Technical guide for the evaluation of the accreditation of biomedical or health research institutes

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MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES
Instituto de Salud Carlos III
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Publication included in the publishing programme of the Ministry of Science, Innovation and Universities.
General Catalogue of Official Publications:
https://cpage.mpr.gob.es/

To obtain this report free on the Internet: https://hdl.handle.net/20.500.12105/26957

Published by: Institute of Health Carlos III
Ministry of Science, Innovation and Universities
NIPO pdf: 156250237
Design and layout: Editorial MIC

The Ministry of Science, Innovation, and Universities (hereinafter MICIU) approves the Technical Guide for Evaluation (hereinafter GTE) as the reference document in the process of obtaining, maintaining, and renewing the accreditation of a Health Research Institute. This guide is binding for the procedures set out in Royal Decree (RD) 279/2016 on the accreditation of biomedical or health research institutes, in accordance with the provisions of Article 12.

The first GTE was approved on February 7, 2007. On April 19, 2019, by ministerial resolution, the GTE IIS 2019 was approved, valid for the period of 2019-2024 until the approval by ministerial order of January 30, 2025, of the current GTE IIS 2025.

The GTE is the result of a dynamic, transparent, and participatory process in its design and periodic review, with contributions from all IIS. This approach seeks to address emerging needs and challenges in health research, adapting to structural, methodological, and technological changes that arise during its implementation.

Its updating is based on both the analysis of annual results and the evolution of the science ecosystem. In the first case, the temporal evolution of results analyzed in meetings with each IIS, together with the reflections of the IIS Auditors Commission and the considerations and decisions of the IIS Evaluation Commission, allow for the refinement of criteria and modification of metrics for greater validity, avoiding unjustified administrative burdens.

In turn, the impact-oriented strategies incorporated, both by the European Commission and in Spain by Law 17/2022, of September 5, amending Law 14/2011, of June 1, on Science, Technology, and Innovation, the 2021-2027 State Strategy for Science, Technology, and Innovation (EECTI) developed in the 2021-2023 and 2024-2027 State Plan for Scientific, Technical, and Innovation Research (PEICTI), and the 2023-2027 National Open Science Strategy, require adjustments to the evaluation criteria to align the GTE with these priorities. Among other aspects, open science, citizen participation throughout the scientific cycle, review of the evaluation incorporating impact metrics in clinical practice, or the implementation of standards in human resources management in R&D&I included in the HRS4R Seal.

The 2025 GTE of IIS represents an evolution from its 2019 predecessor, delving deeper into the evaluation of the effective transfer of the knowledge generated to promote innovation, both in healthcare and in the production sector. The approach of the 2025 GTE IIS therefore represents both an opportunity and a challenge, in response to which the necessary cooperation and follow-up between the IIS and the ISCIII is reinforced in order to maintain its character as a tool aimed at the evolution and continuous improvement of R&D&I in health.

Criteria and Indicators for the Evaluation of IIS

This document develops the criteria and sub-criteria for each of the three dimensions of the technical guide for the evaluation of IIS.

The comments section includes methodological considerations of interest for the evaluation of each criterion. This section indicates the correspondence with the provisions of RD 279/2016 in bold print.

All criteria are considered mandatory, with the exception of those criteria that are mandatory for applicants to the accreditation procedure 2.2.1.3, 2.2.1.4, and 2.2.5.1., or those that are mandatory only for applicants to the re-accreditation procedure 2.2.1.4 and 2.2.6.2. The quantitative criteria include, in addition to the standard of compliance, the thresholds proposed for establishing a level of excellence.

Due to the entry into force in January 2025 of the new Technical Guide for the Evaluation of Health Research Institutes, interested parties are hereby informed that, in accordance with Royal Decree 279/2016, all IIS applying for accreditation or re-accreditation from that date, as applicable, shall be subject to the criteria established in the new guide.

In order to establish a period that allows already accredited IIS to adapt to these new criteria, it is envisaged that those accredited IIS that have applied for, or are in the process of applying for, accreditation renewal during the 2025 fiscal year, and in which non-compliance with some of the requirements set out in the GTE 2025 is identified during their audit, will be re-evaluated within a period of not less than 24 months. Once this period has ended, a new audit will be carried out in accordance with these new criteria, without the accredited status being lost during this transitional period.

The RRI label is incorporated into those criteria that expressly address aspects related to any of the six principles of Responsible Research and Innovation: Ethics, gender equality, responsible governance, open access, science education, and society participation.

1. GOVERNANCE		
1.1 Establishment of the IIS		
1.1.1 Legal relationship		
No./Code	**Quality criterion**	**Comments**
Verification: Current legal relationship establishing the IIS and attached documentation.		
1.1.1.1	The current legal relationship defines: a. Scope. b. Functions. c. Capability of the IIS to carry out its activity. d. Full decision-making capability. e. What the mechanism for following up on the agreement will be. f. Procedure for institutions to join and, if applicable, leave the IIS.	All aspects mentioned in criteria a) to f) must be included. Evaluated period: Five years prior to the application. RD: Article 4 a)
1.1.1.2	The legal relationship in force at the time of the audit is unique, incorporates all the institutions that make up the IIS, and includes the commitments undertaken by each and every one of them. Indicating the contributions made by each party, as well as their updates/approval if their scope requires it in terms of: • Structure. • Infrastructures. • Staff. • Financials. Any others that may be considered.	The current agreement for the creation of the IIS must be unique and must include all the institutions that are part of it. It is essential that it specifies the contributions made by each of the members of the IIS. The provisions of the RD must be complied with. Evaluated period: Five years prior to the application RD: Article 4 a)
1.1.1.3	The current legal relationship specifies that the core of the IIS is a National Health System (SNS) teaching hospital and the corresponding primary care setting. If there are several hospitals or healthcare entities incorporated into the IIS, the agreement will establish which of them is the core of the IIS. In exceptional cases, two hospitals may be recognized as the core of the IIS.	Verify that the core hospital of the IIS is specified in the legal contractual agreement. Accreditation renewal: Exceptionally, this criterion is considered to be met in cases where, since their accreditation, IIS have had two hospitals as their core and both hospitals are accredited as having made an equivalent contribution to the IIS's scientific programs and results achieved. Evaluated period: Five years prior to the application. RD: Article 3.2.
1.1.1.4	The group of healthcare centers that make up the IIS has proven research and teaching capacity over a period of no less than three years in the case of new accreditation or five years in the case of accreditation renewal.	Verify with reports on healthcare, teaching, and research from the healthcare centers to assess their teaching and research capacity. Evaluated period: Accreditation application: Three years prior to the application. Accreditation renewal application: Five years prior to the application. RD: Articles 3.1 and 3.2.
1.1.1.5	The current relationship includes the list of groups and the conditions for their affiliation to the IIS. These conditions have been validated by the External Scientific Committee (CCE). The list of IIS groups is kept up to date.	The relationship describes the groups from each institution that are incorporated into the IIS in its constitution. Once the IIS has been established, group affiliation conditions are approved by the CCE and the governing bodies. (Check the corresponding minutes). The updated list of groups is provided.

1.1.2 Hospital/Primary Care teaching and research core		
No./Code	**Quality criterion**	**Comments**
Verification: Current agreement on University-Hospital-Primary Care collaboration and teaching accreditation. Catalog of accredited positions.		
1.1.2.1	The core hospital of the IIS is a teaching hospital that must have signed an agreement with the University, in accordance with RD 1558/1986, for the training of students in Medicine, Nursing, and other Health Sciences degrees. This collaboration will be established for the clinical and health training of students in all health degrees. The agreement provides for the existence of a University-Health Institution Commission responsible for ensuring its correct application, which must meet at least once a year.	Verification: Request the signed agreement and the minutes of the commission with its resolutions and follow-up on resolutions. At a minimum, teaching accreditations must be valid for undergraduate degrees in: Medicine. Nursing. Evaluated period: Five years prior to the application. RD: Article 3.1 a)
1.1.2.2	The hospital, primary care centers, and healthcare units that form the core of the IIS are accredited for specialized healthcare training, in accordance with RD 183/2008, of February 8, which determines and classifies specialties in Health Sciences and develops certain aspects of the specialized health training system, and Law 44/2003 on the Regulation of Health Professions (Article 26.3 amended by Article 8 of Royal Decree-Law 16/2012, of April 20, on urgent measures to guarantee the sustainability of the National Health System and improve the quality and safety of its services). Or the regulations in force on this matter, in the event of its repeal. The accreditation will specify the healthcare units, with the number of accredited teaching positions. There must be at least 25 accredited teaching units (*) for specialized health training.	Verification: Request accreditation signed by the competent governing body for specialized health training of the corresponding Ministry. Teaching accreditations for specialized health training (MIR, EIR, FIR, PIR, BIR, etc.) must be valid. At least for: a. Medicine. b. Nursing. (*) An exception to this requirement will be made when the core hospital of the IIS is monographic in nature and it is verified that it has accreditation for specialized health training in the specialties of its area of expertise, at least in Medicine and Nursing. Evaluated period: Five years prior to the application. See the catalog of accredited positions in the annual call for specialized health training corresponding to the year prior to the accreditation application. RD: Article 3.1 a)

1.2 Organizational structure		
1.2.1 Governing bodies		
No./Code	**Quality criterion**	**Comments**
Verification: Current regulations of the governing bodies. Minutes of the governing bodies for the three years prior to the accreditation application.		
1.2.1.1	The IIS governing bodies (Board of Trustees, Governing Council, or other bodies with the highest decision-making authority in the IIS) are duly established, their functioning is regulated, and there is evidence of their functioning for at least three years prior to the accreditation application. The composition of the IIS governing bodies is proportionate to the capacities and entities that make up the IIS. Gender balance is respected as far as possible.	The composition of the governing bodies must appear on the website. Verify that all the institutions listed in the current legal relationship are represented. Verify whether there are approved regulations for their operation. Check that there are minutes for the three years prior to the application. All conditions must be met. Evaluated period: Three years prior to the application. RD: Article 4 a) RRI.

1.2.1.2	The IIS governing bodies follow up on and evaluate, at least annually, the results of the IIS's activities, based on the corresponding report from the person in charge of scientific management.	Annual follow-up and evaluation: There must be documented evidence of both. Verify in the minutes of the governing bodies corresponding to the three years prior to the application. Evaluated period: Three years prior to the application. RD: Article 4 a)
1.2.1.3	The governing bodies approve the IIS activity plan annually, taking into consideration the reports from the External Scientific Committee, as part of the implementation of the current Strategic Plan.	Verify the incorporation and implementation of the recommendations of the CCE's annual report in the annual activity plan approved by the governing bodies. The activity plan must include references to the lines of action of the Strategic Plan (PE). Verify, through documentation, the recommendations that have led to changes in the IIS and the nature of these changes. Evaluated period: Three years prior to the application. RD: Article 11 b)
1.2.2 Scientific Management		
No./Code	**Quality criterion**	**Comments**
Verification: Procedure, CV, and appointment (Minutes) of the person responsible for scientific management. Selection procedure approved by the IIS governing bodies.		
1.2.2.1	The IIS has a procedure for electing the person in charge of managing the IIS. The procedure includes, among others, an assessment of the scientific track record, leadership skills, management experience, and, at a minimum, a commitment to continue in this role for the duration of a PE. The person in charge of scientific management must have a stable relationship with the core of the IIS.	Verify, through documentation (CCI, CCE minutes, or other evidence) the existence of the procedure and its approval by the IIS governing body (Minutes). The election of the person in charge of the management of the IIS was carried out in accordance with the aforementioned procedure. Evaluated period: Five years prior to the application. RD: Article 4 b)
1.2.2.2	The person in charge of the management of the IIS has executive authority to carry out the duties established by the legal relationship and its implementing documents.	Verify, through documentation, with examples of decision-making. Evaluated period: Five years prior to the application. RD: Article 4 b)
1.2.3 External Scientific Committee (CCE)		
No./Code	**Quality criterion**	**Comments**
Verification: CCE regulations, CVs of CCE members, and minutes of meetings held.		
1.2.3.1	The CCE's mission, as set out in the regulations, is to act as an advisory body to the IIS, conducting an annual evaluation of the matters mentioned in point 1.2.1.3 and issuing a report, at least once a year, for the governing bodies. The CCE regulations also stipulate that its members must certify that they have no conflicts of interest and that at least one of the members must be a scientist who is not resident in Spain. The report includes the evaluation of the IIS's scientific areas/programs and research groups.	Comments: CCE operating regulations with date of approval. Verify: • The contribution of the report from management of the IIS. • The existence of the conflict of interest document signed by each of the members. • The CV of CCE members. The CCE report for the year prior to the evaluated year (check recommendations and date of issue). Check whether at any point an assessment is made of the activities in relation to the PE. Review the frequency of reports in the CCE minutes for the three years prior to the accreditation application. Evaluated period: – Accreditation application: Five years prior to the application. – Accreditation renewal application: Three years prior to the application. RD: Article 4 e) RRI.

1.2.3.2	The CCE regulations stipulate: • That it is a body with independent judgment and decision-making autonomy in the performance of its functions with respect to the IIS. • That minutes must be taken of all its meetings, whether in person or by electronic means. The agenda items, deliberations, and decisions made at each of the meetings held, as well as the follow-up on the implementation of the decisions/resolutions passed at previous meetings, are recorded in signed minutes. • That its composition complies with gender balance. • That it verifies compliance with the conditions of affiliation established for groups that join the IIS after its establishment.	Verify the existence of CCE minutes, approved by its members (signature or communication of approval), with the frequency established in the regulations (minutes of extraordinary meetings are excluded from the frequency). The number of minutes will depend on the frequency of meetings indicated in the CCE regulations. Evaluated period: – Accreditation application: Five years prior to the application. – Accreditation renewal application: Three years prior to the application. RD: Article 4 e) RRI.
1.2.4 Internal Scientific Committee (CCI)		
No./Code	**Quality criterion**	**Comments**
Verification: CCI regulations and minutes of the meetings held.		
1.2.4.1	There is an Internal Scientific Committee (CCI), chaired by the person in charge of the management of the IIS, the regulations of which establish that it is made up of researchers representing the scientific areas of the IIS. The different types of researchers must be represented and those responsible for training, innovation, and quality at the IIS must be included, as established in the IIS organization. In any case, it complies with gender balance and citizen participation.	CCI regulations in force. Composition of the CCI. Evaluated period: Three years prior to the application. RD: Article 4 b) RRI: Gender balance and citizen participation.
1.2.4.2	The CCI has met, with a quorum present and recording the agenda, attendees, deliberations, and decisions made in signed minutes, in order to fulfill its functions with the frequency established in its regulations: • To advise Management of the IIS on all scientific, strategic, and organizational matters. • To analyze and make proposals on all IIS operating plans and regulations, especially in the PE, including the integration plan and the training plan. • To follow up on the activities of the IIS, especially in relation to these plans. • To validate the annual Scientific Report. • To propose to the governing body the annual scientific objectives to be achieved and the action plan to develop them. • To be the body for the participation of research areas and groups in the scientific governance of the IIS. • To evaluate the quality of project application proposals and establish their prioritization, if so provided for in its regulations. • The minutes of successive CCI meetings can be used to verify the follow-up on the implementation of the decisions made.	Interview with CCI. CCI minutes of the evaluated period. Verify dates and contents of minutes. All minutes include: Agenda, attendees, deliberations, and decisions. The activities that form part of its duties must be listed. There must be evidence of following up on the decisions made in the minutes following the decision. Verify that the regulations include all the activities mentioned in the criterion. Verify that there is evidence of compliance with the activities of the criterion (check against the minutes). Both conditions are necessary. Evaluated period: – Accreditation application: Three years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Articles 4 b) and 11.1.b)

1.2.5 Scientific areas: IIS research is organized around scientific areas or scientific programs.		
No./Code	**Quality criterion**	**Comments**
Verification: Action plan of the scientific areas. Annual activity report of the scientific areas of the IIS.		
1.2.5.1	The action plan for each scientific area details the research groups that comprise it and the mechanisms for interaction and cooperation that are planned.	The action plan provides information on how this function will be carried out. Minutes of the meetings of each scientific area in the 12 months prior to the accreditation application, to verify the performance of this function. Evidence of cooperation between groups. Evaluated period: – Accreditation application: Three years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Articles 4 b) and 11.1.b)
1.2.5.2	The action plan for each scientific area is developed in an annual activity plan, aimed at fulfilling its strategic objectives. The indicators for follow-up are detailed. The annual plan is approved by the CCI.	Approval of the annual plan by the CCI. Verify the follow-up indicators. Evaluated period: – Accreditation application: Three years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Articles 4 b) and 11.1.b)
1.2.5.3	Each area submits an annual proposal to the CCI detailing the training needs of the groups that comprise it, aimed at fulfilling scientific objectives.	Annual training proposals submitted to the CCI and activities carried out. Evaluated period: – Accreditation application: Three years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Articles 4 b) and 11.1.b)
1.2.6 Integration plan approved by the governing body.		
No./Code	**Quality criterion**	**Comments**
Verification: Integration plan.		
1.2.6.1	There is an **integration plan** for the fulfillment of the objectives of the IIS Strategic Plan. The current plan has been approved by the governing body in the last five years. The level of fulfillment of the objectives established in the plan is evaluated annually. Fulfillment of the annual objectives is verified.	Evidence of the joint activity of groups/researchers from the different institutions that form the IIS: Projects, publications, seminars, etc. Verify the level of fulfillment of the annual objectives of the Integration Plan. To verify this, specific questions will be included in interviews with researchers and other IIS staff regarding their knowledge of the plan and their assessment of its usefulness. Evaluated period: Five years prior to the application. RD: Article 5 j)

1.3 Decision-making		
1.3.1 Participation and internal communication		
No./Code	**Quality criterion**	**Comments**
Verification: Minutes of approval by the governing bodies of the information, participation, and transparency system. Evidence of follow-up. Document detailing internal communication channels and procedures and the criteria for assessing their effectiveness. Examples of two-way communication.		
1.3.1.1	The current communication plan defines the channels and participation within the IIS. It is aligned with the PE.	See the internal communication plan and verify whether it refers to the aspects mentioned in the criterion. Evaluated period: Five years prior to the application. RD: Article 11.1 b)
1.3.1.2	The established channels are effective in ensuring internal transparency; information flows are optimized according to the profiles they are aimed at, both researchers and other IIS staff.	In accordance with the communication plan, documented examples of this communication and the participation of IIS staff are requested. Communication via the IIS website is not considered sufficient. To verify this, specific questions will be included in interviews with researchers and other IIS staff regarding its existence and usefulness. In addition, it is verified with examples of communications received. Evaluated period: Five years prior to the application. RD: Article 11.1 b) RRI.
1.3.1.3	There is a website that complies with the requirements under Law 19/2013, of December 9, on transparency, access to public information, and good governance. The website offers at least the following criteria: • Accreditation by the competent Ministry, accreditation date, and logos of the Ministry and ISCIII. • Institutions that make up the IIS and governing bodies. Current legal relationship • IIS Organizational Chart. Contact information. • IIS physical spaces. • List of scientific areas/scientific programs, with the groups included in each area. • Name and summarized CV of: Person responsible for management of the IIS and people responsible for each scientific area and each research group. • Strategic Plan. • Scientific report from at least the last two years. • Quality policy. • Portfolio of products of potential interest for the production sector and/or healthcare environment. • GPC as required by indicator 3.1.2.2. • Mechanisms for citizen participation. • IIS management body: Bylaws and contact details. • Employment and recruitment opportunities. • Summary of the financial report from at least the last two fiscal years.	Verify active web. Check that the IIS website has all the items listed in the criterion. Check the date of the last update of the website. Verify that its content has been updated regularly in the 12 months prior to the accreditation application. RRI.

1.4 Unique and separate management		
1.4.1 Unique and separate structure		
No./Code	**Quality criterion**	**Comments**
Verification: Legal nature and bylaws of the management body. Attention to compliance with the requirements of independence and dedication of the management body to the IIS.		
1.4.1.1	The IIS has a management body, which is separate from the healthcare and teaching management structure, with full autonomy and legal capacity for decision-making.	Verify, through documentation, the existence of an independent management body, with its own legal personality, established in the legal relationship as the single management structure of the IIS, whose duties are as described in RD 279/2016, of June 24. Evaluated period: Five years prior to the application. RD: Article 4. c)
1.4.1.2	There is a person responsible for management, appointed by the IIS governing body, in consultation with the management of the IIS, who will belong to the staff of the management body. The management has executive authority and guarantees the financial independence of the IIS.	Verify the appointment of the person responsible for management.
1.4.1.3	The management structure of the IIS is responsible for its own financial and administrative areas and human resources, so that the services shown in the indicators of criterion 1.4.2 are provided by the management structure of the IIS. Likewise, the management structure provides and supports the management of innovation and the transfer of research results.	Verify whether the legal relationship between the IIS and the bylaws of the management body cover all aspects of this criterion. Verify the existence of an area dedicated to innovation with resources belonging to the management body or to one of the institutions that make up the IIS. Evaluated period: Five years prior to the application. RD: Article 4 c)
1.4.1.4	The management of the funds obtained by the research groups affiliated with the IIS is carried out by the management body of the IIS.	Verification of the funds obtained by the research groups affiliated with the IIS and the management of these funds by the IIS management body during each year in the evaluated period. Calculation *: $\frac{\text{obtained funds* managed by the management body}}{\text{total obtained funds*}} \times 100$ *: This includes funds from both public and private sources, regardless of the form of award (competitive grant, contract, donation, etc.), obtained by the total number of members of the research groups affiliated with the IIS in each annual period. Source: Scorecard. Evaluated period: – Accreditation application: Five years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Article 4 c)
		THRESHOLDS: EXCELLENT ≥ 90%; ACCEPTABLE 50-89%; NON-COMPLIANT < 50%
1.4.1.5	The IIS has a structure and organization for raising competitive and non-competitive, philanthropic, or sponsorship funds for economic sustainability, strengthening its structure, and self-funding.	Verify that there are human resources and an organization in place to carry out proactive actions to raise competitive, non-competitive, and philanthropic funds. Source: IIS information and management system. Activity plan and annual reports. Evaluation period: Five years prior to the application. RD: Article 4 c)

1.4.2 Economic management of research and projects		
No./Code	**Quality criterion**	**Comments**
Verification: Minutes of the governing body where budgets, financial audits, and annual budget execution reports are approved. Accounts audit report.		
1.4.2.1	Each fiscal year, the governing body approves the annual budget and the corresponding financial execution report. The accounts are audited annually by an external auditor.	Verify in the minutes: Approval of the annual budget and the corresponding execution report at the end of each fiscal year by the governing bodies for the last three years. Evaluation period: Three years prior to the application. RD Article 11.1 e)
1.4.2.2	The management structure of the IIS provides the necessary support for the development and effective management of research.	Interviews with researchers from different scientific areas and types (senior, recognized, associated clinical, etc.). Gather examples of this support in response to the needs of researchers. Evaluation period: Five years prior to the application. RD: Articles 4 c) and 11.1 e)
Verification: IIS information and management system. Activity plan and annual activity report.		
1.4.2.3	At least 30% of the indirect costs received annually are allocated to intramural actions aimed at supporting IIS researchers, such as training, education, intramural calls for IIS projects for recognized groups, the cost of publication in open access media, etc. • Taking into consideration the CCE and CCI reports. • Performing an annual evaluation of the results of these actions.	Calculation: (Funds, originating from indirect costs, received by the IIS in the evaluated period dedicated to HR support actions/Total amount of indirect costs received by the IIS in the evaluated period) *100. Review: Planned action plan; evidence of actions carried out and their evaluation. Any type of funding for recruitment or co-funding is specifically excluded. Source: Scorecard. Evaluated period: – Accreditation application: Five years prior to the application. – Accreditation renewal application: Two years prior to the application. **THRESHOLDS: EXCELLENT ≥ 50%; ACCEPTABLE 30-50%; NON-COMPLIANT < 30%**
1.4.2.4	The entity that manages the IIS acts as the sponsor of academic clinical trials awarded in public calls for funding at the regional, state, or international level.	Verify that the sponsor of academic clinical trials awarded to IIS groups is the entity that manages the IIS. Documentary evidence, if applicable, of regional regulations that prevent the management body from acting as a sponsor will be taken into consideration for the assessment of this criterion. Evaluation period: Three years prior to the application.

2. STRATEGY, CAPABILITIES, AND SCIENTIFIC PERFORMANCE		
2.1 Strategic Plan (PE)		
2.1.1 Strategic Plan Objectives		
No./Code	**Quality criterion**	**Comments**
Verification: Current PE.		
2.1.1.1	The PE complies with the provisions of RD 279/2016, Article 5. It was approved by the governing body more than three years ago, and is still in force. It contains at least the following strategic objectives: • Translational research. This strategic objective is aimed at ensuring that the IIS is a translational research organization that generates knowledge that has an impact on the SNS. • Integration of the gender perspective, aligning this strategic objective with state and European guidelines. • Innovation and transfer. This strategic objective is aimed at products, processes, and organizational practices useful to the healthcare organization, the production sector, and society. • International positioning. This objective is aimed at: • strengthening the international leadership of R&D&I in biomedicine developed in Spain. Encouraging participation in international competitive processes. • Participation of society. This strategic objective is aimed at guaranteeing the participation of citizens in the generation and transfer of scientific knowledge. For the fulfillment of at least each of the five objectives of the PE mentioned above, the IIS has an organizational support that includes the actions to be developed and the follow-up system.	Check that there are at least these five objectives, which in turn are aligned with the verifiable elements: • Organizational support for the five objectives: 1.4.1.3 and 1.4.1.4. • Internationalization: 2.2.3.5, 2.2.3.6, and 2.3.2.4. • Innovation in processes and products: 3.1.1.1, 3.1.1.2, and 3.1.3.1. • Translational research: 3.1.1.1, 3.1.1.2, and 3.2.2.1. • Participation of society: 3.2.3.1, 3.2.3.2, and 3.2.3.3. Verify whether a strategy for developing actions and the follow-up system is developed for each of the five objectives. Minutes of the governing body with the approval of the current PE. Verify with revision of the current PE. See 1.4.1.3. See minutes of the CCI and CCE and governing body in which the annual follow-up on the PE is recorded. Evaluation period: Five years prior to the application. RD: Articles 5 and 11.1 b) RRI.
2.1.2 Strategic Plan Follow-up		
No./Code	**Quality criterion**	**Comments**
Verification: PE Scorecard. CCE minutes.		
2.1.2.1	There is a PE follow-up and evaluation system with indicators and a timetable. PE follow-up and monitoring is done using the IIS's own resources for this purpose, such as the information systems (see 2.2.5).	The indicators to be monitored, the frequency with which they are monitored, and the person responsible in each case are specified. Compliance with the timetable established for following up on indicators is verified. The standard set by the monitoring system is achieved. Check the use of proprietary systems with: On-site observation of the IIS information system. Check examples of follow-up results. Evaluation period: Five years prior to the application. RD: Article 5 d)

2.1.3 Quality Plan		
No./Code	**Quality criterion**	**Comments**
Verification: Current IIS Quality Plan. Minutes of the Quality Commission.		
2.1.3.1	The IIS has a plan that develops the quality policy approved by its governing bodies and is not older than five years. The plan defines: Objectives, methodology, channels of participation for staff, including a satisfaction survey, indicators, timetable, and responsible parties. The quality policy is disseminated and known by IIS staff. The usefulness of the channels of participation in the proceedings of the IIS Quality Commission is verified.	Verify, through documentation, compliance with all aspects of the criterion. Minutes of the IIS Quality Commission. Documentary evidence of actions to disseminate the quality policy. Evaluations of its effectiveness. Evaluated period: – Accreditation application: Three years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Article 5 d) RRI.

2.2 Resources and Processes		
2.2.1 Research infrastructures		
No./Code	**Quality criterion**	**Comments**
Verification: Drawings. On-site visit to the facilities. List of IIS infrastructure provisions.		
2.2.1.1	The IIS has an area of at least 3,000 m^2 exclusively dedicated to research and under the direct management of IIS management. The transfer of use of these spaces to the IIS for the scientific activity of affiliated researchers is accredited through documentation.	See drawings. On-site observation. It will be valued as an element of quality that these spaces are located in the core of the IIS. Documented examples of the scientific management of IIS spaces. Suitable identification of spaces. Evaluated period: – Accreditation application: Five years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Article 11 b) **NON-COMPLIANT < 3,000 m^2**
2.2.1.2	The IIS has space dedicated exclusively to research in at least one health center or other primary care research support structure within the IIS's sphere of influence. The transfer of use of these spaces to the IIS for the scientific activity of affiliated researchers is accredited through documentation.	On-site observation during the visit. List of center(s) where these spaces are located. Documented examples of the management of the use of spaces assigned to research activities of IIS research groups/researchers. Evaluation period: Two years prior to the application. RD: Article 11 b)
2.2.1.3 A	The IIS has at least the following common services and platforms, either internal or external, which provide support to the various research groups, organized and structured as follows: Animal facility. Omics laboratories. Biobank. Clinical epidemiology and biostatistics. ICTs applied to biomedical research: Platforms dedicated to comprehensive research support. Clinical Trials Unit.	All 7 are essential. In the case of external services, document (agreement, contract) formalizing the conditions of this provision of services to the IIS. Standard Operating Procedures (SOPs) for these services/platforms. Portfolio of services and rates. Compliance with the regulations in force applicable in each case. Visits and interviews with responsible parties to learn about the organization and operation. Interviews with researchers who are users of the platforms to assess the suitability of the service with respect to their needs. Evaluated period in accreditation: Five years prior to the accreditation application. RD: Article 11 b)

2.2.1.4 A	The IIS has at least four of the following common services and platforms, either internal or external, which provide support to the various research groups, organized and structured as follows: • Structural and molecular analysis. • Metabolomics. • Cell bioimaging with confocal and electron microscopy. • Cytometry and cytogenetics. • Clean room. • Cell cultures.	It must have at least four. In the case of external services, document (agreement, contract) formalizing the conditions of this provision of services to the IIS. Standard Operating Procedures (SOPs) for these services/platforms. Portfolio of services and rates. Compliance with the regulations in force applicable in each case. Visits and interviews with responsible parties to learn about the organization and operation. Interviews with researchers who are users of the platforms to assess the suitability of the service with respect to their needs. Evaluated period in accreditation: Five years prior to the accreditation application. RD: Article 11 b)
2.2.1.4 R	The IIS systematically evaluates the level of use of its support platforms and services. The IIS has incorporated a service or new feature into those available in the previous accreditation, either internal or external, in response to the identified needs.	In the case of external services, document (agreement, contract) formalizing the conditions of this provision of services to the IIS. Standard Operating Procedures (SOPs) for these services/platforms. Portfolio of services and rates. Compliance with the regulations in force applicable in each case. Visits and interviews with responsible parties to learn about the organization and operation. Interviews with researchers who are users of the platforms to assess the suitability of the service with respect to their needs. Evaluated period in accreditation renewal: Two years prior to the application. RD: Article 11 b)
2.2.1.5	IIS groups are part of at least eight SECTI cooperative research networks or consortia, such as RICORS, CIBER, ISCIII platforms, IMPaCT or other similar figures that may be established in the future.	See the website corresponding to each structure to verify the incorporation of the IIS groups. Documentary evidence of participation in networks/consortia/platforms (code assigned to member groups/ publications, attendance at meetings, participation in governing bodies, etc.). Evaluation period: Five years prior to the application. RD: Article 5 i)
		THRESHOLDS: EXCELLENT > 15; ACCEPTABLE 8-15; NON-COMPLIANT < 8
2.2.1.6	The IIS participates in at least three international research infrastructures or networks.	Documentary evidence of active participation in networks/consortia/platforms (code assigned to member groups/publications, attendance at meetings, participation in governing bodies, etc.). Evaluation period: Year prior to the application. RD: Article 5 i)
		THRESHOLDS: EXCELLENT ≥ 5; ACCEPTABLE 3-4; NON-COMPLIANT < 3

2.2.2 Human resources and critical mass		
No./Code	**Quality criterion**	**Comments**
Verification: Human resources plan approved by the governing bodies. Evidence of implementation. Documents of affiliation and accreditation. HRS4R certified.		
2.2.2.1	The IIS has a human resources plan aimed at research, technical, and management staff. The plan includes gender equality and diversity management actions that address: • Aspects of equal opportunity and equity in research careers. • Generational change and female leadership. • Considerations in the policy for hiring research, technical, management, and other service personnel. • Aspects of representation in the various bodies and commissions.	Verify that the IIS has obtained the HRS4R certificate. Document recruitment, professional development, and promotion of research talent, with explicit reference to the incorporation of clinical-research groups, especially in primary care, and mentoring of recognized groups. Documentary evidence of actions taken in the short and medium term. Definition of indicators and methodology for periodic evaluation of the fulfillment of objectives. Interviews with researchers to assess their effectiveness and perceived satisfaction. Evaluated period: – Accreditation application: Three years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Article 5 h) RRI.
2.2.2.2	The IIS reports internally on EURAXESS web services and advertises its job offers for researchers, managers, and technical staff on EURAXESS Jobs.	See examples of internal information and job postings. Advertisements on EURAXESS Jobs will only be considered for job offers that justify it due to their scope or profile. Evaluated period: – Accreditation application: Three years prior to the application. – Accreditation renewal application: Two years prior to the application. RRI.
Verification: Documentary evidence. Interviews with IIS research and technical staff.		
2.2.2.3	Every three years, the IIS evaluates the human resources plan and the gender equality and diversity management plan, implementing improvement measures in accordance with the methodology established therein.	Verify that indicators are available for monitoring the HR plan and that the results of the periodic evaluation of these indicators are provided. Verify, through documentation, the results of the evaluation. Compliance is considered to have been achieved by verifying, through documentation, that the evaluation provided for in the HRS4R program has been carried out. Verify the evaluation of the human resources plan carried out over the last two years and the implementation of improvement measures identified and focused on human resources. Check that there is a protocol for action and prevention of discrimination within the equality plan. Evaluated period: – Accreditation application: Three years prior to the application. – Accreditation renewal application: Three years prior to the application. RRI.
Verification: A record of IIS researchers. Scorecard.		

2.2.2.4	The number of IIS researchers who are principal investigators with active research projects funded through competitive public calls for proposals at the national, European, or international level is greater than or equal to 40.	Calculation: Number of PIs with active projects funded through competitive public calls at the national, European, or international level in at least one of the two years prior to the application. In the case of projects with a PI and co-PI from the same IIS, only one PI is counted. Evaluation period: Two years prior to the application. RD: Article 11.1 c) RRI. **THRESHOLDS: EXCELLENT ≥ 60; ACCEPTABLE 40-59; NON-COMPLIANT < 40**
2.2.2.5	At least 40% of principal investigators (PIs) have been involved in competitive public projects at the national, European, or international level in the last five years.	Calculation: (Number of healthcare researchers who are PIs of at least one project in the last five years/ Number of PIs of at least one project in the last five years of the IIS) *100. Competitive public projects: Projects funded through competitive public calls for proposals. In the case of projects with two PIs, only one PI is counted. Evaluation period: Five years prior to the application. RD: Article 11.1 c) **THRESHOLDS: EXCELLENT ≥ 65%; ACCEPTABLE 40-64%; NON-COMPLIANT < 40%**
2.2.2.6	Researchers in training (corresponding to the R1 profile in the EURAXESS European classification of researcher profiles) represent at least 10% of the total number of researchersin a given year during the evaluated period.	Calculation: (Number of R1 researchers per year/Number of IIS researchers per year) *100. Evaluated period: – Accreditation application: Annual calculation in the five years prior to the application. – Accreditation renewal application: Annual calculation in the two years prior to the application. Annual list of researchers in training as of December 31 of the year prior to the audit visit. Compile information corresponding to the previous five years. Researcher profile classification https://euraxess.ec.europa.eu/europe/career-development/training-researchers/research-profiles-descriptors The document prepared by the 2021 ALLIANCE of IIS regarding the categories of research staff must also be taken into consideration. RD: Article 11.1 c) **THRESHOLDS: EXCELLENT > 20%; ACCEPTABLE 10%-20%; NON-COMPLIANT < 10%**
2.2.2.7	At least 4% of IIS researchers have had a stay of at least two months in other research centers during the evaluated period.	Calculation: (Number of researchers with a stay of at least two months in the last five years/Average number of IIS researchers in the last five years prior to the application) *100. Stay for training or research purposes, authorized and evaluated by the CCI, and carried out at research centers other than those that make up the IIS. Evaluated period: – Accreditation application: Five years prior to the application. – Accreditation renewal application: Two years prior to the application. For each year, the number of researchers is counted as of December 31. RD: Article 11.1 c) **THRESHOLDS: EXCELLENT > 8%; ACCEPTABLE 4%-8%; NON-COMPLIANT < 4%**

2.2.2.8	At least 15% of the groups are recognized groups.	Calculation: (Total number of recognized groups/Total number of established and recognized IIS groups) *100. A record of IIS groups as of December 31 of the year prior to the application. Evaluation period: Year prior to the application. See Glossary for the definition of a recognized group. RD: Article 11.1 c) **NON-COMPLIANT < 15%**
2.2.2.9	At least 25% of the PIs or Co-PIs are researchers with an R2 or R3 EURAXESS Researcher Profile.	Calculation: (Number of healthcare researchers who are PIs of at least one project in the last five years with an R2 or R3 profile (EURAXESS)/Number of PIs of at least one project in the last five years of the IIS) *100. Researcher profile classification https://euraxess.ec.europa.eu/europe/career-development/training-researchers/research-profiles-descriptors The document prepared by the 2021 ALLIANCE of IIS regarding the categories of research staff must also be taken into consideration. Evaluated period: – Accreditation application: Five years prior to the application. – Accreditation renewal application: Two years prior to the application. Research profile classification: https://euraxess.ec.europa.eu/europe/career-development/training-researchers/research-profiles-descriptors **THRESHOLDS: EXCELLENT ≥ 50%; ACCEPTABLE 25-49%; NON-COMPLIANT < 25%**
2.2.2.10	The number of IIS researchers who are Primary Care staff is at least 5% or a number of 30.	Select one of the following calculation methods: 1. (Number of IIS researchers who are primary care staff/number of IIS researchers) *100. 2. Number of IIS researchers, primary care staff. A record of IIS researchers as of December 31 of the year prior to the application. Evaluation period: Year prior to the application. RD: Article 11.1 c) **THRESHOLDS: EXCELLENT ≥ 10% (> 50); ACCEPTABLE 5-9% (30-50); NON-COMPLIANT < 5% (< 30)**
2.2.2.11	The number of IIS researchers involved in healthcare research is at least 4% or a number of 25.	Select one of the following calculation methods: 1. (number of researchers involved in healthcare research/number of IIS researchers) *100. 2. Number of researchers in the field of healthcare. A record of IIS researchers as of December 31 of the year prior to the application. Evaluation period: Year prior to the application. RD: Article 11.1 c) **THRESHOLDS: EXCELLENT ≥ 10% (> 45); ACCEPTABLE 4-9% (25-45); NON-COMPLIANT < 4% (< 25)**

2.2.3 Resource mobilization for research		
No./Code	**Quality criterion**	**Comments**
Verification: IIS information system. Scorecard.		
2.2.3.1	The IIS has obtained funding in competitive public calls for proposals at the state, European, or international level over the last five years for at least 70 research projects.	Calculation: Number of projects funded in competitive public calls for proposals at the state, European, or international level over the last five years. Evaluated period: Five years prior to the application. It is important to check that international competitive projects are actually competitive. See Glossary for competitive calls for proposals. RD: Article 11.1 c)
		THRESHOLDS: EXCELLENT ≥ 150; ACCEPTABLE 70-149; NON-COMPLIANT < 70
2.2.3.2	The IIS has a success rate in competitive public calls for proposals at the state level for at least 25% of the projects requested in the last five years.	Calculation: (Number of projects funded in state public competitive calls for proposals/Total number of projects requested in state public competitive calls for proposals) *100. Evaluated period: Five years prior to the application. Scope: Competitive public calls for proposals at the state level. See Glossary for competitive calls for proposals. RD: Article 11.1 c)
		THRESHOLDS: EXCELLENT ≥ 50%; ACCEPTABLE 25-49%; NON-COMPLIANT < 25%
2.2.3.3	The funding raised, from competitive and non-competitive sources, dependent on public funds, does not exceed 60% of the annual budget of the IIS.	Calculation: (Competitive + non-competitive public funding/Total annual funding) *100. See accounting audit for the last year prior to the accreditation application. Evaluated period: – Accreditation application: Three years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Article 11.1 c)
		THRESHOLDS: EXCELLENT 30-50%; ACCEPTABLE 51-60%; NON-COMPLIANT > 60%
2.2.3.4	The average funding obtained per PI (competitive and non-competitive) in five years is ≥ €45,000.	Calculation: (Total funding obtained by PIs in the IIS in the last five years/Number of PIs that have obtained funding in the last five years). Evaluated period: Five years prior to the application. Total number of PIs five years prior to application. RD: Article 11.1 c)
		THRESHOLDS: EXCELLENT ≥ €100,000; ACCEPTABLE €45,000-€99,999; NON-COMPLIANT < €45,000
2.2.3.5	The ratio of the number of projects funded in European public competitive calls for proposals per PI in the last five years is equal to or greater than 0.1.	Calculation: (Number of projects obtained by IIS PIs in European competitive public calls for proposals in the last five years/Number of IIS PIs in the last five years). Evaluated period: Five years prior to the application. Total number of PIs five years prior to application. RD: Article 11.1 c)
		THRESHOLDS: EXCELLENT > 0.5; ACCEPTABLE 0.1-0.5; NON-COMPLIANT < 0.1

2.2.3.6	The average funding obtained per PI in European funds in five years is ≥ €100,000.	Calculation: (Funding from European sources obtained by the IIS in the last five years/Number of IIS PIs with funding from European sources in the last five years) *100. Evaluated period: Five years prior to the application. Total number of PIs in the last five years. RD: Article 11.1 c) **THRESHOLDS: EXCELLENT ≥ €200,000; ACCEPTABLE ≥ €100,000 and < €200,000; NON-COMPLIANT < €100,000**
2.2.4 Training		
No./Code	**Quality criterion**	**Comments**
Verification: Training plan approved by the governing bodies. Annual training activities report. Evaluation of the training plan. Interviews.		
2.2.4.1	The IIS has a training plan that specifies the strategy for training IIS human resources linked to: • Postgraduate programs, preferably doctoral programs, and their contribution to promoting strategic and emerging lines of research and for supporting and integrating different researchers, groups, and entities that make up the IIS. • Cross-cutting skills in science leadership, communication with clinical and healthcare decision-makers, and social stakeholders. • Specialized technical training aimed at professionals in support units. • Actions aimed at the training needs of the research areas identified by the CCI.	The training plan includes actions focused on these aspects. Participation of IIS researchers in doctoral programs, with special mention of those led by the IIS. Verify that it includes aspects of leadership and communication in some of the training actions. Document that the training plan contains subjects aimed at support units (e.g., animal facility or microscope technicians). Verify that the annual training actions correspond to the training needs of the IIS scientific areas identified in the previous period and communicated to the CCI. Evaluated period: Two years prior to the application. RD: Article 4 g), Article 5 c), and Article 11.1 d)
2.2.4.2	The training plan includes specific mentoring activities aimed at recognized research centers and/or groups that are part of the IIS or its environment.	See Glossary for the definition of a recognized group. Program, attendees, and evaluation of the actions carried out in the two years prior to the application. Evaluated period: Two years prior to the application RD: Article 4 g) and Article 5 c)
2.2.5 Information system		
No./Code	**Quality criterion**	**Comments**
Verification: Review of the information system during the visit.		
2.2.5.1 A	There is an up-to-date and operational information system that includes: • A record of all IIS staff and their affiliation with the centers that make up the IIS, which is updated regularly and contains data on research staff as of the end of the fiscal year on December 31. • A record of the physical, technological, and financial resources of the IIS. • A record of the R&D&I activity owned and authored by the IIS, originating from researchers affiliated with the IIS, including all activities and projects with its funding, and the results and output generated: Scientific publications, clinical trials, patents, and other products of knowledge translation and transfer.	Review the status of the staff record for the month prior to the audit visit to verify whether any changes have been made (if any) as of the end of the fiscal year on December 31 of the year prior to the audit. Updated record for the month prior to the visit. On-site verification of system operability. Check update with randomly selected examples. Evaluated period: Year prior to the application RD: Article 4 i)

2.2.5.2	The information system allows for the traceability of researchers, collaborations, projects requested and awarded, funds obtained, and primary results obtained from their execution.	On-site verification with examples of traceability for all items in the criterion. Evaluated period: Year prior to the application RD: Article 5 d)
2.2.5.3	There is an affiliation policy approved by the IIS governing bodies and known to IIS members.	Verify the affiliation document and the minutes of the governing body where it is approved. Evaluated period: Year prior to the application RD: Article 4 h)
2.2.6 Annual scientific report		
No./Code	**Quality criterion**	**Comments**
Verification: IIS scientific reports approved by the governing body.		
2.2.6.1	An annual scientific report is drawn up, incorporating the gender perspective, with the following **minimum** content: **RESOURCES** • Scientific areas: annual objectives set and degree of execution achieved. • Research staff: annual evolution (researchers classified according to their profile in the European research career). • Administration and management staff. • Research staff funded entirely or partially through competitive calls for proposals and research networks. • Research groups in each Area. **ECONOMIC DATA** • Revenues (Funds from competitive sources, Funds from non-competitive sources). Explain indirect costs according to source. • Expenses (expenses incurred, audited, and approved by the Board of Trustees). Specify the use of the corresponding indirect costs. • Balance sheet (assets, liabilities) **RESEARCH ACTIVITY** • Number of research projects awarded (competitive and non-competitive calls for proposals) • Number of scientific publications, by category (original articles, reviews, etc.). • Exhaustive list of all scientific publications resulting from the IIS's activity. • List of the five publications that each area selects as most relevant in the year. • Total number of active clinical trials. • Clinical practice guidelines (GPC) (see Glossary) developed by IIS researchers in the corresponding year. • List of GPCs developed by IIS researchers and implemented in IIS health centers. • Number of innovations generated by the IIS (*Innovation* as defined in the Glossary). • Follow-up report on innovations under development by IIS. • Number of patents or utility models (applied for, granted, and licensed/transferred). • Number of spin-offs and start-ups created and active. **PLATFORMS/INFRASTRUCTURES** • List of existing platforms, indicating the ISCIII platforms; annual activity indicators, and number of people working in each one of them.	The report must mention all the items cited in the criterion. Evaluated period: Year prior to the application.

2.2.6.2 R	Compliance with ISCIII criteria is evaluated annually in the Scorecard. The scientific report and the Scorecard are communicated to the ISCIII before September 30 of the following year, according to the procedure published by the ISCIII.	Verification, through documentation, of annual completion. Evaluated period: Year prior to the accreditation renewal application. Does not apply to initial accreditation application. RD: Articles 18.1 and 18.2

2.3 Scientific activity

2.3.1 Cooperative science project (PCC)

No./Code	Quality criterion	Comments
Verification: PCC and its evaluations.		
2.3.1.1	The PCC among the integrated centers of the IIS specifies: The scientific areas with their respective action plans, which include objectives, common scientific lines, and actions for their development. The prioritization of strategic lines of research. The innovations in health (see Glossary) that the IIS wants to develop. Actions to promote the integration of the gender dimension in the content of the research and innovation being developed.	Verify whether it includes: Planning. Prioritization of strategic lines. Innovations (5-year outlook). Gender dimension. Identify actions taken in the 12 months prior to the application. Evaluated period: Year prior to the application. RD: Article 5 c)
2.3.1.2	The PCC monitoring and evaluation system, with indicators and timetable, is complied with in at least one complete cycle.	They should specify the indicators to be monitored and the frequency with which they are to be monitored. Verify the annual evaluation of the established indicators and the proposals for improvement incorporated. Evaluated period: Year prior to the application. RD: Article 5 c)

2.3.2 Research results: Indicators related to scientific output in publications.

No./Code	Quality criterion	Comments
Verification: Record of IIS scientific output and scorecard. See annex for indications for calculating bibliometric indicators. The scientific output for these criteria only includes publications with appropriate IIS affiliation according to the standard established for this purpose by its governing body. This condition shall **apply exclusively to publications made after 2025**. Therefore, **it will not be required** in indicators the time frame of which includes previous years. In these cases, the **total scientific output** will be counted, regardless of affiliation. **Application by year of procedure request:** **Procedure requests submitted in 2025**: The **total scientific output** will be counted, without requiring that it be correctly affiliated. **Procedure requests submitted in 2026**: The **correctly affiliated scientific output corresponding to the year 2025**, as well as the **total scientific output from previous years**, will be counted, according to the time frame defined by each indicator and the type of procedure in progress. **Procedure requests submitted in 2027**: The **correctly affiliated scientific output corresponding to the years 2025 and 2026** will be counted, together with the **total scientific output of the previous years**, according to the time frame of the indicator and the type of procedure in progress. **NOTES:** Numerator and denominator must be provided for all indicators.		

2.3.2.1	Normalized Impact Factor: Normalized citation rate during the evaluated period ≥ 1.5.	Publications to be considered: original articles and reviews in JCR-indexed journals. Evaluated period: Accreditation application: Five years prior to the application. Accreditation renewal application: Two years prior to the application. Thus, for applications submitted in 2026, the period to be evaluated will be 2024 and 2025. RD: Article 11.1 c)
		THRESHOLDS: EXCELLENT ≥ 2.5; ACCEPTABLE 1.5-2.49; NON-COMPLIANT < 1.5
2.3.2.2	International Collaboration Indicator. Percentage of publications with international collaboration in the last year ≥ 30%.	Calculation: (Number of publications signed by authors from different institutions and different nationality with at least one IIS researcher as author/Total number IIS publications in the evaluated period) *100. Publications to be considered: original articles and reviews in JCR-indexed journals. Evaluated period: Year prior to the application RD Article 11.1 c)
		THRESHOLDS: EXCELLENT > 40%; ACCEPTABLE 30-40%; NON-COMPLIANT < 30%
2.3.2.3	Intra-institute collaboration indicator. (a) Percentage of collaborative publications by researchers affiliated with groups from at least two institutions that form part of the IIS in the last year ≥ 15%. (b) Percentage of collaborative publications by researchers belonging to different IIS groups in the last year ≥ 15%.	(a) Calculation: (Number of publications authored by researchers affiliated with at least two IIS institutions/ Total number of IIS publications in the evaluated period) *100. (b) Calculation: (Number of publications authored by researchers affiliated with at least two IIS groups/ Total number of IIS publications in the evaluated period) *100. Publications to be considered: original articles and reviews in JCR-indexed journals. Evaluated period: Year prior to the application. RD: Article 11.1 c)
		THRESHOLDS: EXCELLENT ≥ 30%; ACCEPTABLE 15-29%; NON-COMPLIANT < 15%
2.3.2.4	Global Impact Indicator. Percentage of IIS publications that are included among the top 10% of the world's most cited publications in their area of scientific knowledge out of the total number of publications in the same area ≥ 20%.	Calculation: (Number of IIS publications included in D1 of the most cited in its subject area/Total number of publications in the subject area). Highly Cited Papers (10%), publications ranked in the top 10% of the most cited in the international field, taking into consideration the subject category and the year in which they were published. Publications to be considered: original articles and reviews in JCR-indexed journals. Evaluated period: – Accreditation application: Five years prior to the application. – Accreditation renewal application: Two years prior to the application. Thus, for applications submitted in 2026, the period to be evaluated will be 2024 and 2025. RD: Article 11.1 c)
		THRESHOLDS: EXCELLENT ≥ 25%; ACCEPTABLE 20-24%; NON-COMPLIANT < 20%
2.3.2.5	Leadership Indicator. Percentage of publications in which an IIS author is a corresponding, first, or last author ≥ 35%.	Calculation: (Number of IIS publications with an affiliated researcher as first, last, or corresponding author/ Total number of IIS publications in the evaluated period) *100. Publications to be considered: original articles and reviews in JCR-indexed journals. Evaluated period: Accreditation application: Five years prior to the application. Accreditation renewal application: Two years prior to the application. RD: Article 11.1 c)
		THRESHOLDS: EXCELLENT ≥ 45%; ACCEPTABLE 35-44%; NON-COMPLIANT < 35%

2.3.2.6	Indicator of Excellence with leadership. Number of IIS publications considered to be of excellence (included in the top 10% of the most cited publications in the world in their area of knowledge) that meet the leadership criterion (first, last, or corresponding author is an IIS researcher) ≥ 40.	Publications to be considered: original articles and reviews in JCR-indexed journals. Evaluated period: Accreditation application: Five years prior to the application. Accreditation renewal application: Two years prior to the application. Thus, for applications submitted in 2026, the period to be evaluated will be 2024 and 2025. RD: Article 11.1 c)
		THRESHOLDS: EXCELLENT ≥ 100; ACCEPTABLE 40-99; NON-COMPLIANT < 40
2.3.2.7	Visibility indicator. Percentage of publications, published in the last year, by IIS researchers, in which the IIS affiliation is included ≥ 70%. This indicator **will only be applicable in procedure requests submitted in 2025**. As of January 1, 2026, this indicator will not be considered among those included in the 2025 GTE.	Calculation: (Number of publications by IIS researchers with appropriate affiliation with the IIS/Total number of IIS publications in the evaluated period) *100. Publications to be considered: original articles and reviews in JCR-indexed journals. Evaluated period: Year prior to the application. RD: Article 11.1 c)
		THRESHOLDS: EXCELLENT ≥ 95%; ACCEPTABLE 70-94%; NON-COMPLIANT < 70%
2.3.3 Ethics, good practice, and integrity in research		
No./Code	**Quality criterion**	**Comments**
Verification: Document of good practice in IIS research. Evaluation of compliance.		
2.3.3.1	The internal guide or code of good scientific practice, integrity, and ethics in research follows the criteria included in ALLEA's European Code of Conduct for Research Integrity, and actions are taken to implement and monitor it.	Verify, through documentation, the compliance of the IIS Guide to Good Practice in Research with the European Code of Conduct for Research Integrity. *The European Code of Conduct for Research Integrity, Revised Edition. ALLEA.* Verify the actions for implementation by calculating the average number of actions taken annually in the evaluated period. Verify through documentation. Interviews. Evaluated period: Five years prior to the accreditation application. RD: Articles 4 h) and 11.1 c)
		THRESHOLDS: EXCELLENT > 5; ACCEPTABLE 2-5; NON-COMPLIANT < 2
2.3.3.2	A body and procedures have been put in place for the management and resolution of conflicts related to good scientific practice and integrity in research.	Verify through documentation. Analyze an example selected by the audit team from the list of conflicts managed over the last five years provided by the IIS. Interviews with researchers on their knowledge and assessment of these procedures. Evaluated period: – Accreditation application: Five years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Articles 4 h) and 11.1 c)
2.3.3.3	Compliance with data protection regulations in force is accredited.	Verify, through documentation, with examples of reports from the data protection officer designated for the IIS. Evaluated period: Year prior to the accreditation application. RD: Articles 4 h) and 11.1 c)

2.3.4 Open Access policy		
No./Code	**Quality criterion**	**Comments**
Verification: List of publications for the five years prior to the accreditation application. Repositories. IIS documentation in relation to the Open Access policy. Interviews with researchers.		
2.3.4.1	IIS has established and is developing a defined Open Access policy that includes: The mandate and incentives to promote open access to publications, in open access media and in recognized, standardized repositories that are compatible with European infrastructures (e.g., OpenAire). Facilitate the open publication of data in standardized repositories that are recognized in the discipline. The European open data infrastructure EOSC is used as a reference.	Verify current IIS Open Access policy document. It must address both of the above aspects. Evaluated period: – Accreditation application: Five years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Article 11.1 c) RRI.
2.3.4.2	100% of the publications resulting from projects financed with public funds from state calls for proposals, produced during the evaluation period, have been made in Open Access media.	Calculation: (Number of publications in open access media of results of projects financed with IIS public funds/Total number of publications of results of projects financed with IIS public funds in the evaluated period) *100. Evaluated period: – Accreditation application: Five years prior to the application. – Accreditation renewal application: One year prior to the application. RD: Article 11.1 c) RRI.
2.3.4.3	In the last year, at least 75% of research data from publicly funded projects under state calls for proposals, following FAIR principles, is openly available in standardized and recognized open data repositories in the discipline.	Calculation: (Number of publicly funded IIS project research data available in repositories/Total number of publicly funded IIS project research data in the evaluated period) *100 Evaluated period: Year prior to the application. RD: Article 11.1 c) RRI. **THRESHOLDS: EXCELLENT ≥ 90%; ACCEPTABLE 75-89%; NON-COMPLIANT < 75%**
2.3.4.4	The IIS provides support for the creation of research PGDs, as well as advising researchers on obligations, Open Access publishing options, copyright, Creative Commons licenses, etc.	The IIS must explain how it provides this support and advice (through a knowledge transfer office, specific activities, etc.). Verify through documentation or with interviews. Evaluated period: Year prior to the application. RD: Article 11.1 c) RRI.

3. IMPACT ON SOCIETY		
3.1 Translation and impact on the NHS and society		
3.1.1 Translation and innovation plan.		
No./Code	**Quality criterion**	**Comments**
Verification: Translation plan approved by IIS governing bodies. Minutes of the IIS Innovation Commission.		
3.1.1.1	There is a plan for translation and innovation and transfer of scientific results from the IIS to clinical practice and the production sector, both locally and globally. This strategy includes actions for the participation of key non-scientific stakeholders. The innovation and transfer objective in health of the PE is followed up on and evaluated, including objectives related to innovation in products, services, and processes in the clinical care and health services environment.	Existence of the translation and innovation and transfer plan approved by IIS governing bodies. Documentary evidence of actions taken in the 12 months prior to the accreditation application. See PE. It should include indicators or elements for following up on the plan. Minutes of the Innovation Commission. Interview the parties responsible for the Knowledge Transfer Office (OTC). Verify, through documentation, that the evaluation is carried out. Evaluated period: – Accreditation application: Three years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Article 11.1 c) RRI.
3.1.1.2	The innovation and transfer plan describes: A clear, transparent, and coherent vision of technology transfer, with strategic objectives and priorities. The policy for the protection of research results. The spin-off creation policy, including the policy of participation in the capital by researchers and the IIS. Actions among researchers to promote: 3. Increase in registered and licensed patents. 4. Knowledge transfer to the production sector. 5. Development of new marketable health products or medical devices. 6. Implementation of new clinical processes. 7. Creation of spin-offs and start-ups. 8. Academic clinical trials or studies.	See innovation and transfer plan. Interview the party responsible for innovation. Interview the parties responsible for the Knowledge Transfer Office (OTC). Activity reports of the Innovation Commission or the party responsible for this area in the IIS. Verify that the 6 innovation promotion actions have been carried out in one of the topics mentioned in the criterion. Evaluated period: – Accreditation application: Three years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Article 11.1 c) RRI.
3.1.2 Translation to clinical practice.		
No./Code	**Quality criterion**	**Comments**
Verification: Translation to clinical practice. Records of IIS research activity. Interviews. List of IIS GPC**s.**		
3.1.2.1	In the last three years, the number of GPCs published in indexed journals, along with the number of institutional papers in which the IIS has participated, is ≥ 35.	Verify the list of GPCs and institutional documents provided by the IIS. Published originals. See Glossary. Evaluated period: Three years prior to the application. RD: Article 11.1 c) RRI. **THRESHOLDS: EXCELLENT ≥ 65; ACCEPTABLE 35-64; NON-COMPLIANT < 35**

3.1.2.2	The GPCs, developed with the participation of the results of IIS research activity, are included in the IIS information system. They are disseminated both on the IIS website and actively to the hospital and primary care services of the IIS. The impact analysis of the GPCs, with evidence of their implementation, is included in the IIS information system.	Verify on the IIS website. Verify that GPCs are sent to hospitals and primary care services with Information S. Dissemination actions included in the IIS report and/or IIS communication plans in the last 12 months. Verify, through documentation, the results of impact analyses, whether ongoing or completed, of the implementation of GPCs during the evaluated period. Verify that there are indicators for following up on implementation. Evaluated period: – Accreditation application: Three years prior to the application. – Accreditation renewal application: Two years prior to the application. RD: Article 11.1 c) RRI.
3.1.2.3	Over the last three years, at least five or more results from research carried out at the IIS have been transferred to healthcare practice, at least in the health centers that make up the IIS.	Documentary evidence is provided, which details the transfer of five research results on any of the following topics: a) Implementation of cost-effective therapeutic alternatives. b) Advances in diagnostic, therapeutic, or rehabilitation processes, etc. Evaluated period: Three years prior to the application. RD: Article 11.1 c) RRI.
		THRESHOLDS: EXCELLENT > 10; ACCEPTABLE 5-10; NON-COMPLIANT < 5
3.1.2.4	The IIS has identified research results of potential interest for healthcare activities. At least two actions have been taken in the last 12 months to disseminate these results to healthcare institutions and professionals, at least within the IIS environment. Portfolio of products of interest for clinical practice.	Verify the procedures established by the IIS for identifying results of "potential interest" for healthcare activities. Verification, through documentation, of the identification process that took place in the 12 months prior to the accreditation application. Interest: potential for organizational or healthcare improvement. Request a list of results that have been considered of "potential interest" to the IIS. Verify, through documentation, the actions taken (presentation program, invitation, call for proposals, email, etc.) in relation to any of them. Evaluated period: Year prior to the application. RD: Article 11.1 c) RRI.
		THRESHOLDS: EXCELLENT ≥ 4; ACCEPTABLE 2-3; NON-COMPLIANT < 2

3.1.3 Transfer to the production sector.		
No./Code	**Quality criterion**	**Comments**
Verification: Translation to the production sector. Innovation Commission. IIS information systems.		
3.1.3.1	The portfolio of products and research results of potential interest to institutions and companies has been identified. In the last two years, at least one annual action has been organized to publicize the portfolio of products and research results of potential interest to potentially interested institutions and companies.	Request portfolio of IIS products that have been disseminated to companies. Verify, through documentation, the actions taken (presentation program, invitation, call for proposals, email, etc.); Evaluated period: Two years prior to the application. RD: Article 11.1 c) RRI. **THRESHOLDS: EXCELLENT ≥ 4; ACCEPTABLE 2-3; NON-COMPLIANT < 2**
3.1.3.2	The investment made in the last five years to protect inventions is ≥ €50,000.	ETCI indicator. Amount of the costs of processing and maintaining patent applications and granted patents (both priority and extensions), utility models, and protected plant varieties. In addition to procedural fees and annual fees, this includes expenses paid to patent agents and similar professionals for advice, drafting the application, processing, and maintenance. Litigation costs, if any, are not included. Note: Processing and maintenance costs must be included, even if they are subsidized or financed by licensees. Note: This indicator does not include expenses for other types of protection such as trademarks, industrial designs, or intellectual property registrations. **THRESHOLDS: EXCELLENT > €100,000; ACCEPTABLE €50,000-€100,000; NON-COMPLIANT < €50,000**
3.1.3.3	The number of industrial property registrations filed in the last five years ≥ 8.	ETCI indicator. Number of patent applications associated with an invention that are filed for the first time with a national office (USPTO, office of another country), regional office (EPO application), or international office (PCT application) generated by an IIS researcher and filed within the last five years. Utility models, industrial designs, and trademarks may also be counted as registrations. **THRESHOLDS: EXCELLENT > 15; ACCEPTABLE 8-15; NON-COMPLIANT < 8**
3.1.3.4	Number of industrial property/know-how registrations licensed, or number of intellectual property registrations licensed, or number of new health products or medical devices licensed in the last five years ≥ 3.	Evaluated period: Five years prior to the application. RD: Article 11.1 c) **THRESHOLDS: EXCELLENT > 10; ACCEPTABLE 3-10; NON-COMPLIANT < 3**
3.1.3.5	Annual income from inventions exploitation agreements is monitored in relation to the investment made in the year in the protection of inventions.	ETCI indicator. Calculation: Return on investment = (Annual income from invention exploitation agreements/Investment made over the year for the protection of inventions) * 100. Annual income from invention exploitation agreements: exploitation agreements with third parties for patents, utility models, and plant varieties. Includes licensing agreements, license options, and assignment of ownership. Investment made over the year for the protection of inventions: see indicator 3.1.3.2. Verify with operating account and/or audited accounts. Evaluated period: Five years prior to the application. RD: Article 11.1 c)

3.2 Scientific communication and participation.		
3.2.1 Impact-oriented training for scientists.		
No./Code	**Quality criterion**	**Comments**
Verification: Training plan. Report of the training plan for the year prior to the accreditation application. Record of training activities carried out at IIS.		
3.2.1.1	At least once in the last year, training activities have been conducted on: Scientific communication aimed at key non-scientific stakeholders. Mechanisms for translation to healthcare practice.	Training activities for IIS staff with the aim of improving their scientific communication skills aimed at citizens without a research profile. Training activities for IIS staff with the aim of improving their skills in the translation of research results. Training activities are considered to be those included in the training plan and recorded in the IIS information system. Evaluated period: Year prior to the application. RD: Articles 4 g) and 11.1 d) RRI.
		THRESHOLDS: EXCELLENT ≥ 4; ACCEPTABLE 1-3; NON-COMPLIANT < 1
3.2.1.2	At least once in the last two years, training activities have been carried out on participation and co-creation in scientific research or other ways of opening up participation in research to key non-scientific stakeholders.	Training activities will be considered to be those included in the training plan and included in the IIS information system. Verify, through documentation, in the IIS training plan report. See Glossary for the definition of co-creation and participation. Evaluated period: Two years prior to the application. RD: Articles 4 g) and 11.1 d) RRI.
		THRESHOLDS: EXCELLENT ≥ 4; ACCEPTABLE 1-3; NON-COMPLIANT < 1
3.2.2 Scientific communication plan.		
No./Code	**Quality criterion**	**Comments**
Verification: IIS communication plan. IIS information system. IIS Reports.		
3.2.2.1	The communication plan aligns the objectives of the PE and the plan for translation to and impact on society (see 3.1.1) and is oriented towards the outside world of the IIS and also towards creating internal synergies between lines of research.	Verify through documentation. Confirm with participants from different lines. Evaluation period in accreditation: Five years prior to the application. Evaluation period in accreditation renewal: Two years prior to the application. RRI.
3.2.2.2	External scientific communication includes at least two annual actions to: Provide visibility to the IIS. Reinforce the objectives of the PE. Support the plan for the translation to and impact on society and the SNS.	List of activities carried out. Verify, through documentation, the organization, attendees, and evaluation of the actions carried out. • Evaluation period in accreditation: Five years prior to the application. • Evaluation period in accreditation renewal: Two years prior to the application. RRI.
		THRESHOLDS: EXCELLENT > 5; ACCEPTABLE 2-5; NON-COMPLIANT < 2

3.2.2.3	Internal scientific communication includes at least five actions to: • Disseminate knowledge in the IIS and the hospital and primary care environment. • Identify and enhance synergies between lines of research.	List of activities carried out. Record of IIS activities in the information system. • Evaluation period in accreditation: Five years prior to the application. • Evaluation period in accreditation renewal: Two years prior to the application. RRI.
		THRESHOLDS: EXCELLENT ≥ 10; ACCEPTABLE 5-9; NON-COMPLIANT < 5
3.2.3 Stakeholder participation		
No./Code	Quality criterion	Comments
Verification: Activity records.		
3.2.3.1	IIS has involved key non-scientific stakeholders in the design of the PE.	Glossary: see the definition of key stakeholder and participation. Verify with the management team and in the documentation of the meetings for the design of the current PE, as well as the prioritization of the lines of research. Evaluation period: Five years prior to the application. RRI.
3.2.3.2	Key non-scientific stakeholders participate in governing bodies.	Minutes of the meetings of the governing bodies during the evaluated period. Evaluated period: Year prior to the application. RRI.
3.2.3.3	In research projects from the last two years, there is participation of key non-scientific stakeholders in the design of the research. (See Glossary for the definition of participation).	Calculation: (Number of research projects with participation of key non-scientific stakeholders/Number of research projects carried out at IIS in the last two years) *100. Evaluated period: Two years prior to the application. RRI.
		THRESHOLDS: EXCELLENT ≥ 50%; ACCEPTABLE 10-49%; NON-COMPLIANT < 10%

Technical guide for the evaluation of the accreditation of biomedical or health research institutes

Glossary

GOBIERNO DE ESPAÑA
MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES
Instituto de Salud Carlos III
Subdirección General de Evaluación y Fomento de la Investigación

Minutes: Document that records what happened, was discussed or agreed upon at a meeting. The date, attendees and a summary of the topics discussed and the agreements or decisions made must be included.

Dissemination activities: Activities for the diffusion, communication, or promotion of Science and Technology.

Key stakeholders or system stakeholders: Included in this term are individuals and institutions other than researchers who may contribute to or receive value from the research by playing a role in both the scientific process and the 'purpose', 'benefit', or 'use' of the research. That is: decision-makers, managers, and planners of R&D&I in teaching and healthcare; professionals working in clinics, public health, or the social and healthcare sector; teaching staff; scientific societies, civil society organizations, patient and caregiver associations, NGOs; industry; the media; citizens.

Non-scientific stakeholders: People who are not involved in research or R&D&I management, but who can add value to scientific activity by playing a role in both the scientific process and in the "purpose", "benefit", or use of its results. This is understood regardless of the mechanism of incorporation as a non-scientific stakeholder, whether at the proposal of organizations (scientific societies, NGOs, patient associations, etc.) or by personal invitation.

Human resources training: A set of activities aimed at addressing the needs identified by the Health Research Institute (IIS) in terms of human resources adaptation and geared towards expanding the knowledge, skills, and abilities of researchers, technical staff, and management staff, enabling them to carry out their activities and/or responsibilities in a more appropriate and efficient manner. This includes actions with the following profiles, or of a similar scope: research staff training contracts; competitive intramural projects, including the co-funding of staff associated with them; institutional programs for the promotion of research; training programs; mobility grants; grants for internships aimed at acquiring technical skills. Co-funding commitments acquired through the award of contracts and/or human resources grants obtained in competitive public calls for proposals will not be taken into consideration. Concepts such as the economic item corresponding to the registered grant from the Autonomous Community and structural costs are excluded.

Citation: Reference to an earlier, indexed document, included in a published original. It is called self-citation when the researchers / authors who make the reference are also the authors of the cited document.

Co-creation in research: Co-creation is a concept that originated in the business world of innovation. It involves bringing together different parties or social stakeholders to jointly produce a result that provides mutual value to all parties. In the case of research, it would involve joint work between stakeholders in the research system to create results of value to all parties. This may include researchers who do not naturally work together, and other potential 'users' or 'beneficiaries' of the research, such as technology agents, healthcare service or product providers, caregivers, patients, etc.

Commissions with the participation of non-scientific stakeholders: The participation of non-scientific stakeholders in the following commissions will not be taken into consideration: Research Ethics Committee (CEI) and Ethics Committee for Drugs Research (CEIm). Commissions that have not been approved by the highest governing body of the IIS or by the person exercising delegated authority will also not be taken into consideration.

Indirect costs: The indirect cost of a research project or contract refers to overhead or administrative expenses that cannot be directly attributed to a specific activity, product, project, or cost center, but which are necessary to carry out research activities. These include expenses related to infrastructure, general services, administration, maintenance, among others.

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- Share alike: Authorized use includes the creation of derivative works, provided that they retain the same license when disclosed.

For more information, see: https://creativecommons.org/share-your-work/cclicenses/

Competitive calls for proposals: Calls for research funding proposals in open and public competition. The researchers/groups or institutions that compete are subject to evaluation, according to open access regulations, which establish the evaluation criteria and application methodology. Depending on the type of institution issuing the call, a distinction is made between public competitive calls (issued by public administrations or agencies dependent on them, e.g., Horizon Europe, AES, etc.) and private competitive calls (issued by institutions/foundations/corporations not linked to public administrations, e.g., Mutua Madrileña, LaCaixa, etc.). Depending on the scope of application, a distinction is made between competitive calls for proposals at the regional, state, and international levels (including those at the European level).

Data susceptible to deposit in open repositories: In particular, data obtained by genotyping (either in human samples or in samples of animal or microorganism origin) and/or data corresponding to phenotypic characterization, including epidemiological, clinical, environmental, and socioeconomic information, among others, are susceptible to being deposited. Genomic data includes genome-wide association studies (GWAS), single nucleotide polymorphism (SNP) matrices and genome sequencing, transcriptomic, metagenomic, epigenomic, and gene expression data. It is recommended to consult the document on this matter prepared by PEASIIS, available since November 2025.

Institutional Document: A document published by an international organization, or a national or international evaluation agency, which has been commissioned by the latter to support decisions on health, scientific, or health-related policies.

Scientific dissemination: Actions or products designed to inform citizens within target groups of the scientific results achieved. These actions are generally aimed at providing information, participation, or support in decision making based on the knowledge generated by scientific activity. Example: people with Parkinson's disease, diabetes, multiple sclerosis, etc., including family members or main caregivers, associations, etc. Regular media outreach activities (press releases, website, radio, etc.) are excluded.

Research group: A group of researchers, led by a director or group leader, who demonstrate stable collaboration, sharing one or more lines of research, and that meet, at a minimum, the following criteria:

1. Joint development of research projects funded through competitive public, state, or international calls for proposals in the last five years.
2. Common scientific output, with shared authorship publications, maintained over time, with proven quality and sufficient number.

Established / senior research group: Research groups that demonstrate, at least in the last five years:

- Resource acquisition in public, state or international competitive calls for resources for the development of their lines of research and incorporation of human resources.
- Stable lines of research, developed with successive projects.
- Collaborative scientific output of proven quality, together with innovation activity expressed in the sustained development, during the same period, of innovation and translation actions in the clinical field (implementation of Clinical Practice Guidelines (GPCs), innovation in care processes) and in the productive sector (patents, development of health products/medical devices, etc.).
- Proven ability to train predoctoral researchers and technical support staff.

Recognized research group: Groups that meet one of the following criteria:

- Research group that has independently obtained funding for their first project in competitive public calls for proposals at the state level in the last three years.
- Group with stable research activity that has obtained at least two research projects in competitive public calls for proposals at the regional level in the last five years, with authorship (as first, last, or corresponding author) in publications of proven quality in its field of study.

Associated clinical group: This status shall be granted to groups of professionals engaged in clinical activity who can demonstrate, over the last five years, stable collaboration with another IIS research group (whether established or recognized), carrying out activities such as participant recruitment, data collection, and/or information analysis in competitive research projects. This status shall also be granted to groups with research activity in isolated projects with non-competitive funding.

Clinical practice guidelines and institutional documents: Documents containing a set of recommendations, developed systematically, to assist clinicians and patients in the decision-making process regarding the most appropriate interventions to resolve a clinical problem in specific healthcare circumstances. Only GPCs published in peer-reviewed journals or commissioned (by scientific societies or the administration) shall be taken into consideration. That is, GPCs developed by the institution itself and intended for its professionals shall not be taken into consideration. Institutional documents refer to participation in recognized national or international agencies that prepare recommendations or positions on health risk issues or public health positions.

Impact on society: Defined as any effect, change, or benefit in:

- The health and quality of life of patients and people in general.
- The prevention, diagnosis, and treatment of diseases in the health system.
- The accessibility, cost-effectiveness, and sustainability of the health system.
- The economy, society, culture, public policies and services, and the environment. The 'academic' impact of scientific knowledge generation shall not be taken into consideration.

Normalized Impact Factor: Relative citation rate compared to the global median, within the same discipline and year of publication, for the same center/institute. It expresses the ability to achieve citations per published article, using international values for the area of knowledge as a normalization reference, and considering the year of publication and document type.

Intra-institute Collaboration Factor: This consists of two factors:

a. Percentage of collaborative publications by researchers affiliated with groups from at least two institutions that form part of the IIS. Consider:

- Collaboration is not linked to a group leader but to individual researchers.
- These are collaborations between researchers affiliated with IIS groups, but who are each researchers at different institutions, these institutions being understood as those with which they have a contractual relationship and which are part of the legal relationship of the IIS.
- These collaborative publications would include those obtained in mixed groups, i.e., those produced by researchers from the same group but with contractual relationships with at least two different institutions that are part of the legal relationship of the IIS.

b. Percentage of collaborative publications by researchers belonging to different IIS groups. Consideration shall be given to:

- Publications produced by researchers affiliated with different IIS groups.
- In the event that the same researcher is affiliated with two different groups, this researcher shall be considered to be affiliated with the group with which they have been working steadily for the longest period of time, i.e., the first group they joined at the IIS.

Health innovation: Innovation enables health systems to incorporate the knowledge generated by their professionals and use it in the development of their social mission. It is defined as the result of the process of applying scientific and technical knowledge to solving problems that arise in health, promoting change in the products, services, or organization of the institution. In the healthcare field, if the technology is newly applied, it will be considered an innovation, whether or not it is commercialized, when it introduces diagnostic, therapeutic, prognostic, or preventive improvements, contributes to promoting health, improving the approach to and monitoring of disease, preventing avoidable costs or interventions, promoting the patient's quality of life, etc. The user-centered innovation is an approach to innovation that aims to identify latent needs or unresolved problems of users, so as to generate a new range of products or services designed to meet users' needs in a more efficient, reliable, and secure manner. A distinction can be made between: product or service innovation; process innovation; and organizational management innovation.

Integrity in research: Values and principles regulating research activity to maximize its ethics, quality, independence, and respect for good practice. The "European Code of Conduct for Integrity in Research"[1] developed in 2011 by All European Academies (ALLEA) and the European Science Foundation (ESF), last revised in 2018, is taken as a reference.

[1] https://www.allea.org/wp-content/uploads/2018/01/SP_ALLEA_Codigo_Europeo_de_Conducta_para_la_Integridad_en_la_Investigacion.pdf

Research in health care: This term provides an integrated view of research from a care perspective, as a term that refers to all research relevant to the nursing profession.

Recognized researcher: Corresponds to the definition of "R2, *Recognized Researcher*" in the European classification of researcher profiles.

Established researcher: Corresponds to the definition of "R3, *Established Researcher*" and "R4, *Leading Researcher*" in the European classification of researcher profiles.

First stage researcher: Corresponds to the definition of "R1, *First Stage Researcher*" in the European classification of researcher profiles.

These categories are available at:

https://euraxess.ec.europa.eu/europe/career-development/training-researchers/research-profiles-descriptors.

Principal Investigator (PI): Researcher affiliated with (i.e., with a civil service, statutory, or employment relationship with one of the institutions that form part of the legal relationship of the IIS) responsible for at least one competitive project that is ongoing during the evaluated period (active projects).

Recognized Principal Investigator: Researcher affiliated with one of the institutions that form the IIS or contracted by the IIS, responsible for at least one competitive project that is ongoing during the evaluated period. Holding the status of recognized in their activity as PI applies when the time they have been accredited as leader of projects funded in competitive calls for proposals is less than four years. This may correspond to the stages of researcher profile R2, in an advanced phase, or R3, in an initial phase.

Participation in research: For the European Commission, participation in research is the interaction between the researcher (or team of researchers) and the system stakeholders and/or the general public. This interaction can take various forms:

- **Reporting**: One-way interaction where the research activity is communicated to the system stakeholders or the general public with balanced and objective information.
- **Consulting**: Researchers obtain the views of the system stakeholders or the general public on key aspects of the research.
- **Creating involvement**: Work is done in a two-way manner (dialogue) and directly with stakeholders or key stakeholders so that aspirations and concerns are understood and considered in a shared and consistent manner before decisions are made.
- **Co-creating:** Work is done in a multi-way manner by partnering with different system stakeholders in every aspect of the decision in research and in implementation.

Patent: Intellectual property title granted to the author of a technological invention, granting them the exclusive right to exploit the invention, and which exploitation may generate a certain amount of income. The patent is granted in a specific territory (at the state, European, or international level) and for a specific period of time (20 years) in exchange for making the invention public knowledge.

Patent applied for or registered patent: Patent that has been filed for granting or for licensing. In Spain, it is applied for at the Spanish Patent and Trademark Office, but it can also be applied for at other international or foreign agencies.

Licensed patent: Patent whose owner grants the rights to exploit it to a third party. The license is also a contract, which sets out the conditions for granting the exploitation rights, including the obligation to achieve results that the licensee must comply with. Since the license is a contract stipulating these obligations, failure to comply with them may result in the termination of the license agreement and the return of the exploitation rights to the licensor.

IIS Strategic Plan: A five-year action program that defines the scientific objectives of the IIS, agreed upon by its member institutions, as well as the strategy for achieving them. It is based on an analysis of both the internal and external environment (capabilities, needs). It has a continuous monitoring and evaluation system to ensure that the proposed objectives are achieved. It is the core element of the IIS scientific policy and, as such, guides all its plans (training, quality, integration, etc.) and actions.

Research Profile: Defined by the level of training and skills demonstrated by each researcher in the course of their work, it reflects their progression in terms of training and leadership capacity in R&D&I teams. To standardize criteria, the European classification of researcher profiles available on the EURAXESS website is used[2]:

- *R1, First Stage Researcher.*
- R2, *Recognized Researcher.*
- R3, *Established Researcher.*
- R4, *Leading Researcher.*

Healthcare research staff: Healthcare professionals working in a healthcare position in one of the healthcare institutions that form part of the IIS, who carry out activities as researchers affiliated with the IIS, forming part of one of its research groups, regardless of their healthcare duties.

Associate Professor: Person holding accreditation as an Associate Professor granted by a state or regional agency (e.g., ANECA, etc.).

Adjunct professor: Individual occupying a teaching and research position affiliated with a university, which entails maintaining an active healthcare appointment at a public health institution.

Active project: An active project is considered to be a project that is currently in progress, including any extensions granted to it in the year evaluated and funded through competitive calls for proposals from public bodies, whether national in the State Plan or international. Networks and consortia established at the state level (institutional strengthening grants) are excluded from the definition of project, but not research projects funded by networks or consortia. Funding obtained in competitive calls for proposals for human resources, awards, infrastructure grants, and grants for disclosure purposes are also not included.

Publication or indexed publication: Original article or review published in a scientific journal indexed in the Journal Citations Report (JCR).

General public: Unlike system stakeholders, the general public are the people who have no defined role in the scientific process or in its 'purpose', 'benefit', or 'use'.

JCR Q1 journals: Publications ranked in the top 25% in terms of impact factor among those included in the Journal Citation Reports (JCR) in the same subject area or field of knowledge for a defined period of time.

Spin-offs and start-ups: Spin-off companies that have been promoted by one or more researchers and are created, with the support of the IIS, with the aim of exploiting the results and knowledge that these researchers have obtained in their research activity. If these companies prosper and make a profit, they pay a portion of their income to the host institution as a financial return on the investment made by the institution (infrastructure, resources, human resources, etc.).

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[2] https://euraxess.ec.europa.eu/europe/career-development/training-researchers/research-profiles-descriptors.

Subjects in research activity: Subjects who participate in research studies and/or provide samples or data for research purposes, in accordance with good research practice standards.

ACRONYMS

AP: Primary Care.

C&C: Researcher's Charter and Code of Conduct for the Recruitment of Researchers.

CCAA: Autonomous Communities.

CCE: External Scientific Committee.

CCI: Internal Scientific Committee.

CEIC: Clinical Research Ethics Committee.

EOSC: European Open Science Cloud.

ETCI: Knowledge Transfer and Innovation Survey.

EU: European Union.

FAIR: Findable, Accessible, Interoperable, and Reusable.

GPC: Clinical Practice Guideline.

HRS4R: Human Resources Strategy for Researchers.

IIS: Health Research Institute.

JCR: Journal Citation Report.

OTC: Knowledge Transfer Office.

PESTLE: Political, Economic, Social, Technological, Legal, and Environmental.

PE: Strategic Plan.

PGD: Data Management Plan.

PI: Principal Investigator.

RD: Royal Decree.

RRI: Responsible Research and Innovation.

SNS: National Health System.

SWOT: Strengths, Weaknesses, Opportunities, and Threats.