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IIS-FJD Code of good research practice

- Approved by the IIS-FJD Integrity Committee in December 2024.

March 2025

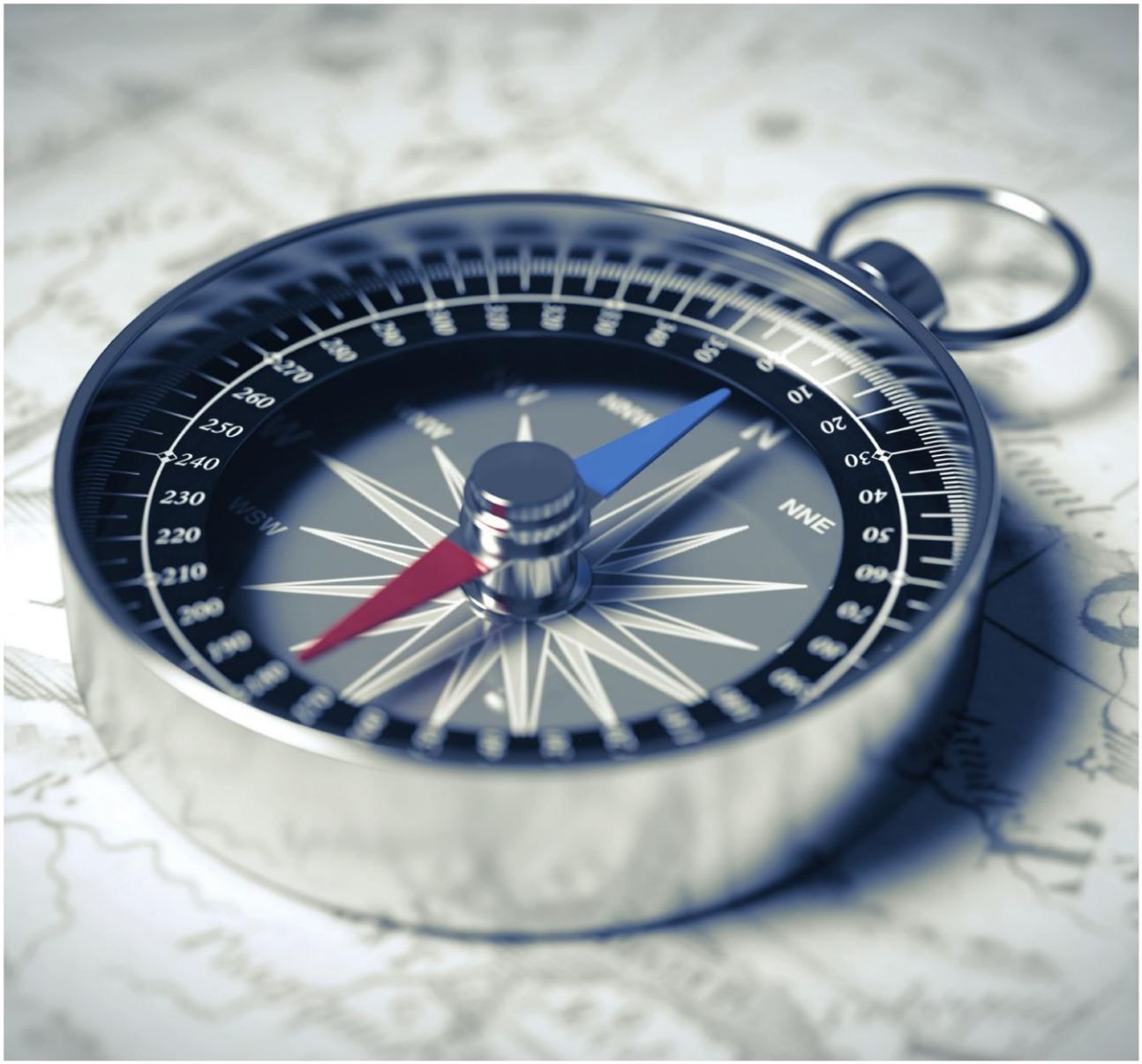
HR EXCELLENCE IN RESEARCH

IIS FJD

INSTITUTO DE INVESTIGACIÓN SANITARIA FUNDACIÓN JIMÉNEZ DÍAZ

Hospital Universitario Fundación Jiménez Díaz

Grupo quirónsalud



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Main Messages

- Good Research Practice is founded on the core principles underpinning Scientific Integrity: reliability, honesty, respect and accountability (ALLEA The European Code of Conduct for Research Integrity – Revised Edition 2023, Berlin. DOI 10.26356/ECOC)

- The responsible conduct of scientific research requires adherence to these principles throughout all stages of the research process, including the planning, proposal, conduct, analysis and dissemination of research results.

- These principles should also guide the training and supervision of researchers, the evaluation, review and editing of research projects, and the organisation, planning and management of research resources.

- All individuals involved in research are responsible for complying with these principles

- Deviations from Good Research Practice constitute a breach of professional responsibility, undermine the research process, damage relationships between researchers, erode trust in and the credibility of research, waste resources, and may expose research participants, users, society or the environment to unnecessary harm.

1. Introduction, objectives and scope

Law 16/2003 of the 28th of May on the Cohesion and Quality of the National Health System established in Article 50, which was subsequently repealed by Articles 88 and 89 of Law 14/2007 of the 3rd of July on Biomedical Research, that the establishment of Health Research Institutes (IIS) through the association of research centres should be promoted. The main objective of these Institutes is to bring basic and clinical research closer together and, secondly, to strengthen the concept of the hospital as a research centre.

In accordance with the principles established by the Carlos III Health Institute (ISCIII), Health Research Institutes "should be established on the basis of existing research centres and groups of proven quality which, through their association, meet the necessary requirements established in the Royal Decree 339/2004, to enhance the prestige of the centres comprising the Institute through institutional recognition, thereby facilitating an increase in human resources, infrastructure and new technologies to expand and consolidate the quality and capacity of research teams and research lines. To this end, the Ministry of Health and Consumer Affairs published Order SCO/1245/2006 in the Official State Gazette (BOE) of the 28th of April 2006, regulating the accreditation procedure. Our institution obtained its first accreditation as a Health Research Institute in December of 2010 for a five-year period. Since then, its accreditation has been renewed on two further occasions, in 2015 and 2021.

The mission of the IIS-FJD is to develop an environment for scientific management and basic, translational and clinical research aimed at addressing healthcare challenges within the National Health System and improving citizens' quality of life, based on proven quality and excellence, which enables the Institute to become a leading national and international reference centre. To achieve this, research activities must be governed by the scientific, methodological and ethical principles and values commonly accepted by the scientific community.

The objective of this IIS-FJD Code of Good Research Practice is to provide the Institute with a framework for action that is accepted and respected by all individuals conducting research activities within the institution. The planning, conduct and communication of research activities must be carried out according to the rules and guidelines set out herein, as well as with applicable national and international regulations and ethical standards. Regarding the national regulations, Law 14/2011 of the 1st of June on Science, Technology and Innovation, as amended by Law 17/2022 of the 5th of September, establishes as a fundamental objective the promotion of research, experimental development and innovation as key elements underpinning sustainable economic development and social well-being. Among the innovative measures introduced is the incorporation of a professional ethical dimension, reflected in the establishment of the Spanish Research Ethics Committee, which applies internationally accepted criteria and guidelines.

This Committee, which was recently established: (**https://www.lamoncloa.gob.es/serviciosdeprensa/notasprensa/ciencia-e-innovacion/Paginas/2023/270423-morant-comite-etica-investigacion.aspx**), is a collegiate, independent and advisory body on matters relating to professional ethics in research and Scientific Integrity and serves as the national reference body for scientific integrity and responsible research. Its functions include "establishing the general principles for the development of codes of good practice in scientific and technical research, including the management of conflicts of interest. These codes shall be developed by the ethics committees of organisations that conduct and fund research."

The IIS-FJD Code of Good Research Practice represents the commitment undertaken by IIS-FJD scientific staff to ensuring research quality and integrity. Accordingly, this Code applies to all research staff, including researchers in training or on placements who carry out scientific activities within the institution, as well as technical and research support staff, regardless of the nature of their relationship with IIS-FJD or whether such relationship is permanent or temporary.

2. Scientific integrity

2.1. Definition

Scientific Integrity can be defined as active adherence to the framework of principles, values and professional responsibilities that characterise responsible conduct in research and underpin Good Research Practice. Both researchers and research-performing institutions must observe and promote the principles of integrity in the conduct and teaching of research. The principles and values of Scientific Integrity include:

- Adherence to ethical codes of conduct within research teams and to Good Clinical Practice guidelines, as well as to the regulations applicable to research involving cell lines and laboratory animals.
- Protection of research participants.



- Intellectual honesty in the proposal, conduct and communication of research.
- A collaborative approach to scientific interaction and a willingness to share resources.
- Impartiality in the peer-review process.
- Accuracy in the written or oral representation of scientific contributions or proposals.
- Transparency regarding actual or potential conflicts of interest.
- Rigorous and dedicated leadership and supervision.

Codes of Good Research Practice comprise a set of **actions** that reflect the principles, values and responsibilities that constitute Scientific Integrity. They provide rules and guidelines for self-regulation and self-monitoring. Ensuring Scientific Integrity requires the involvement, training, monitoring and supervision of all staff, regardless of their seniority or position.

Researchers must act honestly regarding their own actions and those of other researchers. This responsibility extends to the full range of research-related activities, including experimental design, data generation and analysis, funding applications, the disclosure of actual or potential conflicts of interest, the publication of results, and the acknowledgement of all direct or indirect contributions made by colleagues, collaborators and others.

2.2. Deviations from good Research Practice

Deviations from good research practices violate professional responsibility, harm the research process, undermine relationships among researchers, erode trust in and the credibility of research, waste resources, and may expose research participants, users, society, or the environment to unnecessary harm.

Any deviation from the conduct of research based on the principles of Scientific Integrity is currently regarded as Research Misconduct (hereinafter RM). Scientific Fraud is understood as any form of Research Misconduct carried out with the primary intention of deception. It constitutes the most serious breach of the Code of Good Research Practice.



RM traditionally includes Fabrication (the invention of results and their recording or publication as if they were genuine), Falsification (the manipulation of research procedures or the alteration or omission of data or results), and Plagiarism (the appropriation of another person's research material without appropriate acknowledgement) in the proposal, conduct, review or communication of research results. In addition, there are other unacceptable practices, as described below:

- Allow funders, sponsors or other parties to compromise the independence and impartiality of the research process or the objectivity of its results.
- Misuse seniority to encourage breaches of research integrity or for personal gain.
- Unduly delay or hinder the work of other researchers.
- Misuse statistical analysis results, for example, to suggest statistical significance.
- Conceal the use of Generative Artificial Intelligence (GenAI) or other automated tools in content creation or the drafting of publications.
- Withhold research data or results without justification.
- Fragmenting research results to increase the number of publications (salami slicing)
- Citing sources selectively or inaccurately.
- Unnecessarily expanding the reference list of a study to satisfy editors, reviewers or colleagues, or to manipulate bibliometric data.
- Manipulating authorship or diminishing the role of other researchers in publications.
- Republishing substantial parts of one's own previous publications, including translations, without appropriately acknowledging or citing the original work (duplicate publication or self-plagiarism).
- Deliberately establishing, supporting or using journals, publishers, events or services that undermine research quality (predatory journals, predatory conferences and paper mills).
- Participating in reviewer and author cartels that collude to manipulate publications.
- Misrepresenting research achievements, data, participation or interests.
- Maliciously accusing a colleague of misconduct or other breaches.
- Ignoring suspected breaches of research integrity by others or concealing inappropriate institutional responses to cases of RM.

Retaliation against individuals who report a suspected case of Research Misconduct (whistleblowers) is also considered an unacceptable research practice.

2.3. Scientific integrity committee

IIS-FJD, as part of its commitment to promoting an institutional culture of Scientific Integrity, endorsed the National Declaration on Scientific Integrity in 2017 and has had a Scientific Integrity Committee (CIC) in place since that same year. The Committee's functions include promoting training and raising awareness among Institute staff regarding developments, needs and guidance relating to the ethical and professional aspects of biomedical research; ensuring compliance with the principles set out in this Code; and addressing queries and mediating in any conflicts that may arise in this area. The Committee's composition and operating procedures are set out in a specific document available in https://www.fjd.es/iis-fjd/en/organisational-structure/scientific-integrity-committee. In addition, the Committee is supported by the Quality Area and the Research Committee.

3. Responsibilities of researchers

3.1. Professional conduct

The researcher must be aware that they have responsibilities towards their employers, funding bodies and other public or private organisations, as well as towards ethical principles and society as a whole. In particular, researchers receiving public funding are responsible for the efficient use of taxpayers' funds. They must therefore adhere to the principles of sound financial management, transparency and efficiency, and cooperate with authorised audits of their research activities carried out by funding bodies, Research Ethics Committees or the relevant competent authority, as applicable.

Researchers should make every effort to ensure that their scientific activity is relevant to society and does not unnecessarily duplicate work carried out at other institutions. They must avoid conduct that deviates from the principles of Good Research Practice and respect the principles of intellectual property and shared ownership in the case of work conducted in collaboration with other researchers. Where any aspect of their work or responsibilities is delegated, researchers must ensure that the person to whom it is delegated has the appropriate competence to carry it out.

Researchers must be familiar with the strategic objectives of their area of work, as well as with the available funding mechanisms, and must obtain the relevant approvals before commencing their activities or accessing available resources. The funding or supervisory body must be informed if the research project is delayed, redefined or completed, and must also be notified if the project needs to be terminated before the planned completion date for any reason

In any application for research funding, the Principal Investigator (PI) of the project is also responsible for the accuracy of the information concerning the resources committed.

When preparing a Curriculum Vitae (CV), authors are responsible for the accuracy of its content. As evidence of its authenticity, it is advisable to sign the CV. In the case of a collective CV, it must be signed by the person responsible for the application.

Any research protocol involving the use of healthcare facilities or equipment, whether belonging to the institution or to third parties, or any research facilities or equipment shared within IIS-FJD, shall require the approval of the corresponding person responsible within IIS-FJD

3.2 Supervision of researchers in training

Institutions promoting research must ensure that early-career researchers have a clearly identified supervisor to whom they can report the results of their research activities. The supervisor must have sufficient expertise in the relevant research area and the time, knowledge, experience, specialisation and level of commitment required to provide appropriate support to the researcher in training.

In this regard, team leaders and principal investigators are responsible for fostering a working environment consistent with Good Research Practice that encourages cooperation, the development of individual skills, and the free exchange of scientific knowledge. These leaders must also ensure the appropriate direction of research activities and the proper supervision and training of researchers. They are expected to provide guidance and oversight throughout the entire research process, including the formulation of hypotheses, the development of methodology, funding applications, data recording, analysis and interpretation, as well as the assessment and resolution of any issues relating to research ethics or Scientific Integrity that may arise.

Researchers in training, for their part, must maintain regular and structured contact with their supervisors and departmental representatives to derive maximum benefit from these relationships. This should include keeping records of progress and new findings, obtaining feedback through reports and seminars, and implementing suggestions in accordance with the research timelines, milestones and expected outcomes. They must also commit to attending and making the most of all training opportunities offered by IIS-FJD, including courses, scientific meetings, workshops and seminar

In this regard, the training and professional development of early-career researchers constitute a key priority within the IIS-FJD quality and integrity policy. The institution will regularly provide courses on Good Research Practice and organise training activities on research ethics.

To achieve the overarching objective of research excellence, IIS-FJD implements a single, integrated Training Plan for the different members of the Institute, with the following specific objectives:

- To equip professionals with the competencies required to carry out their research activities.
- To facilitate the adaptation of professionals to new and evolving scientific and technological environments.
- To align training activities with the priority strategic areas of the Scientific Project.
- To provide a channel for the dissemination of research results.
- To foster a culture of continuous learning and research excellence.
- To strengthen relationships among the different professional groups and organisational units, while promoting the shared use of human and material resources.
- To increase researchers' motivation to progress towards research excellence.
- To promote the efficient allocation of training resources.

4. Planning and conduct of research

4.1. Description of the research protocol

During the planning phase of a research project, a research protocol must be developed. This protocol shall constitute the core document in which all elements necessary for the appropriate conduct of the project are defined in advance. The research protocol should:

- Clearly and accurately state the objectives and research plan. The content should be sufficiently detailed and comprehensive to enable any researcher to conduct the study with comparable results, or to assess the validity and reliability of the study procedures.
- Be written in a manner that allows its content to be clearly understood by project reviewers, researchers and technical staff involved in its implementation.
- Be organised in such a way that the relationship between the different phases of the study and their consistency within the overall document can be clearly understood. To this end, the protocol should be structured into interrelated sections, ensuring a coherent and logical flow throughout its content.



- The core sections that every research protocol must include shall be those established, according to the type of study concerned, in the relevant national and international guidelines (International Ethical Guidelines for Health-related Research Involving Humans developed by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), Good Clinical Practice Guidelines, and the International Council for Harmonisation). These sections should include: title; information on the sponsor, research team and participating centres; study timeline; abstract; theoretical or conceptual framework and rationale; general and specific objectives; study design; study procedures; variables to be collected and analyses to be performed; statistical considerations; communication and dissemination plan; budget and available resources; ethical considerations; references; and any relevant appendices.

- Every research protocol must include a specific plan for the collection of data and any biological or chemical material generated during the conduct of the research, as well as information regarding its custody, preservation and storage following the completion of the study, where applicable.

Any significant change to a research project must be incorporated into the original protocol and submitted for review and approval by the competent authority in each case.

4.2. Evaluation and approval of the research protocol

All research projects to be submitted to competitive funding calls must be reviewed and approved by the IIS-FJD Research Committee. In addition, in accordance with current legislation, research projects involving human participants or experimental animals shall require a preliminary ethical evaluation by the Research Ethics Committee (REC/CEIm) and/or the Animal Ethics and Welfare Committee (AEWC), respectively.

Should the project receive funding, it must be resubmitted for evaluation at a plenary session of the relevant committee and, where applicable, to the corresponding competent authority for approval.

4.3. Conduct of the research

4.3.1. Study registration

Any research study involving the prospective enrolment of human participants must be registered in a publicly accessible database before the first participant is enrolled. Through its Clinical Research Unit, IIS-FJD provides support to researchers in this regard by advising on the most appropriate registry according to the type of study being conducted, managing user account creation in those registries where registration is performed under an institutional account (IIS-FJD), such as www.clinicalTrials.gov, and providing assistance throughout the registration process whenever required.

4.3.2. Data management

The Principal Investigator must anticipate the resources required to ensure the proper custody and preservation of the documentation generated through experiments and observations.

The research team is responsible for collecting all data and results required by the study protocol. All relevant information, regardless of its nature, must be recorded and incorporated into the designated logbooks or data collection forms, ensuring that any modifications can be reviewed and traced throughout the research process.

Any intermediate or final data must be traceable to the original source documents (source documents, such as a patient's medical record in a clinical trial). Errors, negative results, unexpected findings or discrepant results must never be omitted. Any corrections must be clearly identifiable, and the individual making such corrections must be systematically documented.

Any documentary record of data generated during a research project must remain permanently accessible to all members of the research team. All team members have a mutual obligation regarding the sharing, processing and interpretation of the data obtained.

All documentation generated in the course of a research project (including logbooks, data collection forms, metadata, protocols, codes, software, and related materials) is ultimately the property of IIS-FJD and must remain appropriately safeguarded within the institution in accordance with the criteria established by the Principal Investigators of the project

If a member of the research team moves to another institution, the Principal Investigator may provide that individual with a copy of all or part of the records, whenever deemed necessary. Where the departure involves the Principal Investigator, the process shall be assessed and coordinated under the supervision of the IIS-FJD Scientific Directorate.

All original primary information (including data, metadata, protocols, codes and software) must be retained for the minimum period necessary to fulfil the purpose for which the data were collected and to meet the responsibilities arising from the research following the first publication of the results, and always in accordance with the regulations applicable to the specific type of study



In research projects, a Data Management Plan (DMP) should be established from the outset of the project. A DMP describes and defines each data management activity carried out throughout a clinical research study, from the initial list of variables or data dictionary through to the final data transfer for analysis. The purpose of the DMP is to provide instructions regarding the data management processes of a clinical study, defining: (i) data standards; and (ii) access rules for researchers, collaborators and external requests.

The Principal Investigator is responsible for ensuring compliance with the Data Management Plan (DMP). Data generated during the project shall comply with the FAIR principles (https://www.go-fair.org/fair-principles): Findable, Accessible, Interoperable and Reusable.

Researchers must inform participants about how their data will be used and reused, as well as about their rights of access, storage and erasure, in accordance with applicable Data Protection regulations. The results of a research project should be made publicly available and shared with the scientific community. Data sharing shall require information regarding the purpose for which the data are requested, the awareness and involvement of the research team, the establishment of a data-sharing agreement approved by the person responsible for the research, and the assumption by the requester of any costs associated with the data-sharing process. Access to data by third parties may be restricted for reasons of availability, confidentiality or competitiveness. In all cases, data sharing must be carried out in accordance with applicable legislation.

4.3.1. Management of biological, chemical and other kind of materials

The Principal Investigator must anticipate the resources required to ensure the proper custody and preservation of any biological, chemical or other materials obtained through experiments and observations.

A system for tracking repositories of biological, chemical or other materials must also be maintained.

Any material held within such repositories during a research project must remain permanently accessible to all members of the research team. All team members have a mutual obligation regarding the information derived from such materials, as well as the processing and interpretation of the data obtained.

All biological, chemical or other materials generated or collected during a research project are ultimately the property of IIS-FJD and must remain appropriately safeguarded within the institution in accordance with the criteria established by the Principal Investigators of the project.

The storage arrangements and final disposition of biological samples remaining after the completion of a research project must be clearly defined and justified in the study protocol, in accordance with the options provided for under the applicable regulations, namely destruction or storage for use in future research projects, either as part of a collection or within a biobank.

Where a participant has provided consent for the storage of biological samples for research purposes following the completion of the project, the scope of their potential use (whether restricted to a defined line of research or allowing broader use), the possibility of transfer to third parties, and the duration of storage shall be determined by the storage regime selected and consented to by the participant.

If a member of the research team moves to another institution and wishes to take aliquots of biological, chemical or other materials, a request must be submitted to the Principal Investigator, who shall assess the appropriateness of the request in accordance with the governance framework established for the project. Where the departure involves one of the Principal Investigators, the transfer of biological, chemical or other materials shall be assessed and, where appropriate, authorised under the supervision of the IIS-FJD Scientific Directorate, with the knowledge of the Research Ethics Committee for Medicinal Products (in Spanish, CEIm) and, where applicable, the management of the institutional biobank.

4.4. Collaborative projects

Where a research project involves the participation of different IIS-FJD teams, teams from different centres within the same country, or centres from different countries, it is advisable to formalise an agreement setting out the terms under which the different teams will collaborate.

In addition to the requirements applicable to a research protocol, the collaboration agreement should address the following aspects:

- A clear and unambiguous description of all elements of the research plan to be carried out within the framework of the collaboration.
- The criteria by which the progress of the research will be communicated and monitored among the participating teams or centres.
- A clear allocation of the responsibilities, rights and obligations of the participating teams or centres, both in relation to the tasks to be performed and the results to be obtained. This should include arrangements for the custody and storage of data and samples, measures to ensure confidentiality, potential commercial implications of the results, and any other relevant aspects.
- A plan for the presentation and dissemination of results in any setting. Authorship of publications must comply with the principles of ethics and Scientific Integrity, and should, whenever possible, be agreed upon in advance by the collaborating team.

Collaborative studies involving researchers from different countries present challenges, as they often involve differences in research cultures, regulatory and legal frameworks, as well as organisational and funding structures.

To ensure compliance with the principles of Scientific Integrity in this type of collaboration, particular attention should be paid to the issues addressed in the Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations (https://www.wcrif.org/guidance/montreal-statement accessed nov 2024).

5. Ethical and regulatory requirements

All research projects to be conducted at IIS-FJD must comply with:

- The fundamental principles set out in the Declaration of Helsinki and its subsequent revisions, the Council of Europe Convention on Human Rights and Biomedicine, and the UNESCO Universal Declaration on the Human Genome and Human Rights.
- The fundamental principles established in Law 41/2002 of the 14th of November on Patient Autonomy and on Rights and Obligations concerning Clinical Information and Documentation, as well as in Law 26/2011 of the 1st of August on the legislative adaptation to the United Nations Convention on the Rights of Persons with Disabilities.
- The principles established in Regulation (EU) 2016/679 of the European Parliament and of the Council of the 27th of April of 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and in Organic Law 3/2018 of the 5th of December on the Protection of Personal Data and the Guarantee of Digital Rights.
- The requirements established under Spanish and European legislation governing biomedical research.

The applicable legislation and some general considerations according to the type of research to be conducted are outlined below:

- All projects involving research with human participants, the use of human biological samples, genetic analyses, or the performance of invasive procedures must comply with the provisions of Law 14/2007 of the 3rd of July on Biomedical Research (LIB) and Royal Decree 1716/2011 of the 18th of November, which establishes the basic requirements for the authorisation and operation of biobanks for biomedical research purposes and regulates the processing of human biological samples.
- Such projects must be accompanied by the corresponding approval issued by the Research Ethics Committee / Research Ethics Committee for Medicinal Products (REC/CEIm). In addition, the study start date must be recorded in the appropriate system to enable monitoring by the IIS-FJD Research Management Area.
- All animal experiments must be conducted in accordance with the applicable legislation governing the use, protection and welfare of laboratory animals (Directive 2010/63/EU on the protection of animals used for scientific purposes and Royal Decree 53/2013 of the 1st of February, which establishes the basic rules applicable to the protection of animals used for experimental and other scientific purposes, including education).

The corresponding protocols must be approved by the appropriate authorised body within IIS-FJD and must also receive approval from the Regional Government of Madrid (Comunidad de Madrid, CAM). Animal housing and all related experimental procedures must be carried out with clear identification of the PROEX code corresponding to the procedure approved by CAM. Research staff involved in the design and/or conduct of procedures involving experimental animals must hold the appropriate legal accreditation and authorisation established by CAM.

- Projects involving the use of genetically modified organisms (GMOs) must comply with the provisions of Law 9/2003 of the 25th of April on the contained use, deliberate release and placing on the market of genetically modified organisms, as well as the regulations implementing that Law.
- Projects involving the use of biological agents must comply with the provisions of Law 31/1995 of the 8th of November on the Prevention of Occupational Risks, as well as the Royal Decrees implementing it in relation to risks associated with exposure to biological agents.
- Clinical trials involving medicinal products must be conducted in accordance with Regulation (EU) No 536/2014 of the European Parliament and of the Council of the 16th of April of 2014, and Royal Decree 1090/2015 of the 4th of December, which regulates clinical trials with medicinal products, Research Ethics Committees for Medicinal Products (CEIms), and the Spanish Clinical Studies Registry.
- Observational studies involving medicinal products must be conducted in accordance with Royal Decree 957/2020 of 3rd of November, which regulates observational studies involving medicinal products for human use.
- Clinical investigations involving medical devices must be conducted in accordance with Regulation (EU) 2017/745 of the 5th of April on medical devices, Royal Decree 192/2023 of the 21st of March regulating medical devices, and Regulation (EU) 2017/746 of the 5th of April on in vitro diagnostic medical devices.
- Ethical issues related to medicine; the life sciences and associated technologies applied to human beings must be consistent with the UNESCO International Declaration on Human Genetic Data (2003).
- Research projects involving the use of human cells and tissues in the field of regenerative medicine must comply with the provisions of Law 14/2006 of the 26th of May on Assisted Human Reproduction Techniques; Royal Decree 176/2004 of the 30th of January approving the Statute of the National Transplant and Regenerative Medicine Centre; Royal Decree 2132/2004 of the 30th of October establishing the requirements and procedures for the authorisation of research projects involving stem cells obtained from surplus pre-embryos; and Royal Decree 1527/2010 of the 15th of November regulating the Guarantees Committee for the Donation and Use of Human Cells and Tissues and the Research Projects Registry.

In the event of any amendments or updates to the legislation referred to above, IIS-FJD shall always apply the regulations in force at the time the research project is conducted.

6. Authorship, publication and dissemination of results

The publication and dissemination of research results are essential if scientific knowledge is to be used effectively and in the public interest. Publication makes research findings available to the scientific community for verification, scrutiny and replication, thereby initiating a process through which new knowledge and further results can be developed from the original findings. It is, therefore, an ethical imperative.

The communication and dissemination plan for research results should be agreed in advance and aligned with the policies and requirements of the institutions involved (IIS-FJD, collaborators, funding bodies, etc.). Where appropriate, support may be provided by the institution's Communications Department.

6.1. Authorship, publication and dissemination of results

All IIS-FJD researchers, whether they are staff employed directly by the Institute or researchers affiliated with it through the institutions that comprise IIS-FJD, must indicate their affiliation with IIS-FJD in publications and communications arising from work conducted within the Institute, using the following designation:

- Instituto de Investigación Sanitaria Hospital Universitario-Fundación Jiménez Díaz, Universidad Autónoma de Madrid (IIS-FJD, UAM), Madrid 28040, España.
- Health Research Institute Fundación Jiménez Díaz University Hospital, Universidad Autónoma de Madrid (IIS-FJD, UAM), 28040 Madrid, Spain.

Researchers affiliated with the Institute through any of its constituent institutions must also include a reference to their home institution. In cases where an author holds multiple affiliations, the criteria established in the "Report on Authorship and Affiliations in Scientific and Technical Publications" issued by the Spanish Research Ethics Committee in November 2023 shall be followed (https://www.ciencia.gob.es/eu/Noticias/2023/noviembre/).



Regarding the authorship of scientific publications, researchers shall adhere to the principles of Good Research Practice in accordance with the provisions set out in The European Code of Conduct for Research Integrity (All European Academies, Revised Edition 2023):

- Authors shall formally agree on the order of authorship, recognising that authorship must be based on commonly accepted criteria, such as those established by the International Committee of Medical Journal Editors (ICMJE, 2024), which are set out below.
- Whenever possible, authors shall include an Author Contributions section in the final publication describing the responsibilities and specific contributions of each author.

- Authors acknowledge the work and contributions of those who do not meet the criteria for authorship, including collaborators, assistants and funding bodies that have made the research possible.
- Authors shall disclose any conflicts of interest, as well as all sources of support or funding for the research and its publication.
- Authors and editors shall publish corrections or retract publications when necessary. Where retraction procedures are transparent and the reasons for retraction are clearly stated, the publication of post-publication corrections should be recognised as good research practice.
- Authors, research institutions, publishers, funding bodies and the research community recognise that negative results may be as relevant as positive results for publication and dissemination purposes.
- Authors shall communicate accurately and honestly with colleagues, policymakers and society at large.
- Authors shall be transparent in their communication, dissemination and public engagement activities regarding the assumptions and values influencing their research, as well as the strength of the evidence, including uncertainties and knowledge gaps.
- Authors shall apply the same standards and criteria described above irrespective of whether they publish in subscription-based journals, open-access journals, or any other form of publication, including preprint servers.

According to the ICMJE (https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html), an individual must meet all the following criteria to be considered an author of a research publication:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work.
- Drafting the work or revising it critically for important intellectual content.
- Final approval of the version to be published.
- Agreement to be accountable for all aspects of the work, ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Responsibility for ensuring that authorship criteria are met rests jointly and indivisibly with all co-authors. In this regard, the following practices are considered unacceptable:

- Gift Authorship: the practice of granting authorship to a senior or junior colleague with the explicit or implicit expectation that the favour will be reciprocated in the future.

- Honorary Authorship: acceptance of authorship solely by virtue of holding a position of authority within the department or unit where the research was conducted, without having made a significant contribution and therefore without meeting the authorship criteria. If an individual has contributed to securing funding, this contribution should be acknowledged in the Author Contributions section.
- Guest Authorship: inclusion of prominent or influential individuals as authors to increase the likelihood of publication and/or enhance the impact of the article once published.
- Ghost Authorship: omission of any individual who has made contributions that fulfil the authorship criteria. This is considered a form of misappropriation of intellectual property by the remaining authors.

To prevent these practices, IIS-FJD encourages researchers to follow the recommendations of the CRediT (Contributor Roles Taxonomy) initiative (https://credit.niso.org/) when describing individual contributions to research.

Authors must also disclose the use of external services and automated tools, including Generative Artificial Intelligence (GenAI), in accordance with current recommendations and guidelines: (https://research-and-innovation.ec.europa.eu/document/download/2b6cf7e5-36ac-41cb-aab5-0d32050143dc_en?filename=ec_rtd_ai-guidelines.pdf).

As a general guideline, the following principles may be used when determining the order of authorship. The first author is the individual recognised by the rest of the research team as having made the most significant contribution to the conception and conduct of the research, and who prepared the first draft of the manuscript prior to publication.

- The last author should be the individual who bears ultimate responsibility for the research protocol.
- The remaining authors may be listed according to the significance of their contribution or simply in alphabetical order.
- Authors have the right to justify the order of authorship in a footnot.
- In some cases, two authors may have contributed equally to the conduct of the research and the preparation of the manuscript. In such cases, and with the agreement of the rest of the research team, both individuals may be designated as joint first authors, if this is explicitly stated in the published article.

The preparation of internal drafts, reports, technical reports, working documents and any other materials intended for third parties must acknowledge the authors of the research under the same criteria that would apply to a scientific publication.

For multicentre studies involving many contributors, it is advisable to agree in advance on collective authorship arrangements and the designation of a writing committee. Where a nominal list of authors is established, the order of authorship should be determined based on objective criteria, such as the number of participants contributed to the study by each author.

In all cases, the Area Coordinator may review the manuscript prior to its submission for publication and may provide comments and recommendations as appropriate. The Area Coordinator shall always retain the right to require the authors to include a disclaimer statement where necessary to protect the Area Coordinator's personal position or that of the research area.

6.2. Publication practices

The communication and dissemination of research results to the media should take place only after their scientific publication. Prior dissemination would only be justified for reasons of public health. In such cases, authors should consider the possibility of having the results reviewed through an expedited process by a scientific journal or agree with the journal editors on the scope of such exceptional communication before final publication.

The researcher with overall responsibility for the research programme shall be responsible for authorising the publication of the content, ensuring the integrity of the results, appropriate peer review, adequate protection of intellectual property rights, and the selection of the publication venue.

The publication of research findings in journals or other outlets that are subject to peer review constitutes an essential component of the research process, and researchers should make every reasonable effort to ensure their publication.

Following the launch of the Coalition S initiative (https://www.coalition-s.org/), from 2021 onwards, all scholarly publications reporting the results of research funded by public or private grants awarded by regional, national or international funding bodies should be published in Open Access journals, on Open Access platforms, or made immediately available to the scientific community through Open Access repositories.

When participating in the evaluation of the scientific output of an individual researcher or a research group for promotion or funding purposes, assessment should be based on the quality and potential significance of the research output rather than solely on bibliometric indicators such as the number of publications or the impact factor of the journal in which the work is published. This approach is consistent with the principles set out in the Declaration on Research Assessment (DORA) (https://sfdora.org/read/read-the-declaration-espanol/).

The following publication practices are considered unacceptable:

- Failure to publish, undue delay in publication, publication bias in the reporting of results, or exaggeration of the significance of findings for clinical practice or health policy.
- Redundant or duplicate publication. Authors must not publish the same data in different journals.
- Salami publication (fragmentation of results into multiple small publications), which is only justifiable when there is a legitimate need to communicate important findings at an early stage through the publication of preliminary data.
- The proliferation of publications with multiple authors solely for the purpose of increasing publication output.

6.3. Intelectual property rights of the research results

Prior to submitting a manuscript for publication or presenting research results at scientific meetings, the feasibility of protecting the industrial and/or intellectual property rights associated with those research results should be assessed.

As a general principle, the moral rights of authorship shall always belong to the researchers responsible for the work that generated the results, in accordance with the applicable legislation and taking into account, among other factors, the contribution of Institutional Staff (i.e. personnel employed by or holding statutory appointments within the institution) and other categories of personnel, such as trainees or interns, involved in generating the results.

Where research results are eligible for protection through industrial and/or intellectual property rights, IIS-FJD researchers who have made an intellectual contribution to the generation of those results shall be recognised as inventors, while ownership of such results shall vest in IIS-FJD.

In the case of research results developed in collaboration with researchers from other institutions, a specific agreement shall be established among all participating entities to determine the proportion of ownership attributable to each party.

The institution’s policy regarding the distribution of benefits arising from the commercial exploitation of industrial and/or intellectual property rights generated by its personnel, in line with the policies of other Public Research Organisations (PROs), establishes the following allocation of revenues:



a) One third shall be allocated to IIS-FJD.
b) One third shall be allocated to the inventor or inventors.
c) One third shall be distributed in accordance with the criteria established by the Governing Board of the institution, considering the importance and significance of the patent, the benefits it may generate, and the participation or contribution of personnel other than the inventor(s). This portion may be used to cover patent maintenance costs or, where appropriate, may be partially allocated to the inventor(s) based on the strategic value of the invention, opportunity considerations, or other relevant criteria.

The proper protection of intellectual and/or industrial property rights is only possible if researchers maintain accurate, complete and up-to-date records of their data. This is essential not only to demonstrate good research practice, but also to effectively address any questions that may arise regarding authorship and ownership of research results.

Where research findings may have patent potential, the research team must comply with the IIS-FJD procedures governing the protection (including patents, royalties and intellectual property registration) and transfer of R&D&I results, which are available on the IIS-FJD website. Through its Innovation Support Unit, which forms part of the ITEMAS Platform, IIS-FJD provides support to researchers in the management of knowledge transfer activities identified within the Institute. The Unit acts as a single point of contact for researchers seeking access to the services of the Research Results Transfer Office (OTRI) and carries out activities related to the promotion of innovation, the valorisation of research results and the implementation of healthcare innovations.

As research is inherently a collaborative process involving many individuals with shared scientific interests, IIS-FJD researchers have an obligation to cooperate with the wider scientific community by sharing research results, including knowledge, know-how, reagents, data, samples and other materials generated through their work, with appropriately qualified researchers within a reasonable period following publication of the results.

6.4. Research projects sponsored by private entities

Regarding research projects sponsored by private entities and conducted within the framework of IIS-FJD or any of its constituent institutions, the following considerations should be considered:

- The life sciences and healthcare industry often needs to conduct certain types of research within public and private institutions, particularly in the areas of experimental and technological development.
- Research sponsored by companies in the healthcare and life sciences sector is both valuable and necessary, as it promotes technology transfer and can provide significant financial resources.
- In scientific relationships with such companies, it is essential to establish appropriate safeguards to ensure that the principles and objectives of intellectual freedom are not compromised.
- Scientific personnel who benefit from funding and public trust have an obligation to ensure that their discoveries are developed and applied in accordance with the public interest.

While researchers may frequently require access to confidential information provided by the sponsoring entity, acceptance of such confidentiality obligations must never restrict their ability to publish new research findings, except where specific restrictions established in the following sections apply:

- Where researchers are to participate in a project sponsored by a company and make substantial contributions to its design and execution, they must inform IIS-FJD and seek advice on technology transfer matters to ensure the appropriate negotiation of intellectual property agreements. Such agreements should also address all aspects of direct or indirect financial compensation related to the research and must be accessible to all parties involved.
- Agreements may be established allowing the sponsoring entity to review manuscripts or research findings for their commercial potential and, where appropriate, to formalise arrangements for the shared ownership of intellectual property. Under such agreements, the sponsoring entity may be granted exclusive rights to all results obtained for a specified period. Researchers should also be advised on how to safeguard their intellectual independence, avoiding excessively restrictive confidentiality agreements or unjustified limitations on publication.
- Where researchers participate solely in the data collection phase of a protocol developed by another team or institution, the conditions governing the communication and publication of the results obtained shall be agreed jointly with the sponsoring entity.



- All financial arrangements between the sponsoring entity and the researcher(s) or research group, as well as any other form of compensation or benefit established directly or indirectly in connection with the research, must be included in a single agreement between the sponsor and IIS-FJD, or the collaborating institutions to which the researchers belong. Such financial arrangements must be accessible to the relevant institutional bodies, committees and scientific boards, as well as to those individuals with responsibility for the matters covered by the agreement.

7. Conflict of interest

A conflict of interest is understood as a situation in which a person's judgment regarding the primary interests of scientific knowledge or the care and welfare of research participants is influenced by a secondary interest, such as financial, academic, political or personal gain. Conflicts of interest may lead to inappropriate scientific conduct, compromising the principles of Scientific Integrity and jeopardising the credibility and reputation of both the individual professional and the institution. It is therefore essential that they are identified and appropriately managed.

Conflicts of interest may arise in any activity related to research, including the design, conduct and publication of a research project, as well as the evaluation of funding applications and other research-related activities.

Being in a situation involving a conflict of interest does not in itself constitute ethically unacceptable behaviour, provided that the objectivity and integrity of the researcher's participation in the matter concerned have not been compromised.

Attention should be paid not only to actual conflicts of interest, but also to perceived and potential conflicts. Perceptions regarding a researcher's conduct may influence the attitudes of third parties and may undermine the reputation of IIS-FJD.

When faced with a conflict of interest, researchers should ask themselves: "Would I feel comfortable if others knew about or perceived a secondary interest in this matter?" If the answer is no, they should act responsibly to maintain the highest possible degree of objectivity, either by resolving the conflict of interest or by withdrawing from the matter concerned.

All members of IIS-FJD are expected to recognise when they are in a situation involving a conflict of interest, to disclose it to their supervisors, and to manage it in an ethically appropriate manner.

IIS-FJD shall promote training and awareness-raising activities aimed at preventing conflicts of interest and ensuring their appropriate management.

8. Institutional Policy on good research practice

8.1. Update and dissemination

The Scientific Integrity Committee shall coordinate the periodic review of this Code and distribute any subsequent updates to all IIS-FJD research staff. Whenever new members join the institution, they shall be provided with the current version of the Code of Good Research Practice together with the rest of the welcome documentation. In both cases, everyone must confirm receipt and acknowledgement of having read the document. The Research Management Area shall maintain a record of the distribution of the Code of Good Research Practice, including the date of receipt and the name of the recipient. In addition, a dedicated section is available on the IIS-FJD website, providing access to the current version of the Code of Good Research Practice and other relevant documentation, thereby facilitating access to these resources. (https://www.fjd.es/iis-fjd/es/estructura-organizativa/comite-integridad-cientifica/ documentacion-interes).

Periodic activities will be organised to promote awareness of, and self-assessment against, the principles and content of the Code of Good Research Practice among research staff.



8.2. Strategic plan

The IIS-FJD Strategic Plan 2024–2028 includes, within Strategic Objective 5, a specific Action Plan on Ethics and Scientific Integrity (https://www.fjd.es/iis-fjd/es/informacion-corporativa/plan-estrategico.ficheros/3278078-PLAN%20ESTRATEGICICO%202024-2028.pdf).

9. References

9.1. Research involving human participants

- World Medical Association Declaration of Helsinki (latest revision adopted at the 75th WMA General Assembly, Helsinki, Finland, October 2024).
- Law 41/2002 of the 14th of November on Patient Autonomy and on Rights and Obligations concerning Clinical Information and Documentation.
- Council of Europe Convention on Human Rights and Biomedicine, ratified by Spain the 23rd of July of 1999.
- UNESCO Universal Declaration on the Human Genome and Human Rights.
- Law 26/2011 of 1 August on the legislative adaptation to the United Nations Convention on the Rights of Persons with Disabilities.
- International Ethical Guidelines for Health-related Research Involving Humans, Fourth Edition. Geneva: Council for International Organizations of Medical Sciences (CIOMS), 2016.
- ICH Harmonised Guideline, Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice, ICH E6(R2).
- Law 14/2007 of the 3rd of July on Biomedical Research.
- Royal Decree 1716/2011 of the 18th of November, establishing the basic requirements for the authorisation and operation of biobanks for biomedical research purposes and the processing of human biological samples, and regulating the organisation and operation of the National Biobank Register for Biomedical Research.
- Law 9/2003 of the 25th of April on the Contained Use, Deliberate Release and Placing on the Market of Genetically Modified Organisms (GMOs).

- Law 31/1995 of the 8th of November on the Prevention of Occupational Risks.
- Regulation (EU) No 536/2014 of the European Parliament and of the Council of the 16th of April of 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.
- Royal Decree 1090/2015 of the 4th of December regulating clinical trials with medicinal products, Research Ethics Committees for Medicinal Products (CEIms), and the Spanish Clinical Studies Registry.
- Royal Decree 957/2020 of the 3rd of November regulating observational studies involving medicinal products for human use.
- Regulation (EU) 2017/745 of the 5th of April on medical devices.
- Royal Decree 192/2023 of the 21st of March regulating medical devices.
- Regulation (EU) 2017/746 of the 5th of April on in vitro diagnostic medical devices.
- UNESCO International Declaration on Human Genetic Data (2003).
- Law 45/2003 of the 21st of November amending Law 35/1988 of the 22nd of November on Assisted Reproduction Techniques.
- Royal Decree 176/2004 of the 30th of January approving the Statute of the National Centre for Transplants and Regenerative Medicine.
- Royal Decree 2132/2004 of the 29th of October establishing the requirements and procedures for the authorisation of research projects involving stem cells obtained from surplus pre-embryos.
- Law 42/1988 of the 28th of December on the Donation and Use of Human Embryos and Fetuses, and of Their Cells, Tissues and Organs.
- Directive 2004/23/EC of the European Parliament and of the Council of the 31st of March of 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

9.2. Research involving animals

- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

- Royal Decree 53/2013 of the 1st of February laying down the basic standards for the protection of animals used for scientific and educational purposes, including the protection of animals used in experimental procedures and teaching activities.

9.3. Scientific integrity

- National Declaration on Scientific Integrity, December 2015. https://www.csic.es/sites/default/files/Declaracio_n%20Nacional%20Integridad%20Cienti_fica%20definitiva_0.pdf. (accessed, May 2019).
- The European Code of Conduct for Research Integrity. Revised Edition. All European Academies (ALLEA), Berlin, 2017.
- CSIC Code of Good Scientific Practice. 2011.
- MRC ethics series. Good research practice: Principles and guidelines. https://mrc.ukri.org/research/ policies-and-guidance-for-researchers/good-research-practice/ (accessed, May 2019).
- Teaching the Responsible Conduct of Research in Humans (RCRH). Office of Research Integrity, U.S. Department of Health & Human Services. https://ori.hhs.gov/education/products/ucla/default.htm (accessed, May 2019).
- Guidelines for Investigators in Scientific Research; University of Medicine & Dentistry of New Jersey.
- Good Scientific Practice; Biotechnology and Biological Science Research Council.
- Code of Good Scientific Practice of the PRBB (5th Edition, October 2014).
- Code of Good Scientific Practice. Illinois Institute of Technology.
- Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. International Committee of Medical Journal Editors. Updated December 2018.

9.4. Protection of personal data

- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons regarding the processing of personal data and on the free movement of such data.
- Organic Law 3/2018 of 5 December on the Protection of Personal Data and the Guarantee of Digital Rights.

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