interest to IDIVAL. Their composition and duties will be established by their current governing regulations.

16.1. Clinical Research Ethics Committee of Cantabria (CEIC-C). In accordance with Royal Decree 223/2004, of 6 February, regulating clinical trials with medication, the CEIC-C is an independent body, comprising healthcare professionals and non-healthcare members, responsible for protecting the rights, safety and welfare of subjects participating in a trial, and for offering a public guarantee on the trial, but issuing an opinion on the trial protocol, the suitability of researchers and adequacy of facilities, as well as the methods and documents that will be used to inform subjects of the trial so as to obtain informed consent. It also exercise the duties established by Law 14/2007, of 3 July on Biomedical Research, for Research Ethics Committees according to additional provision three of that Law.

The CEIC-C is governed by its own Action Regulation, available on the IDIVAL website. IDIVAL supports the Clinical Research Ethics Committee of Cantabria in terms of facilities, computer equipment and administrative personnel in compliance, by delegation from healthcare authorities, with Article 13 of Royal Decree 223/2004.

16.2. University of Cantabria Bioethics Committee. The US Bioethics Committee is responsible for issuing reports on projects and assessing activities that require experimenting with animals or the use of biological agents or genetically modified organisms. The Committee will ensure that the use of the latter entails no risk for personnel involved or the environment. It is also responsible for the duties of ensuring compliance with good practice related to the use of animals, and for drafting reports for the University's governing bodies on ethical and legal problems that may be caused by research and teaching.

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This Committee has a regulation which determines its duty primarily as an issuer of reports required by National Plan projects involving the use of experimental animals and/or biological agents and genetically modified bodies.

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SECTION 4. HIERARCHICAL FUNCTIONAL STRUCTURE

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Article 17. Personnel

17.1. In-house and associated personnel. In compliance with Article 14 of the Articles of Association, IDIVAL will have in-house Foundation research, technical and management personnel under an employment contract, and associated personnel from other public or private institutions by any system provided for in current regulations. The tasks carried out at the Institute by associated personnel will be considered, for all purposes, as the activity of their source entities.

17.2. Employment regime. Personnel will maintain the legal regime in each case applicable to the entity they belong to. Therefore, each contracting institution will effectively exercise employment powers over setting schedules, granting time off, holidays and leave, as well as inspection, management and disciplinary powers. Notwithstanding the above, in exercising these powers IDIVAL may seek the reasoned opinion of other institutions to adequately fulfil the duties of each service or unit where in-house personnel are working.

In-house Foundation personnel will have an employment contract according to the principles of equality, merit, capacity and publication.

Regardless of the institute they are associated with, all IDIVAL research and teaching personnel will have equal rights regarding subsidies, use of infrastructure, and management of and participation in IDIVAL projects and contracts.

17.3. Authorisation and communication. Assigning new IDIVAL personnel to the Cantabrian Health Service and the University of Cantabria, as well as any other centre or body decided in the future by the parties, must be approved by Management.

Recruitment proposals by Foundation research personnel who will conduct their research jointly or under the scientific management of individuals from the Cantabrian Health Service or the University of Cantabria in their spaces, must be communication by researchers to the relevant Department Directors or Department Heads for their approval and to ensure the physical and technical means are available for them. Forms will also be created to communicate this information to the respective Units responsible for personnel management.

Article 18. Research Areas

18.1. Research Area. A Research Area is a group of scientific activity which comprises a series of IDIVAL groups and which has been recognised according to a strategic analysis. The Board will be informed of any modification to IDIVAL Research Areas recognised according to recommendations by the External Scientific Council and the Scientific Director.

18.2. Modification of Areas. The IDIVAL research policy will be dynamic so as to enhance Research Area performance requirements to maintain their status, and it will open channels to create, modify or withdraw IDIVAL Research Areas under the advice of the Internal Scientific Council.

18.3. Area Coordinator. Each Area will be headed by a Coordinator appointed by the Scientific Director, after having consulted with the group leaders from each Research Area. Area Coordinators will perform the following duties:

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1. Coordinate the smooth operation and ensure the scientific productivity of the Area's Research Groups, within the general policy defined in the Strategic Plan.

2. Maintain IDIVAL Management permanently informed of the area's work and programmes established, proposing any measures that may improve operations and contribute relevant information for drafting the Activity Report.

3. Convey information on Internal Scientific Council meetings, IDIVAL Management decisions and the IDIVAL organisational structure to area group leaders.

4. Represent the area groups they coordinate before the Internal Scientific Council.

5. Advice Scientific Management and General Management, particularly on issues related to the operations of the area they coordinate.

18.4. Identification of Areas. The identity of Research Areas will be public, presented in the Activity Report and permanently updated on the IDIVAL website.

Article 19. IDIVAL's Research Groups

19.1. Definition. IDIVAL Research Groups are basic structure units of IDIVAL research comprising in-house Institute personnel or personnel associated with the Foundation who, regardless of the institution or entity they belong to, have a scientific connection or carry out their activity under the management, supervision or parameters set by the group's Head Researcher. The group must be defined by its research theme and not necessarily by its support or departmental association. Groups must work within an IDIVAL Research Area.

19.2. Group personnel requirements. Research Group personnel must comply with the following requirements:

1. Be in-house personnel -an employee of the IDIVAL Foundation- or associated personnel from other public or private institutions that are members of the Institute.
2. Voluntarily join an IDIVAL Research Group, except IDIVAL in-house personnel, who must belong to a Group.
3. Personnel joining or leaving a group must be notified in writing to the relevant group leader.

19.3. **Procedure for acquiring group status.** The process of acquiring this status will begin at the request of a researcher from a founding institution who takes on the role of group leader, addressed to the Scientific Director, and which must meet the following requirements to be subject to the relevant external assessment:

1. Be signed by the leader and other group members recognising them as the leader.
2. The application must be made using a specific form requested from IDIVAL Management. The application will include at least the following information on the Research Group's research activity:
    - Group Leader identification details;
    - Composition of the research groups, with the identification details of each member;

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- More relevant scientific publications in the last five years, indicating their impact factor;
- Projects obtained from competitive calls in the last five years, explaining the principal investigator, sum received and duration of the projects;
- Participation in research networks and consortia;
- Patents promoted;
- Participation in clinical practice guidelines;
- Brief description of the group's current research activity;
- Five-year plan.

3. The application must be endorsed by the head of the relevant source institution in each case.
4. Scientific Management will conduct an initial assessment after which it may propose to the groups potential variations in their composition based on strategic aspects; and on achieving a balanced approach to the Institute's different research lines.
5. The application must be notified by the Internal Scientific Council.
6. The group will be assessed by the External Scientific Council which, in the case of a positive assessment, will consider placing the group in one of the IDIVAL categories or areas.
7. IDIVAL group status will be acquired when accepted by Scientific Management and notified to the Board.

19.4. Types of groups. IDIVAL Research Groups are divided into:

1. **Consolidated**. Groups with their own stable, relevant scientific outcomes, projects with stable external competitive funding over at least the last five years, and with technical and research personnel working exclusively on research tasks.

2. **Emerging**. Recently created research groups that have been carrying out their activity 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 Associated or Consolidated following the relevant assessment by the External Scientific Council. The External Council may exceptionally maintain Emerging Group status for another two years following its 3-year assessment.

3. **Associated**. Research Groups with over three years' history which, in the opinion of the External Scientific Council, do not meet the thresholds to be classified in the Consolidated Group category.

4. **Cross-disciplinary.** Do not require classification and need not be included in a specific Research Area. Cross-disciplinary Research Groups are characterised by the fact that their research activity is considered basic for other groups and with a cross-disciplinary theme.

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5. **Newly created**. Groups with over three years' history such that they cannot be considered Emerging, but are new at the Institute without meeting 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 relevant assessment by the External Scientific Council.

19.5. Rights and duties. IDIVAL Research Group status means groups can publicly use this name and have access to facilities, institutional support and the organisation, and to the relevant IDIVAL promotion and support measurements in each case.

Research Groups must send all projects submitted to competitive National Plan calls and European calls, regardless of the Group's association (University, Hospital or the Institute itself).

19.6. Follow-up. IDIVAL groups will regularly be assessed in their scientific career, ideally every five years. These assessments may require a public presentation by the leader of each group on its composition, research lines, scientific outcomes, applicability of results and any information considered relevant by Scientific Management and the External Scientific Council.

The documentation required by the Scientific Director must be submitted for assessment and, once reviewed, it will be sent to the External Scientific Council. Should any document or information be missing, the group leader will be required to provide it within a maximum period of one month. Any group may request assessment by the External Scientific Council to confirm its status or change its classification.

Assessment may imply a change in the type of group if deemed appropriate by Scientific Management and the External Scientific Council.

Any Research Group may request assessment by the External Scientific Council to confirm its status or change its classification.

19.7. Loss of group status. IDIVAL Research Group status will be lost:

1. By written withdrawal by the group leader, endorsed by the signatures of at least 30% of the group members.
2. By loss of status decided by the Board at the proposal of the IDIVAL Scientific Director and following a process established by the External Scientific Council.
3. By non-renewal of IDIVAL Group status during regular assessments.

Article 20. IDIVAL's Research Group Members

20.1. Composition. Research Groups comprise personnel who, according to Article 14 of the Articles of Association, may be in-house or associated. IDIVAL group member status is regardless of the nature of the relationship with the source entity or institution associated with IDIVAL.

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Group personnel usually comprises a leader, researchers, collaborators, nursing staff, residents and technicians. They may also have a joint leader and other categories deemed appropriate.

20.2. Head Researcher. The IDIVAL group leader is the IDIVAL group member who takes on scientific management of the group, as well as acting as a liaison and mediator with IDIVAL Area Coordinators and the Scientific Director. The group leader must ensure compliance with the research commitments signed by their group, notify all group members of IDIVAL scientific guidelines, and provide the information required by Institute Management at any time, particularly the group's annual report.

IDIVAL group Head Researchers will be appointed by the Scientific Director after assessment by the relevant advisory bodies.

20.3. Joint Head Researcher. The Joint Head Researcher is the IDIVAL group member who shares all group scientific management responsibilities with the Head Researcher. This position is considered especially advisable by IDIVAL in groups in which the Head Researcher is in the last five years of their career so as to facilitate handover of head researcher responsibilities.

IDIVAL group Joint Head Researchers will be appointed by the Scientific Director after consulting the relevant advisory bodies assigned with this duty to advise the Board.

20.4. IDIVAL Researcher. An IDIVAL Researcher is an IDIVAL group member who has had a national or international competitive project in the last five years.

20.5. Collaborator. A collaborator is all support or teaching personnel with higher qualifications but who have not achieved researcher status.

20.6. Group technicians. Group technicians are those would carry out research technique duties, other than support or teaching duties, regardless of their qualifications and association.

20.7. Rights and duties of IDIVAL Research Group members. IDIVAL group member status implies acceptance of these Regulations and the rights and obligations arising from it, and of the lines established in the Strategic Plan. It also implies compliance with the commonly accepted ethical principles and methodological criteria detailed in the IDIVAL Quality, Ethics and Good Scientific Practice Code, as well as respect and consideration for colleagues and the institution's management bodies.

20.8. IDIVAL personnel appraisal. IDIVAL Research Group in-house research personnel, i.e., those with an employment relationship with IDIVAL, will be regularly appraised on aspects relating to their scientific performance. The External Scientific Council will participate in this appraisal and the following aspects will be considered:

a. Translational and collaborative nature of research lines.

b. Active national and international projects with competitive funding, differentiating between projects as a head researcher and a collaborator.

c. Work published, differentiating between national and international projects, with an impact factor in the fourth quartile, and as first or last author in the first impact quartile.

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e. Membership of collaboration networks and written collaboration agreements -whether regional, national or international-, and those requiring funding or not.

g. Transfer of research activity reflected in patents requested and active in which the member participates as inventor, and income from royalties.

20.9. Withdrawal from a group. Withdrawal from a Research Group may be voluntary or required. Members may withdraw freely at any time notwithstanding any restrictions set by the IDIVAL Scientific Director to integration in another group or provision of support tasks in research activity. Members may be required to withdraw by the Group Leader when agreed by the IDIVAL Scientific Director following a report from the Research Area coordinator and the Internal Scientific Council. An opinion may also be requested from the External Scientific Council when scientific questions are posed.

IDIVAL researchers who lose their status by being excluded from a group will maintain their employment or civil service status at their associated institution. However, when these researchers are IDIVAL in-house personnel they must be part of a Research Group and must join another Group within six months following their withdrawal from the Group, or they must submit a research line that can qualify them as a Group Leader in a Research Area according to the criteria of the External Scientific Council.

20.10. Incorporation and withdrawal of Research Group personnel. The incorporation or withdrawal of group members must be communicated by the group leader to the IDIVAL Scientific Director either by updating the group composition in the group's annual Activity Report, in which the new members must add a written endorsement, or by letter sent to the IDIVAL Scientific Director, signed by the leader and by the member joining or leaving the group. This inclusion will be reviewed and may be validated by the Scientific Director, who may require complementary information.

20.11. Information and dissemination. The website will include permanent, updated information on the composition of IDIVAL Research Group members with details of their qualifications, associated group, research area, scientific outcomes, projects funded and innovation actions in recent years, as well as the translational relevance of their activity.

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Chapter 5. CENTRAL RESEARCH SUPPORT UNIT

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The IDIVAL Central Research Support Unit comprises IDIVAL's common scientific personnel, infrastructure and equipment, both in-house and associated, that support and provide technical and methodological advice to Institute researchers, and to external researchers when requested. The Central Research Support Unit comprises the following six areas:

a. Project Management Area.

b. Training and Methodology Support Area.

c. Clinical Trial Area.

d. Technology Support Services Area.

e. Innovation Area.

f. General Services Area.

IDIVAL Management may define new areas in the Central Support Unit activity, divide any of the above Areas into functional units, or withdraw them following a positive report from the Executive Committee. These modifications will be subject to consideration by the Board for incorporation, where appropriate, into these Regulations. IDIVAL Management may also freely attribute responsibility for one or more areas by defining specific positions created by the Board to take responsibility for the area or part thereof.

Areas whose content is described in this document, or areas that are necessary at any time for the normal activity of IDIVAL, in terms of their personnel and infrastructure, may belong to any of the founding entities, in which case the appropriate use agreement will be formalised.

Article 21. Projects Area

22.1. Duties. The Projects Area is the functional unit which supports IDIVAL research management; its purpose is to organise the IDIVAL administrative services.

21.2. Area Resources. Services in this area must have specific technical training to ensure researchers have suitable access to national and international, public and private information related to research and sources of funding, they must also provide effective management of resources obtained for research projects and compliance with their control obligations. The area will be organised according to the internal operating management needs of IDIVAL and Research Groups, and proportionate to the workload supported.

21.3. Area Organisation. The Area may be organised in different Units**.** These Units may be increased, withdrawn or modified according to Institute needs. The current areas are:

a. National Fund Management Support Unit

b. Regional Fund Management Support Unit

c. Private Fund Management Support Unit

d. International Fund Management Support Unit

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Article 22. Technology Research Support Services Area

22.1. Duties. The aim of the Technology Research Support Services Area is to provide specific technical research support activities. Its technical and human resources are organised into teams under a functional leader. Technology support services may be IDIVAL Foundation in-house services or associated services.

To carry out its activity, the IDIVAL Technology Support Services Area has scientific and technical infrastructure to be used in research projects by both IDIVAL and external research groups. This area also management all activities necessary to ensure a proper supply of equipment, their control, maintenance and repair, and it manages the sale of technology services of each infrastructure considered.

22.2. Operating rules. IDIVAL Foundation in-house technology services will be subject to the specific IDIVAL operating rules established. If the source institution is not the Foundation, services will be subject to the rules of the source institution.

22.3. Technology Support Services. IDIVAL will have at least the following support services:

1. Biological sample biobank for biomedical research. This platform will manage biological sample collections used in biomedical research and obtained for hospitals; it will be responsible for ensure donor rights. The Biobank will be authorised by the relevant authority of the Autonomous Region, and it will operate according to current ethical and legal regulations related to the use of biological samples for biomedical research.

2. Laser and electronic microscopy platforms, which will have latest generation, high technology equipment operated by specialist technical personnel.

3. Cell flow and separation cytometry platform, which will have flow cytometers and equipment to separation cell populations for cell separation using other technologies operated by qualified technical personnel.

4. Genomic analysis services. These services may be in-house IDIVAL services or provided by the HUMV or other research groups, or contracted from external suppliers. They will be provided with latest generation technology and technical personnel trained in technical development and data analysis.

5.5. Neuroimaging Unit. This platform offers quantitative medical imaging services obtained by MRI using specific software, and it will have highly qualified personnel with experience in the area.

6. Other platforms. The Technology Support Services Area may have other service units based on the use of other in-house technical and scientific equipment, on the sale of services related to the know-how of Centre researchers or contracted externally.

22.4. Marquesa de Pelayo Library. The Marquesa de Pelayo Library is a functional unit that aims to provide healthcare professionals with online access to the most updated biohealth scientific and technical information for their healthcare, teaching or research activity at the Institute.

1. Head Librarian. The Marquesa del Pelayo Virtual Library will have a head librarian employed by IDIVAL, who will report to IDIVAL and Marqués de Valdecilla University Hospital Management and, where appropriate, to the Board.

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2. **Headquarters.** The Marquesa de Pelayo Virtual Library will be based at the Marqués de Valdecilla University Hospital, where the Library's historical collections are based. These collections are the heritage of the Cantabrian Health Service and electronic subscriptions used to support them will be coordinated from here.

3. **Operation.** The Marquesa de Pelayo Virtual Library operation will optimise its performance in terms of an appropriate selection of services and the effective control of their use. In any case, it must operate according to the needs of Cantabrian Health Service and Ministry of Health personnel. It will have the administrative and technical support personnel necessary to do this.

4. **Cooperation.** The Marquesa de Pelayo Virtual Library will seek cooperation and collaboration with other entities or institutions providing similar services in the interest of an efficient use of its resources, proposing the relevant documents to legally formalise this cooperation. In this regard, coordinated action with the University of Cantabria will be priority.

22.4. Technology Support Services Area Coordinator. The research Technology Support Services Area will have a general coordinator who will depend on Institute management, and will be proposed by IDIVAL Management and appointed by its Board. The Coordinator's duties are:

1. Drafting the annual technology services report.
2. Supervising human and material resources.
3. Preparing and updating the services portfolio and rates for their use.
4. Assessing Area need.
5. Preparing rules of use for subsequent validation.
6. Advising management on aspects related to these services.

22.5. Unit Head or Scientific Director. Each Technology Support Service Unit may have a head who will be proposed by IDIVAL Management and appointed by its Board. When they are IDIVAL Researchers, they may be authorised to use the title of Scientific Director of the Unit in question. These heads will assume the following general obligations to the Scientific Director:

1. Advise the Technology Support Services Coordinator and Management on aspects related to the service they coordinate.
2. Supervise the correct operation of the services they coordinate.
3. Collaborate in disseminating the services offered among IDIVAL researchers and external researchers.
4. Ensure the high scientific and technical quality of the service and its efficiency.
5. Collaborate in training technical personnel who support these services.

22.6. Operating rules. Technology Support Services will have their own operating rules based on a service approach, excellence and sustainability.

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22.7. New Technology Support Services. The Board may authorise the incorporation of new technology support services or close others at the proposal of IDIVAL Management.

22.8. Dissemination. IDIVAL will offer permanent, updated information on existing services on the website, in its report and, when deemed necessary, through training activities, specific dissemination activities and information leaflets.

Article 23. Training and Methodology Support in Research Area

23.1. Duties. The Training in Research Area is a functional unit that aims to facilitate training in research and provide consultancy in research methodology related to study design, analysis and communicating research results.

23.2. Scope of action. This area will carry out its actions according to the IDIVAL Training Plan and depending on the specific training needs of researchers, technicians and, especially, trainee researchers. In its activity it will give priority to supporting and training emerging groups, primary care researchers and nursing researchers.

23.3. Coordination with other structures. This area must make special efforts to coordinate with personnel from other structures dedicated to research training and methodological support activities in our environment so as to unify criteria, optimise resources, and achieve maximum synergy.

Article 24. Clinical Trial Area

24.1. Duties. The Clinical Trial Area is a functional unit that aims to facilitate and encourage Clinical Trial activity, and ensure that it adapts to general ethical requirements and specific requirements, if applicable.

24.2. Organisation. The Area has a Clinical Trial Agency and a Clinical Trial Unit.

24.3. Clinical Trial Agency. The Clinical Trial Agency will provide support services to design, organise, implement, monitor, justify and public clinical trial results. It will support Clinical Trial Unit management.

It will also support the Clinical Research Ethics Committee of Cantabria regarding facilities, computer equipment and administrative personnel to the extent that healthcare authorities delegate to IDIVAL compliance with Article 13 of RD 223/2004, of 6 February, regulating clinical trials with medication.

24.4. Clinical Trial Unit. The Clinical Trial Unit will have spaces and human resources at the HUMV to conduct clinical trials, especially highly complex trials, and it will be coordinated by the HUMV Clinical Pharmacology Service and based at the HUMV.

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Article 25. Innovation Area

25.1. Duties. The Innovation Area is a functional IDIVAL unit that, acting in conjunction with the Cantabrian Health Service, aims to facilitate and encourage a culture of innovation, foster dynamic relationships between the scientific community and the healthcare environment, companies and other socioeconomic agents to leverage R&D capacities and results of its activity, and to correctly manage innovation. Within these lines of action it will provide support for the identification, protection, funding and suitable use of research results. This includes incorporating these results in support, training and research processes, and obtaining financial profit.

25.2. Organisation. The Innovation Area will have an Innovation Unit and a Research Results Transfer Office.

25.3. Innovation Unit. The Innovation Unit will have the necessary legal and technical support teams to improve the development of technology innovation to ensure its solvency.

25.4. Research Results Transfer Office (OTRI). The OTRI will have resources to carry out its tasks, will be accredited and will operate pursuant to national regulations. The IDIVAL OTRI will be responsible for all industrial protection activities. These include managing brands, patents, royalties, intellectual property protection and the transfer of R&D results.

25.5. Itemas Network. The Innovation Area will work according to guidelines established by the Carlos III Health Institute Innovation in Healthcare and Medical Technologies Network, insofar as IDIVAL is part of that network.

Article 26. General Services Area

23.1. Duties. The Systems Area is a functional unit to support aspects related to accounting, contracting and information systems for the operation of the Central Research Support Unit and Research Groups.

23.2. Organisation. This area will have the in-house and outsourced resources necessary to comply with its duties, especially in aspects related to accounting, budget, taxation, and design, optimisation and maintenance of information systems.

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Chapter 6. IDIVAL SPACES

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Article 27. IDIVAL Spaces

27.1. IDIVAL Building Spaces. IDIVAL is based at the IDIVAL Building, on Avda. Cardenal Herrera Oria s/n, next to the "Residencia Cantabria" building, and within the Marqués de Valdecilla University Hospital complex. Its facilities have two types of spaces: laboratory spaces and the Central Research Support Unit.

a. Laboratories: Essentially found on the first and second floors of the building. IDIVAL Research Group personnel are based there. They have laboratory spaces, offices and common areas (meeting rooms, cultivation rooms, cold rooms, storage, washrooms, etc.).

b. Central Research Support Unit. Its spaces include:

- **Technology Support Services spaces.** Essentially found on the ground floor of the building.
- **Administrative personnel spaces.** Essentially found on the third floor of the building.

27.2. Other spaces. IDIVAL has spaces for its member institutions, which are part of the Institute if they have been considered as such by the Board.

Article 28. Distribution and Use of Laboratory Spaces

28.1. Space assignment. Spaces are assigned to Research Groups by the Scientific Director according to the criteria and guidelines set by the Internal Scientific Council. The External Scientific Council will be informed of the distribution of these spaces.

28.2. Assignment criteria. The following types of spaces will be considered for distribution: Laboratory, Common Areas and Offices. Different aspects of the applicant group will be taken into account for assigning Laboratory spaces, these are essentially:

a. Technical personnel assigned to the laboratory. Current number and short-term forecast of individuals.

b. Equipment to be stored in the laboratory.

c. Main laboratory techniques to be developed in relation to:

- Research with pathogens that require specific conditions (e.g., biosafety rooms).
- Special facility requirements: dark rooms, special electrical installations, gas installations, etc.
- Techniques developed that entail a specific risk for personnel or environmental contamination, and which require specific waste collection systems (radioactivity, risk pathogens, chemical waste, etc.).

a. Group scientific outcomes.

b. Research spaces already used by the group to avoid duplicating spaces.

e. Building common areas are, by definition, shared.

28.3. Review of space assignment. A space is provisionally awarded to the group and reviewed every three years. It may be reviewed sooner if requested by the group or according to the criteria of Scientific Management.

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28.4. Use of facilities. IDIVAL research personnel will respect the rules of use of facilities indicated in the respective internal regulations.

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CHAPTER 7. MANAGING KNOWLEDGE.

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Article 29. Intellectual and Industrial Property

The general framework of ownership, management and exploitation of intellectual and industrial property rights mentioned in Article 15 of the Articles of Association will be as follows.

29.1. Scope of application. This article regulates the management and ownership procedure of research results developed by personnel working for IDIVAL in research, management and/or support.

In terms of industrial and intellectual property rights, any knowledge, information, material, invention and other research results are subject to these Regulations, whether they may be exploited or marketed or not, which have been created and/or developed by personnel working for IDIVAL in their duties or using IDIVAL resources.

Based on existing agreements, these Regulations apply to the intellectual and industrial property of the Cantabrian Health Service.

These Regulations cover, but are not limited to: inventions that may be patented or registered as utility models according to Law 11/1986, of 20 March, on Patents and/or any implementing regulation or equivalent regulation replacing it in the future; designs subject to protection as industrial designs, drawings or models according to Law 20/2003, of 7 July, on the Legal Protection of Industrial Design or according to EU Regulation 6/2002 on Community designs or models; plant varieties subject to the protection of Law 3/2000, of 7 January, on the Protection of Plant Varieties; computer programmes as indicated in Royal Legislative Decree 1/1996, of 12 April, approving the Consolidated Text of the Intellectual Property Act; the topography of semiconductor products according to Law 11/1998, of 3 May; industrial secret regulations; international treaties and conventions ratified by Spain on Industrial and Intellectual Property, and applicable EU regulations. These Regulations will also apply to results that may lead to intellectual property deeds related to the creation of computer programmes and databases.

29.1.1 Personnel working for IDIVAL are:

- Research, management and support personnel contracted by IDIVAL.
- Interns from IDIVAL calls.
- Students participating in training programmes called by IDIVAL, whether paid or not.
- University students who, with no grant and who are not registered in IDIVAL training programmes, are on training placements directed by IDIVAL or Cantabrian Health Service personnel authorised by their respective universities.

29.1.2 For this purpose, these Regulations will apply to the activities personnel takes part in on behalf of IDIVAL throughout their working, function, training or service relationship. However, inventions for which registration applications are submitted within the year following termination of the employment, administrative or service relationship with IDIVAL may be claimed by IDIVAL. In this sense, the provisions of Articles 17 and 19 of Law 11/86 on Patents are applicable.

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29.1.3. The researcher or researchers must notify the OTRI, prior to any disclosure, of any research results that may be subject to industrial or intellectual property protection according to applicable legal provisions. This notification must be sent by any means providing proof of delivery and must contain all necessary documentation and information for the correct identification and assessment of the result. All researchers must cooperate with the OTRI in any action initiated related to the protection and defence of appropriate protection of industrial property.

29.2. Ownership of and rights to research results. Ownership of the research results indicated in the above article belongs to IDIVAL when the results come from personnel working for IDIVAL and, to the Cantabrian Health Service when the results come from personnel working for it.

In any case, and based on agreements signed by IDIVAL and the Cantabrian Health Service, IDIVAL, through its Research Results Transfer Office (OTRI), has exclusive responsibility for processing industrial and intellectual property rights arising from the activity of the Cantabrian Health Service, and for managing transfer procedures for knowledge results; its activity covers the identification, protection, management, maintenance and exploitation of these results.

When, under the terms of the above article, individuals or institutions, whether public or private and external to IDIVAL and the Cantabrian Health Service, have participated in achieving the result, they will only hold the part of the rights relevant to the percentage of participation of their personnel in the research activity. This will generate a situation of joint ownership which must be governed by the provisions of the relevant agreement.

When research results come from collaboration with public or private entities or individuals external to IDIVAL or the Cantabrian Health Service, formalised in agreements or public calls, a joint ownership agreement must be signed between IDIVAL and the participating bodies. This agreement must define, at least, the ownership percentage of each institution, the entity that will manage the protection of results, and the terms of any applicable international extension.

When the R&D activity arises from agreements signed with companies or other types of entities, the relevant agreement must indicate ownership of the results obtained; unless otherwise agreed, ownership will be understood to lie exclusively with IDIVAL or the Cantabrian Health Service. Should the agreement with the company contemplate partial or full transfer of the results or a licence for their use, this agreement, unless expressly agreed otherwise, will never include the transfer or licence for knowledge or rights previously owned by IDIVAL or the Cantabrian Health Service. In the case of the exclusive transfer or licence of results to the company, IDIVAL and Cantabrian Health Service personnel will always be entitled to use the results in subsequent research and R&D work. Any agreement to the contrary will be void.

In R&D work order agreements, unless the specific agreement signed contains a provision to the contrary, IDIVAL and the Cantabrian Health Service offer no legal guarantees on the use of these results on the market, nor on the suitability of their application for the specific business purposes of the contracting company.

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However, the inviolable right of any researcher who appreciably participated in obtaining the result to be mentioned as such on the relevant industrial or intellectual property deed is recognised. For this purpose, appreciable participation is when the researcher is deemed to provide an intellectual, inventive or creative contribution to the end result.

Therefore, IDIVAL may publish, disseminate, transform, use or protect these results with industrial property deeds or, regarding computer programmes, intellectual property deeds, or it may keep them secret.

In the specific case of intellectual property rights for computer programmes and databases, regardless of the type of protection adopted, the work will indicate the following:

"*Copyright © <year> IDIVAL. All rights reserved.*", in the case of results arising from personnel working for IDIVAL.

"*Copyright © <year> SCS. All rights reserved.*" , in the case of results arising from personnel working for the Cantabrian Health Service.

29.2.1 Notwithstanding the provisions of the above section, a researcher will be entitled to participate in the profit obtained by IDIVAL from the exploitation or transfer of its rights to the results mentioned above.

These profits, having deducted the protection and management expenses incurred, will be distributed according to the following percentages:

I. 50% for IDIVAL, use to fund its budget

II. 40% for the inventor or inventors (or author or authors, as applicable) understanding that, unless agreed otherwise in writing and signed and notified to IDIVAL management, it will be distributed equally among them. An author or inventor is the individual who provides an appreciable intellectual, inventive or creative contribution to the end result.

III. 10% to be distributed among the IDIVAL Research Group or Groups the inventors or authors are associated with. If the inventor or author is not associated with any Research Group, their stake will be assigned to the Service they belong to.

29.2.2 IDIVAL may licence research results to their inventors or authors and/or to the technology company they created in the following cases:

- IDIVAL is not interested in protection or exploiting a specific research result.
- IDIVAL decides to abandon the registration application in a specific country or territory. In this case, the licence will be for the country where protection is abandoned, notwithstanding any funding agreement by researchers in existing protection procedures so that they may remain ongoing.

In the cases indicated in this article, IDIVAL will maintain a non-exclusive, indefinite, non-transferable and free right to use the research result. Furthermore, when profits are obtained from the exploitation of rights obtained from these research results, IDIVAL will be entitled to a 20% stake in the net exploitation profits.

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29.2.3 Notwithstanding the provisions of the above article, IDIVAL may agree that the licence is transferred free or for a charge regarding both the deed granted and its application.

Article 30. Research Results Transfer Management

30.1. Research Results Transfer Office (OTRI). The OTRI will be responsible for the operative management of aspects related to IDIVAL industrial and intellectual property and will act according to the internal procedure established. The OTRI will liaise with the researcher, analyse the patentability, registration and follow-up of information, evaluation and transfer, and liaise with other OTRIs from other institutions. It may have external support for its actions whenever necessary.

30.2. Exploitation of results. In the exploitation process, IDIVAL will initiate any legal procedures and agreements with third parties necessary to ensure the return of biohealth R&D to the Health Service, and a stake in profits for professionals, using the most suitable formula, whether this entails negotiating temporary patent licences, development and marketing agreements with companies, joint ventures or spin-offs, protecting ownership, in any case, with the necessary mechanisms.

30.3 Agreements. Regarding non-commercial transfer of knowledge, IDIVAL will be responsible for drafting the Confidentiality Agreements, Scientific and Technical Cooperation Agreements and Biological Material Transfer Agreements required in R&D projects conducted under the scope of the Cantabrian Health Service.

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