POS-IISFJD 2024-2028
V.2

OPEN SCIENCE POLICY 2024-2028

CHANGES FROM THE PREVIOUS VERSION		
Version	**Date**	**Change**
1	November 2019	
2	November 2023	Context Update and Review of Proposed Actions

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1. INTRODUCTION AND BACKGROUND

On November 21st, 2014, under the Italian Presidency, the **Rome Declaration on Responsible Research and Innovation** (RRI) was adopted. This document defines RRI as the **process of aligning research and innovation with the values, needs and expectations of society**, as a means of ensuring that R&D&I contributes to the development of smart, inclusive and appropriate solutions to societal challenges. It is understood as a process that enables the identification of solutions that might otherwise go unnoticed by involving new perspectives, new innovators and new talent from across society. In this way, RRI helps generate the trust necessary for citizens to engage with public and private institutions, both in supporting R&D&I and in the adoption of innovative products and services. Finally, the RRI process includes the assessment of risks, and the consideration of how such risks should be managed.

The Rome Declaration represents a **call to action** for **institutions**, **Member States, authorities and organisations involved in the funding** of innovation to build RRI capacities and to review and adapt the metrics and frameworks associated with R&D&I. It also calls upon **organisations engaged in research and innovation** to implement the changes necessary to promote RRI. Among the changes required of organisations conducting R&D&I activities, the following are highlighted:

- Reviewing procedures and practices to identify barriers to RRI and opportunities for its promotion at the organisational level.
- Creating experimental spaces to engage societal stakeholders in the research process, both as sources of knowledge and as partners in innovation.
- Developing and implementing strategies and guidelines for the recognition and promotion of RRI.
- Adapting curriculum and developing training activities to raise awareness and foster knowledge, experience and competencies in RRI.
- Incorporating RRI criteria into the assessment and evaluation of research staff.

The key pillars of RRI are:



1.- Responsible Research and Innovation. Based on information available from the RRI Tools (https://www.rri-tools.eu/)

In this context, **Open Science** represents a paradigm shift in the way science is conducted, extending beyond the concept of open access to R&D&I results, commonly referred to as Open Access. The Foster dictionary defines Open Science as the practice of conducting science in such a way that others can collaborate and contribute, where research data, laboratory notebooks and other research processes are made freely available under licences that allow the reuse, redistribution and reproduction of research outputs, the underlying data, and the methodologies on which they are based.

La Ciencia Abierta es un conocimiento transparente y accesible que se comparte y se desarrolla a través de redes de colaboración[1].

(Vicente-Sáez & Martínez-Fuentes 2018).

Open science is an essential component of good scientific practice, a concept closely linked to transparency towards both the research community and society at large, maximising public benefit while avoiding the waste of resources. The application of open science principles helps to strengthen trust in science itself and to accelerate the pace at which new discoveries are generated. It also enables constructive feedback on research processes and outcomes, while contributing to internationalisation and inclusiveness. Among the reasons why open science has become a central focus of R&D&I policies, the literature identifies, among others, (1) the slowing

[1] "*Open Science is transparent and accessible knowledge that is shared and further developed through collaborative networks*

pace of scientific progress, (2) concerns regarding the reliability of published results, associated with the failure to replicate published studies and the tendency for studies reporting positive results to be more likely to be published than those reporting negative findings, and (3) the loss of resources resulting from a lack of openness in research.

An open research process should encompass all stages of the research cycle, from study design to replication, including data collection, as well as the publication and dissemination of results:

- By specifying the study design, hypothesis and analysis plan before the project is executed.
- Research data are the direct product of scientific research and constitute a crucial element to ensure the reproducibility of experiments. They also enable data reuse, extending their value and allowing new research questions to be addressed without the need to duplicate experiments. Consequently, open research data should be accessible to anyone wishing to use, share or build upon them.
- To support the reproducibility of research and enable the reuse of findings in other studies, it is essential that the methodologies applied are made openly available and accessible.
- The sharing of laboratory notebooks facilitates the dissemination of knowledge generated during the R&D&I process, enhancing transparency and reproducibility while also supporting the protection and proper management of intellectual property.
- The open publication of research results through Open Access facilitates the rapid advancement of research and provides a means of returning to society the benefits generated by publicly funded research.
- The replication of results is a fundamental aspect of the scientific method, as it enables the validation of research findings while also enhancing the credibility of results and strengthening the confidence of research funders.

LMU Open Science Center (available at https://osf.io/mcjnq/)

Although the concept and implementation of Open Science continue to evolve, the areas that are currently most developed and widely recognised are Open Access, Open Data, Open Peer

Review and Open-Source Software, all of which constitute core elements of the various Open Science models. Other dimensions, such as Citizen Science and Open Education, still require further discussion, refinement and definition. The full implementation of Open Science still requires substantial changes not only in the routine conduct of R&D&I activities, but also in the procedures, mechanisms and assessment metrics used to recognise and reward scientific achievements, among other aspects (source: Foster Platform, available at https://www.fosteropenscience.eu/). Nevertheless, open science has already become an established reality and has been incorporated into the policies and regulations governing the development and funding of R&D&I, particularly in relation to open access to research outputs.

The main regulations, legislation, agreements and policy documents that promote and regulate Open Science at the international, national and regional levels are outlined below.

1. Open science policies, strategies and initiatives – international context

Commission Recommendation (EU) 2018/790 of the 25th of April of 2018 on access to and preservation of scientific information:

https://eur-lex.europa.eu/legal-content/ES/TXT/PDF/?uri=CELEX:32018H0790

European Union Research and Innovation Framework Programme for the period 2021–2027, Horizon Europe, which includes Open Science as a cross-cutting principle and as a subject of research and innovation within several work programmes.

https://www.horizonteeuropa.es/que-es

Recommendation on Open Science of the United Nations Educational, Scientific and Cultural Organization (UNESCO), 2021.

https://www.unesco.org/es/legal-affairs/recommendation-open-science

2. Open science policies, strategies and promotion initiatives – national context

Law 14/2011 of the 1st of June on Science, Technology and Innovation (Ley 14/2011, de 1 de junio, de la Ciencia, la Tecnología y la Innovación), Articles 37 and 38.

https://www.boe.es/buscar/act.php?id=BOE-A-2011-9617

Spanish Strategy for Science, Technology and Innovation 2021–2027 (Estrategia Española de Ciencia, Tecnología e Innovación, EECTI 2021–2027).

https://www.ciencia.gob.es/dam/jcr:e8183a4d-3164-4f30-ac5f-d75f1ad55059/EECTI-2021-2027.pdf

State Plans for Scientific, Technical and Innovation Research.

https://www.ciencia.gob.es/dam/jcr:e1f1deb1-7321-4dd9-b8ca-f97ece358d1c/Plan_Estatal_de_Investigacion_Cientifica_y_Tecnica_y_de_Innovacion_2021-2023.pdf

Organic Law 2/2023 of the 22nd of March on the Spanish University System (Ley Orgánica del Sistema Universitario, LOSU), Article 12.

https://www.boe.es/buscar/act.php?id=BOE-A-2023-7500

The National Open Science Strategy (in Spanish Estrategia Nacional de Ciencia Abierta, also known as ENCA 2023–2027) is built upon the various commitments to Open Science adopted by different stakeholders within the research and innovation system.

https://www.ciencia.gob.es/Estrategias-y-Planes/Estrategias/ENCA.html

The Strategic Action in Health (in Spanish Acción Estratégica en Salud**,** also known as AES) requires that any scientific publications arising from the funding awarded be made available through open access.

https://www.isciii.es/documents/20119/526965/BOE_EXTRACTO_AES2024.pdf/e2a4f600-4426-b5e2-0cb7-42572f1f145d

The Technical Guide for the Evaluation of Health Research Institutes establishes the implementation of an Open Science policy as a requirement for these institutions.

https://www.isciii.es/institutos-investigacion-sanitaria-procedimientos

3. Open science policies, strategies and promotion initiatives – Regional context (Community of Madrid)

Order 679/2009 of the 19th of February, that establishes the regulatory framework for grants to R&D activity programmes involving research groups in the Community of Madrid and the call for proposals in technology co-financed by the European Social Fund (Article 7.9).

https://mcyt.educa.madrid.org/uploads/informacionidi/convocatorias/2009/documentos/Orden_679-2009_19-02-09_Convocatoria_Ayuda_Programas_Actividades_Tecnonologia.pdf

The Fundación Jiménez Díaz Health Research Institute (IIS-FJD) was originally established through the association of research groups from Fundación Jiménez Díaz University Hospital and the Autonomous University of Madrid. Subsequently, through a significant modification to its structure, the Rey Juan Carlos University Hospital, the Infanta Elena University Hospital, the General de Villalba University Hospital and the CIEMAT were incorporated into the Institute.

The institutions comprising IIS-FJD have implemented the following actions in the field of Open Science:

The Autonomous University of Madrid (UAM) is a member of the Madroño Consortium, the Consortium of Universities of the Community of Madrid and UNED for Library Cooperation. On December 5th, 2017, the Consortium signed a Declaration in Support of Open Access to Academic and Scientific Information, through which it publicly expressed its commitment to the principles of Open Science and promoted the adoption of measures to support its implementation. The recommendations set out in this Declaration apply to researchers, the universities which belong to the Consortium and research centres within the Community of Madrid. The document establishes a set of guidelines aimed at fostering the implementation of Open Science at all levels.

Additionally, the consortium publishes its **Research Data Management Policy**.

Among the consortium's active working groups is an open science working group, whose efforts have led to the launch of the **INVESTIGAM Open Science Portal**, aimed at disseminating the research outputs and achievements of member and associated institutions.

In addition, **e-cienciaDatos** is a multidisciplinary data repository designed to host scientific datasets generated by researchers from the public universities of the Community of Madrid and UNED, with the aim of ensuring their preservation and facilitating their access and reuse.

IIS-FJD has implemented the following actions in the field of open science:

The Epidemiology and Biostatistics Unit provides support to IIS-FJD researchers in a range of areas, including the selection of study design and methodology, sample size calculation, randomisation procedures, the design of data collection forms, and statistical analysis. In 2023, the Unit provided guidance and support in a total of 223 consultations requested by Institute staff. Moreover, unit staff deliver the accredited Biostatistics course and the Good Clinical

Practice (GCP) and Clinical Trial Development course. The IIS-FJD Research Ethics Committee for Medicinal Products provides advice to researchers on matters related to data security and data management. In addition, the Innovation and Projects Area provides support for the development of research data management plans for projects that require them, particularly European-funded projects. The Bioinformatics unit also provides collaborative support to research groups upon request in the processing of data suitable for bioinformatic analysis or integration, including large-scale datasets, commonly referred to as omics data.

Furthermore, IIS-FJD has applied to the RRI award calls issued by the Carlos III Health Institute. As a result of these initiatives, IIS-FJD was awarded prizes in the 2020 and 2022 editions:

- 2020: “Promoting Responsible Conduct in Research: Development of Scientific Integrity Policies”. Link to the project summary:
    - https://www.youtube.com/watch?reload=9&v=dFnN_ttgvYM
- 2022: “Moving towards Open Science”. Link to the project summary:
    - https://www.youtube.com/watch?v=pl48VZIRjS8

This document establishes the policy and actions through which IIS-FJD promotes and advances Open Science within its sphere of competence.

2. OPEN SCIENCE PRINCIPLES

IIS-FJD adopts the following Open Science principles:

1. IIS-FJD is committed to Open Access policies as a means of making research more effective and its results more visible, reducing duplication of effort, fostering knowledge translation and technology transfer, and promoting innovation and collaboration.
2. The Institute shall promote Open Science, and particularly the openness of the scientific outputs arising from its research activities, whether in the form of publications, data, methodologies or processes, while contributing, whenever possible, to ensuring that researchers retain their rights over their publications.
3. The Institute shall promote the publication of research results arising from its activities in open-access journals or through open-access platforms.
4. IIS-FJD will facilitate the open publication of research data in recognised and standardised repositories, such as the European Open Science Cloud.
5. It will collaborate with other stakeholders within the Science, Technology and Innovation System to promote the publication of research data in recognised, standardised repositories that are compatible and interoperable with European research infrastructures.
6. The Institute shall promote science with and for society within its area of activity, fostering societal engagement within the framework of Responsible Research and Innovation (RRI).
7. It will align with international guidelines for the improved assessment and evaluation of the scientific activities of its professionals, incorporating aspects, tools and initiatives associated with the Coalition CoARA.

3. ACTIONS FOR THE IMPLEMENTATION OF THE IIS-FJD OPEN SCIENCE POLICY

IIS-FJD will undertake the following actions to facilitate the implementation of these Open Science principles:

a) **Training in open science** for researchers and for technical and management staff within the Institute, incorporating specific Open Science actions into its R&D&I Training Plan. In particular, at least one training activity will be delivered annually focusing on the following topics:

   a. Open Science principles.

   b. Open Access publishing options.

   c. Training on intellectual property rights, copyright and Creative Commons licences.

   d. Development of research data management plans, with particular emphasis on regulatory requirements related to data protection.

   e. Scientific communication aimed at key non-scientific stakeholders.

   f. Participation and co-creation with society.

   g. Mechanisms for the translation and transfer of research results.

   h. Aspects related to Responsible Research and Innovation.

b) **Creation of a joint working group** with UAM and FJD to avoid duplication and enhance the efficiency of Open Science-related efforts. This working group will **establish the Open Science roadmap for the Institute**, making use of existing resources, such as repositories, training activities, infrastructures and other available tools, thereby avoiding duplication and maximising their impact.

c) Expansion of the IIS-FJD service portfolio to provide support **for researchers in the field of open science** to improve their knowledge and capabilities in areas such as Open Access publishing and the development of Research Data Management Plans.

d) To consolidate its **strategy for engagement with society**, facilitating both the dissemination of the knowledge generated and the participation of society in the

research and innovation process. This activity is also included in the IIS-FJD Strategic Plan 2024–2028 (Action Plan 6.4). In this regard, close collaboration has been established with the Institute's Advisory Council of Social Stakeholders (in Spanish known as CAAS).

e) To facilitate, whenever it is possible, the **funding of open access publications through both the green and gold routes**. Through the green route, authors deposit their publications in an open repository after the applicable freezing period has expired (typically between 12 and 24 months). Under the gold route, articles are made immediately and permanently accessible to any interested reader upon publication, without any freezing period. This activity focuses initially on on researchers and groups with more limited resources available to cover open access publication costs

f) To develop and implement an IIS-FJD **CoARA Action Plan** to align the assessment of research activities with emerging trends in research evaluation and assessment. To this end, it will draw upon the resources and guidance provided by the Coalition CoARA, which has developed a guide for the design of this Action Plan. (https://coara.eu/news/guidelines-for-action-plan-preparations-published).

The further implementation of these actions, which have been progressively developed in recent years, will continue from 2024 onwards.

4. MONITORING AND EVALUATION

To monitor the implementation of the Open Science Policy, a specific annual assessment will be executed and it will focus on the following indicators:

- Total of publications arising from publicly funded projects published through Open Access channels (Target ≥25%).
- Percentage of research data generated through projects funded by national, European and/or international competitive public funding programmes that are deposited in open repositories during the year under evaluation (Target ≥50%).
- Total of open science training activities delivered (Target ≥ 1/year).
- Volume of Open Access advisory services provided.
- Total of research data management plans developed/requested (Target= 100% requested/year).
- Number and percentage of projects involving the participation of societal stakeholders in their design and implementation (Target ≥10% over the previous two years).
- Total of outreach activities aimed at the public over the previous five years (Target ≥5).

The results will be analysed by the Research Committee, which may propose any improvement actions it considers necessary to the IIS-FJD Scientific Directorate. These actions will be jointly reviewed by the Scientific Directorate and the Institute's Management Directorate. The outcome will then be presented to the External Scientific Committee and, subsequently, to the governing body of IIS-FJD for approval.