INCLIVA | VLC
Biomedical Research Institute

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CODE OF GOOD RESEARCH PRACTICE

This document has been drafted and prepared by the Deputy Director of Scientific Affairs and approved by the INCLIVA Governing Board by means of a resolution dated 29 September 2025.

This approval was granted within the scope of the powers conferred and in accordance with the procedures laid down in the organisation's internal regulations.

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1. PRESENTATION

The Research Foundation of the Hospital Clínico Universitario de València was established in 2000 as the first Valencian research foundation affiliated with a public hospital. Ten years later, various groups of excellence in biomedical research from the University of Valencia and the Carlos Simón Foundation joined the Foundation through the establishment of specific agreements, thus creating the INCLIVA Biomedical Research Institute (hereinafter, INCLIVA).

INCLIVA manages the biomedical research carried out by the Hospital Clínico Universitario de València and its Department of Health, as well as by the other entities that make up the Institute, within the context of its activities, including the promotion of teaching and scientific activities. Its fundamental mission is to be a centre dedicated to biomedical research of excellence, aimed at generating useful, high-quality knowledge to provide solutions to the population's health problems.

With this overarching objective, the research projects carried out within the framework of INCLIVA aim to lead the way in basic, clinical and translational scientific research, serving as a trusted benchmark for society, the scientific community and public and private institutions at both national and international levels. The ultimate aim is to contribute significantly to the generation of new knowledge, its dissemination, and its application for the benefit of society.

All of this must be carried out in accordance with a code of ethical and legal conduct that ensures the research conducted within our Institute is consistent with the principles of Responsible Research and Innovation (RRI) promulgated by the European Commission and with the European Code of Conduct for Integrity in Research (ALLEA, 2023)[1] . For this reason, this new Code of Good Research Practice (CGRP) is intended to be a comprehensive and supportive document covering various aspects applicable to the conduct of scientific activities. It also incorporates new provisions to bring research into line with recent changes in regulations and ethical guidelines on scientific integrity and their implementation in society.

This CGRP must be adopted as an individual commitment by all INCLIVA staff, with the aim of improving the quality and integrity of research, by applying the following principles in the conduct of their scientific and research activities, thereby ensuring an appropriate standard of work and compliance with current legislation, namely Law 14/2007 of 3 July on Biomedical Research.

The premises underpinning this CGRP are:

- **Reliability** in ensuring the quality of research, reflected in the design, methodology, analysis and use of resources.
- **Honesty** in developing, conducting, reviewing, reporting and communicating research in a transparent, fair, comprehensive and impartial manner.
- **Responsibility** for research, from conception to publication, for its management and organisation, for training, supervision and mentoring, and for its impact in the broadest sense.
- **Respect** for life, the law and the public interest, justifying any research proposal, with particular sensitivity where this involves people, animals and the environment itself.

Full details of INCLIVA's Code of Good Research Practice are available on the Institute's website.

[1] ALLEA (All European Academies). (2023). The European Code of Conduct for Research Integrity. Berlin. https://allea.org/wp-content/uploads/2024/01/The-European-Code-of-Conduct-2023-ES.pdf

2. SCOPE AND OBJECTIVES

This Code shall apply to all research carried out wholly or partly at INCLIVA or by research staff associated with it (whether permanent or seconded), including visiting staff, research fellows or students who may be involved in such research. This commitment is formalised by signing this Code.

The principles on which this Code of Good Research Practice is based are set out below:

- Any research involving human participants, the use of human biological samples or personal data must be approved by the Ethics Committee for Research Involving Medicines (CEIm) of the Hospital Clínico Universitario de València.
- All research involving animals must be approved by the Animal Experimentation Ethics Committee (CEEA) of the University of Valencia and authorised by the competent authority: the Regional Ministry of Agriculture in the case of the Valencian Community.
- All projects must comply with applicable legal regulations at regional, national and international levels, and must obtain the necessary administrative authorisations where required.
- The results of any research must be published once they have been sufficiently verified, whilst respecting the confidentiality of the project participants until that time.

In return for the commitment of the research staff, the Management and its scientific management bodies assume the following responsibilities:

- Ensuring that research projects meet quality criteria and comply with the provisions of this CGRP.
- To update this CGRP to bring it into line with applicable legal regulations.
- To act as a mediating body in cases of ethical disputes, conflicts of interest or suspected research misconduct.
- Ensure the monitoring of procedures leading to the relevant administrative authorisation, depending on the nature of the research project.
- To inform the management bodies of the entities comprising INCLIVA about the various research projects being carried out within their remit and to seek their approval where necessary.
- To assure staff that the facilities meet the necessary requirements and that the relevant authorisations are in place to carry out any scientific practice subject to specific regulations.
- Comply with the requirements governing the use, handling and storage of radioactive material, genetically modified organisms and any other potentially hazardous biological agents.

Its objectives are:

- To ensure that research carried out within the INCLIVA framework is conducted in accordance with the highest standards of rigour, integrity, responsibility and respect, whilst facilitating the dissemination of findings to the scientific community and society at large.
- To foster the adoption of good research practices in all aspects, dimensions and stages of scientific activity.
- To safeguard the rights of participants in research projects, as well as to apply the principles of animal welfare in studies involving animal models.
- To maintain our commitment to society by carrying out projects that improve the prognosis, diagnosis and treatment of diseases, thereby positively impacting the well-being of the public.

3. RESEARCH STAFF

3.1. Leadership and organisation of research teams

Research teams, defined as the group of researchers, technical staff and any other professionals involved to a greater or lesser extent in the project, must have at least one person in charge or a leader.

Leadership within teams must be exercised with responsibility, integrity and transparency, promoting a collaborative, inclusive and equitable working environment.

Team leaders must:

- Foster open and effective communication, ensuring that each member understands their roles and responsibilities within the project.
- Establish a clear organisational structure that promotes efficiency in resource management, evidence-based decision-making and compliance with ethical and scientific standards.
- Support the professional development of researchers, particularly those in training, by providing mentoring and opportunities for growth.
- Promote cooperation with other research teams to encourage the exchange of ideas among researchers. Under no circumstances shall the research work of potential competing groups be hindered, the dissemination of scientific results be delayed, or their publication be prevented.

Likewise, all members of the research team:

- Must actively participate in the activities proposed and organised within the teams.
- Must comply with mechanisms for conflict resolution and the prevention of malpractice, ensuring that research is conducted to the highest standards of quality, rigour and social responsibility.
- Must be open to criticism, queries and comments expressed by other teams and by society in general.

3.2. Mentoring and training of research staff

INCLIVA ensures that all research staff receive ongoing, high-quality training in research design, methodology and analysis, and provides an environment that facilitates the professional development of researchers through appropriate training programmes in scientific integrity, good practice and the most relevant legal regulations.

3.2.1. Mentoring of trainee research staff

Anyone affiliated with a research group through a contract or grant will be assigned a responsible research supervisor, who will oversee the training process.

Mentoring is a key process for guiding the academic and professional growth of trainee research staff. At INCLIVA, mentors are responsible for providing scientific, methodological and ethical guidance, fostering the progressive autonomy of trainee researchers.

Supervisors must submit proposals to the Training and Mobility Committee for the development and improvement of INCLIVA's biennial Training Plan, with the aim of updating it and incorporating initiatives that enhance researchers' training activities by adding value.

Tutors of trainee researchers are subject to the following obligations:

- To inform the institution about the trainee researchers under their supervision.
- To have proven experience and a track record in research and supervision, so that their work serves as a role model for researchers in training.
- Ensure that the institution provides researchers in training with the necessary resources and a suitable scientific environment, taking into account their training needs.
- To promote awareness of and compliance with this Code of Good Research Practice, with the aim of fostering a critical approach to the evaluation of their scientific work.
- Supervise the tasks assigned, ensuring their completion through personal and regular interaction with the trainee.
- Recognise the work carried out by the trainee researcher and ensure that they publish at least one scientific article as first author.

The number of people under the supervision of tutors shall be limited so that they can fulfil all their obligations towards researchers in training.

3.2.2. Research staff in training

As part of their commitment to scientific excellence, trainee researchers must actively integrate into work teams, contributing responsibly and collaboratively to the projects in which they participate.

It is essential that they follow the guidelines and recommendations of their supervisors, keeping them regularly informed of their progress, difficulties and any initiatives they consider relevant to their professional development.

They must also comply with the institute's internal regulations and safety protocols, adhering to the Code of Good Research Practice and applicable ethical regulations.

They must participate in academic activities, seminars, conferences and scientific forums included in the Training Plan for INCLIVA research staff, with the aim of promoting continuous training and their integration into the research community.

With regard to the dissemination of results, trainee researchers must obtain their supervisor's authorisation before communicating their findings orally or in writing, ensuring that the publication of these findings complies with the principles of scientific integrity and gives due recognition to the team's contributions. Furthermore, they must respect the confidentiality and duty of secrecy regarding information obtained in the course of their research.

Finally, trainee researchers shall make responsible use of the resources, facilities and equipment available, valuing and respecting the management and administrative work that makes research activity possible.

3.3. Curriculum vitae

Researchers' *curriculum vitae* (CV) must truthfully and accurately reflect their academic, scientific and professional background, ensuring transparency and integrity in the presentation of their achievements. All information included must be verifiable and adhere to the principles of honesty and rigour, avoiding any form of exaggeration, omission or falsification of data. In this regard, as the person responsible for the accuracy of the content, the researcher must always sign the CV submitted. In the case of a collective CV, it is sufficient for it to be signed by the person responsible for the application.

In the case of publications, collaborations or awards, individual authorship and contributions must be correctly indicated, in accordance with the criteria established within the scientific community.

Research staff must use the Standardised CV provided by the Spanish Foundation for Science and Technology (FECYT)[2] for all calls for applications for grants from Public Health Research Funds, or else adhere to the official formats recommended by evaluation and funding bodies, thereby promoting comparability and objectivity in the processes of selection, promotion and the awarding of research grants.

3.4. Collaborations

All collaborations undertaken within INCLIVA, whether with public or private entities, must be formalised through written agreements that clearly define the objectives, responsibilities, distribution of tasks, authorship policy and management of intellectual and industrial property rights.

These agreements shall ensure transparency, fairness and the protection of the interests of all parties involved, whilst respecting the confidentiality necessary for the exploitation of research and the transfer of knowledge.

INCLIVA will ensure that these collaborations comply with current legislation and applicable national and international guidelines, promoting high-quality research with scientific integrity.

3.5. Conflicts of interest

A conflict of interest arises when a secondary interest—such as financial gain, personal relationships or hierarchical ties—may influence or appear to influence professional judgement regarding a primary interest, such as the validity of the research or the fulfilment of professional responsibilities.

It is important to note that finding oneself in a conflict of interest situation is not inherently unethical; however, it is essential that research staff identify, declare and manage these conflicts appropriately to maintain the integrity and credibility of the research.

INCLIVA research staff must:

- Identify and declare to the **Commission for Integrity and Management of Conflicts of Interest** any actual, potential or apparent conflict of interest—whether financial, professional or personal—that may influence their professional judgement.
- Refrain from acting or intervening in situations where a conflict of interest may compromise the objectivity of the research, or, alternatively, make it public and address it in accordance with the policies of the contracting entities, evaluation bodies or publication publishers.
- Avoid accepting gifts, favours or services that may compromise their independence or duties as public servants.

INCLIVA undertakes to develop and maintain clear institutional criteria for dealing with any conflicts of interest that may arise, thereby ensuring the independence, impartiality and credibility of the research carried out. Adherence to these guidelines by all staff is essential to preserve the trust of the scientific community and society at large.

[2] https://cvn.fecyt.es/editor/#HOME

4. RESEARCH PROTOCOLS AND PROCEDURES

4.1. Research and Innovation Protocols

Any research and innovation project to be carried out within INCLIVA must be set out in writing in a detailed protocol that guarantees the planning, transparency and quality of the study.

This document must include the background, working hypothesis, objectives, methodology to be employed, composition of the research team, distribution of tasks, work plan with its timetable, necessary material resources and a detailed financial assessment of costs and the budget, as well as the expected results and the impact generated. Furthermore, a plan for disseminating the results must be established, taking into account criteria for authorship and recognition of individual contributions.

Any protocol must be authorised by the relevant committees and, where third-party facilities, equipment or materials are used, must obtain the necessary approval.

In projects involving collaboration with other research groups not belonging to INCLIVA, it is essential to formalise a written agreement defining the scope, conditions and deadlines of the collaboration.

Prior to implementation, the protocol must be assessed by the Committee on Ethics in Research Involving Medicines (CEIm) of the Hospital Clínico Universitario de València, ensuring that it complies with applicable legal and ethical requirements. For research involving laboratory animals, validation by the University of Valencia's Committee on Ethics in Animal Experimentation (CEEA) and authorisation by the competent authority will be required. Furthermore, it is recommended that studies involving human subjects be registered in a publicly accessible database free of charge prior to the selection of the first participant.

The principal investigator must conduct the study in accordance with the approved protocol. Any modifications deemed necessary must be included in a new version of the protocol, submitted for review by the relevant committee and communicated, where appropriate, to the project's funding bodies. These procedures ensure scientific integrity, regulatory compliance and adherence to ethical principles in health research.

4.2. Research team

The research protocol shall describe in detail the composition of the team, identifying the principal investigator and collaborating staff, together with their training, experience, degree of involvement and level of commitment to the project. This information shall be reflected in the document *"Research Team* Commitment" (Annex I) specific to this institution, in which each member expressly accepts the applicable regulations.

Where the participation of several research groups from different centres is envisaged, the terms of collaboration shall be formalised in writing, including the rights, duties and deadlines agreed between the parties through a consortium agreement. The principal investigator assumes responsibility for the proper conduct of the study at the centre, including the selection of a suitable team.

Likewise, the curricula vitae (FECYT CVN) of all team members must be attached, stating any possible incompatibility or conflict of interest, except in those cases where the call for applications establishes a specific template for this purpose.

The research team must undertake to adhere strictly to the authorised research protocol. No unilateral modifications shall be made without the consent of the rest of the team, the sponsor (where applicable), and

without the approval of the Committee on Ethics in Medical Research (CEIm) of the Hospital Clínico Universitario de València. Any modification shall be documented in a new version of the protocol and, where applicable, communicated to the funding body in accordance with established procedures.

In studies without funding, the principal investigator shall ensure that the conduct of the study does not incur any costs for the centre. If any expenditure is anticipated, this must be communicated in advance to INCLIVA's Scientific Directorate and Management for their assessment.

Finally, R&D&I projects submitted to competitive public or private funding calls may be reviewed by the institute's Research Committee with the aim of improving their content and success rate. Furthermore, in cases where the funding body imposes a restriction on the number of applications submitted per centre, the institution's advisory committees shall select the most suitable proposal(s) based on the published criteria.

5. ETHICAL REQUIREMENTS IN RESEARCH

5.1. Research involving human subjects

The conduct of research projects involving human subjects, using biological samples of human origin, or utilising personal data must comply with the provisions of the regulatory framework set out in Law 14/2007 of 3 July 2007 on Biomedical Research and must always include, as a minimum, a favourable report from the Committee on Ethics in Medicinal Research (CEIm) of the Hospital Clínico Universitario de València.

Any project involving intervention on individuals must have the informed and express consent of the participants, or, where applicable, of their legal representatives in the case of minors or incapacitated persons. This consent must be freely given, specific, informed and provided in writing, as well as complying with the requirements set out in Law 14/2007 of 3 July on Biomedical Research and other applicable national and regional regulations. Only in exceptional and duly justified circumstances may the CEIm authorise a waiver of informed consent[3] . Where applicable, projects must clearly specify any financial compensation offered to participants, ensuring that this does not involve coercion or unduly influence their decision to participate.

For the purpose of ensuring liability insurance for interventions involving human subjects, in accordance with Article 18 of the Biomedical Research Act on compensation for damages and liability insurance, if the research project involves any intervention on human subjects (stress tests, monitoring, sample collection, etc.), prior liability insurance for the corresponding damages must be in place.

The confidentiality and protection of personal data shall be a priority throughout the research process: from collection and processing to storage and publication. As a general rule, the research team must receive and use anonymised data. In cases where it is not possible to conduct the research using this type of data, the research team should only receive the data after the application of pseudonymisation mechanisms that prevent the identification of participants.

At all times, current legislation on the protection of personal data shall be strictly complied with. Specifically, this includes the provisions of *Organic Law 3/2018 of 5 December on Data Protection and the Guarantee of*

[3] In the event that the project does not require direct action involving individuals, but only the processing of their personal data, the consent required (unless another legal basis is available), as well as the information to be provided, must be as set out in Regulation 2016/679 (General Data Protection Regulation). INCLIVA has secure environments for conducting research using patient data. Please contact the Platforms Coordination Team or the Quality and Data Protection Unit for further information.

Digital Rights, and *Regulation* (EU) *2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons* with regard to the processing of personal data, which govern research involving health data. To support this work, INCLIVA has a Data Protection Unit which ensures compliance with these requirements (email:protecciondatos@incliva.es).

Personal data and biological samples obtained within the framework of a project may not be transferred to third parties, reused in other studies or used for purposes other than those originally intended, unless explicit consent has been obtained from the donors or approval has been granted by the CEIm.

Clinical trials with medicinal products and medical devices

All studies must be conducted in accordance with the ethical principles set out in the Declaration of Helsinki, in line with Good Clinical Practice (GCP) guidelines and applicable regulatory requirements. The responsibilities of all parties involved shall be defined in accordance with the provisions of the Good Clinical Practice Guidelines (ICH E6 (R3) Guideline)[4] and Royal Decree 1090/2015.

Prior to the start of the study, a favourable opinion must be obtained from a Medicines Research Ethics Committee (CEIm). Furthermore, in accordance with Royal Decree 1090/2015, a contract must be signed with all participating centres and the study must be registered in a publicly accessible database prior to the inclusion of the first subject. In Spain, registration with the Spanish Clinical Trials Register (REec) is mandatory for clinical trials involving medicinal products.

Furthermore, depending on the type of study, authorisation from the Spanish Agency for Medicines and Health Products (AEMPS) will be required. Specifically, it will be necessary to apply for such approval via on the European CTIS portal in the case of a clinical trial involving medicinal products, defined as any research in humans intended to:

1. Discover or verify the clinical, pharmacological or pharmacodynamic effects of one or more medicinal products;
2. Identify any adverse reactions to one or more medicinal products;
3. To study the absorption, distribution, metabolism or excretion of one or more medicinal products with the aim of determining their safety and/or efficacy.

In addition, at least one of the following conditions must be met:

- The subject is pre-assigned to a therapeutic strategy that is not part of the Member State's standard clinical practice;
- The decision to prescribe the investigational medicinal product is made at the same time as the decision to include the subject in the study;
- Diagnostic or monitoring procedures are applied that go beyond standard clinical practice.

If none of these conditions are met, the study will be considered an observational study involving medicinal products. In the Valencian Community, prospective observational studies will require the approval of the

[4] International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH Harmonised Guideline. Guideline for Good Clinical Practice E6 (R3). https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf

CAEPO (Autonomous Committee for Ethics in Research Involving Medicinal Products in the Valencian Community).

Any systematic research involving one or more human subjects with the aim of evaluating the safety or performance of a medical device will require, depending on the case, authorisation or notification to the AEMPS:

- Product without a CE mark or with a new indication intended to obtain the CE mark: Approval by the AEMPS.
- Product with CE marking and used within the approved indication: Notification to the AEMPS.
- Product without a CE mark or with a new indication where there is no intention to obtain the CE mark: Consult the AEMPS on a case-by-case basis.

In performance studies involving in vitro diagnostic medical devices, approval from the AEMPS will only be required if surgically invasive samples taken exclusively for research purposes are used.

Research involving human embryonic material

Any research project involving the collection, processing and/or storage of biological material of human embryonic origin or functionally similar cells must request a report from the Commission for the Safeguarding of the Donation and Use of Human Cells and Tissues[5] , attached to the Carlos III Health Institute. Prior to this, it must also have the approval of the Animal Experimentation Ethics Committee (CEEA).

Applicable legal framework

- Law 14/2007 of 3 July on Biomedical Research.
- Organic Law 3/2018 of 5 December on Data Protection and the Guarantee of Digital Rights.
- Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data.
- ICH E6 (R3): Guidance on Good Clinical Practice. 6 January 2025.
- Royal Decree 1090/2015 of 4 December regulating clinical trials with medicinal products, Ethics Committees for Research involving medicinal products and the Spanish Register of Clinical Trials.

5.2. Animal research

At INCLIVA, the use of animals in scientific research must be governed by the strictest ethical, scientific and legal principles. Research using animal models will only be carried out when no valid alternative methods exist and with the aim of achieving advances relevant to human, animal or environmental health.

INCLIVA has the Animal Experimentation Ethics Committee (CEEA) of the University of Valencia, whose main function is to ensure compliance with current regulations on animal protection and welfare. The CEEA will evaluate and issue reports on all projects involving the use of animals, whether for research, teaching or training purposes, prior to their submission to the competent authority: the Regional Ministry of Agriculture of the Valencian Regional Government. This Committee also acts as an advisory body to the Institute's management and its researchers on all matters relating to animal experimentation.

[5] Carlos III Health Institute (ISCIII). Ethics Committee. Available at: http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/fd-organizacion/fd-estructura-directiva/fd-subdireccion-general-investigacion-terapia-celular-medicina-regenerativa/fd-comites/comision-de-garantias.shtml

In accordance with the provisions of Royal Decree 53/2013, Law 32/2007, Directive 2010/63/EU and Order ECC/566/2015, any procedure involving the use of animals shall require a prior assessment to ensure:

- The scientific and ethical justification for the use of animals, in the absence of alternative methods.
- The replacement of animals where viable alternatives exist.
- The reduction of the number of animals to those strictly necessary to obtain statistically valid results.
- The refinement of procedures to minimise pain, suffering, distress or lasting harm to the animals.

To obtain authorisation from the Regional Ministry of Agriculture of the Valencian Regional Government as the competent authority, it will be necessary to submit to the CEEA a detailed project report that includes at least:

- Title, objectives, principal investigator and department involved.
- Start and end dates of the procedure.
- Justification of the need to use animals.
- Species, number and final destination of the animals.
- Methodology and experimental procedures.
- Anaesthesia, analgesia and euthanasia techniques, as well as end-point criteria.
- Accreditation of the personnel involved and their training in accordance with current regulations.

Animals must be kept in authorised facilities, under constant veterinary supervision, in standardised environmental conditions that ensure their welfare and allow, wherever possible, the expression of species-specific behaviours.

The principal investigator shall be responsible for ensuring compliance with the legal requirements applicable to each project, as well as the accuracy of the scientific data generated.

Animal welfare is a fundamental ethical commitment for our Institute, and all staff involved in projects involving animal experimentation must act in accordance with these principles, with professionalism, respect and responsibility.

Research involving genetically modified organisms (GMOs)

The use of genetically modified organisms (GMO) in research projects must strictly comply with current legislation, ensuring safety for human and animal health and the environment. Any procedure involving the use, production, handling, transport or release of GMO must have the relevant prior administrative authorisation, in accordance with the provisions of Law 9/2003 of 25 April on the legal regime governing the contained use, deliberate release and marketing of GMOs, and its implementing regulations set out in Royal Decree 178/2004 of 30 January. Contained activities involving GMOs must be classified according to their risk level (from 1 to 4) and shall be subject to notification or authorisation depending on that classification.

Laboratories, facilities and procedures must be adapted to the technical and biosafety requirements for each level. Furthermore, it shall be mandatory to have a Biological Risk Prevention Plan and a biosafety officer to supervise activities involving GMs.

Staff involved must have specific training in the safe handling of GMO. All work must adhere to the principles of precaution, traceability, adequate containment and minimal exposure, promoting responsible use in accordance with authorised scientific purposes.

<u>Applicable legal framework</u>

- Law 32/2007 of 7 November on the care of animals in farming, transport, experimentation and slaughter.
- Directive 2010/63/EU of the European Parliament and of the Council of 22 September on the protection of animals used for scientific purposes.
- Royal Decree 53/2013 of 1 February, establishing the basic rules applicable to the protection of animals used in experimentation and other scientific purposes, including teaching.
- Order ECC/566/2015 of 20 March establishing the training requirements to be met by personnel handling animals used, bred or supplied for experimental and other scientific purposes, including teaching.
- Law 9/2003 of 25 April establishing the legal framework for the contained use, deliberate release and marketing of genetically modified organisms.
- Royal Decree 178/2004 of 30 January, approving the General Regulations for the implementation and enforcement of Law 9/2003.

5.3. Collection, registration, storage, safekeeping and preservation of samples and research results

Biological samples of human origin and associated data for research purposes

The principal investigator is responsible for managing the registration, storage and custody of biological samples and associated data within the framework of a research project. These activities must be reflected in the study protocol and follow the procedures established by a Biobank, in accordance with Article 22 of Royal Decree 1716/2011.

A biobank is defined as a facility that houses one or more collections of biological samples of human origin for biomedical research purposes, organised as a technical unit in accordance with quality criteria relating to both the origin and intended use of the samples. Informed consent for the donation of samples to a biobank is open-ended, meaning that the samples may be used for any biomedical research project that has been positively assessed by a scientific committee and an ethics committee.

INCLIVA has a Biobank officially authorised by the Directorate-General for Planning, Evaluation, Research, Quality and Patient Care of the Regional Ministry of Health of the Valencian Regional Government. This Biobank is registered in the National Biobank Register (No. B.0000768) and forms part of both the Valencian Biobank Network and the ISCIII Platform for Biomodels and Biobanks (https://www.incliva.es/servicios/plataformas/biobanco/).

The collections, for their part, are structured and permanent groups of human samples stored outside the organisational framework of a biobank, also intended for biomedical research. To use them, consent linked to a specific line of research is required, detailing the team responsible and the centre or centres where the studies will be carried out. These samples may not be used or transferred beyond what is specified, unless new consent is obtained. It is mandatory for there to be a person responsible for the collection, who must register it with the ISCIII National Register (collections section).

In cases where samples are stored for a specific research project, specific consent must be obtained detailing the research team, the centres involved, the duration of the project and other conditions. These samples may only be used in that specific project and may not be transferred to third parties, unless new consent is obtained from the source subject.

Samples taken prior to the Biomedical Research Act may only be used in accordance with the second transitional provision of Act 14/2007.

Every informed consent document must state the final destination of the samples, which may be: destruction of the sample, anonymisation, or free inclusion in a collection or biobank (registered in the ISCIII National Register), for which the subject's specific consent will be required (Article 27, Royal Decree 1716/2011).

In the case of samples intended exclusively for research purposes, they shall be retained only for as long as necessary for the purposes that justified their collection. Therefore, in the case of samples for a specific project, which by definition is time-limited, the samples and data must be destroyed upon completion of the project (unless new consent is given for a different use: collection, biobank or new project). Storage in collections or biobanks may be indefinite. In any case, the source subject retains the right to withdraw consent at any time, in which case the sample must be destroyed immediately.

Applicable legal framework

- Royal Decree 1716/2011 of 18 November, establishing the basic requirements for the authorisation and operation of biobanks for biomedical research and the processing of biological samples of human origin, and regulating the operation and organisation of the National Register of Biobanks for biomedical research.

Personal data: protection and confidentiality guarantees

Any research project involving the use of data that can be linked to individuals must guarantee the protection of privacy and respect for the rights and freedoms of participants, and must comply with current regulations, in particular Regulation 2016/679 on the Protection of Personal Data (RGPD) and Organic Law 3/2018 of 5 December on Data Protection.

To this end, INCLIVA has *institutional data protection and information security policies*[6] , which ensure compliance with the National Security Framework. This information is available on the institute's website.

Any research project using personal data should include in its protocol the data flow from collection to final disposal and must apply the relevant security measures, including:

- **Data location.** Any digital file or database containing personal data, provided it enables the project to be carried out, must remain within the IT infrastructure of the Hospital Clínico Universitario de València or INCLIVA, in order to benefit from the security measures provided by these networks. If, for other reasons, the data must be stored elsewhere, a location with appropriate security measures for this type of data must be selected.
  Furthermore, when information needs to be transferred, under no circumstances shall non-corporate, unencrypted channels be used for the transmission of the information, and the information itself must be encrypted.

  It is prohibited to store data on external devices without proper authorisation (personal, non-corporate computers, USB drives, flash drives, etc.), as well as to share or store information in cloud storage services outside of INCLIVA (Google Drive, WeTransfer, personal email accounts such as Hotmail, Gmail, etc.).

[6] https://www.incliva.es/wp-content/uploads/2025/05/org_1_-1_ENS_POL_001_Politica_de_Seguridad_de_la_Informacion_v1.pdf

- **Duty of confidentiality.** Any person who, in the course of their duties in relation to medical care and/or biomedical research, whatever the scope of either, and who accesses personal data, shall be subject to a duty of confidentiality, which shall continue even after the research or medical care has ceased, in accordance with the provisions of Article 5 of Law 14/2007 on biomedical research.
- **Confidentiality undertakings.** Any person with access to personal data must have a confidentiality undertaking which, in the case of staff with employment contracts linked to Hospital Clínico Universitario de València, University of València, the Carlos Simón Foundation and INCLIVA, is included in their employment contracts.
- **Physical media.** Personal data on physical media (signed informed consents, questionnaires, medical records, etc.) must be safeguarded using security measures that prevent access by unauthorised persons. The transfer of data from one location to another must take place if, and only if, required by the nature of the project and via secure means that guarantee the integrity, traceability and confidentiality of the data.
- **Encryption and pseudonymisation.** The encryption and pseudonymisation of data are fundamental measures to ensure the protection of the privacy of participants in research projects. Encryption involves replacing personally identifiable data with a code, whilst pseudonymisation allows data to be processed without directly identifying the subject, whilst retaining the possibility of re-identification via a secure key held by authorised personnel. All research staff must ensure that these techniques are rigorously applied, in compliance with current data protection regulations, and must restrict access to identifying information to only those persons strictly necessary for the project. In the event that the research team is not required to know the identity of the participants, the person responsible for coding and safeguarding the correspondence of such codes must be from a functional area separate from the research team, in accordance with the provisions of the Seventeenth Additional Provision of Organic Law 3/2018 on the Protection of Personal Data.

Research staff must undertake to use personal data exclusively for the purposes authorised in the project and not to disclose it to third parties without the relevant consent. Furthermore, they are responsible for ensuring that data is stored securely and destroyed appropriately once the research has been completed, unless consent has been obtained for its retention for additional scientific purposes.

INCLIVA will promote the continuous training of research staff in data protection and confidentiality, fostering a culture of respect and responsibility in the handling of personal information in scientific research.

Applicable legal framework

- Organic Law 3/2018 of 5 December on Data Protection and the Guarantee of Digital Rights.
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data.
- Law 14/2007 of 3 July on Biomedical Research.

6. Publication, dissemination of results and authorship

6.1. Publication and dissemination of results

The publication and dissemination of results constitute a fundamental ethical responsibility of research staff, as they form an essential part of the scientific process and the duty of accountability regarding the use of public and private resources allocated to research. The communication of findings—whether positive, negative or inconclusive—must be carried out with honesty, transparency and rigour, thereby contributing to the advancement of knowledge and fostering scientific debate within the research community.

Results should preferably be published in specialist scientific journals before being disseminated to the general public, always respecting the principles of truthfulness, accuracy and fidelity to the data. Plagiarism and/or falsification of data are unacceptable and constitute grounds for disciplinary action.

All publications must include acknowledgement of the Research Ethics Committee that approved the study, where applicable, as well as the funding body. In the event of dissemination in the general media, this shall only be permitted following prior scientific publication and with institutional approval, ensuring that the language is adapted for non-specialist audiences.

Redundant or fragmented publication of the same study for the sole purpose of increasing the number of publications shall be avoided, except for justified reasons of length or editorial requirements. The removal of cases or variables must be duly documented and justified. Should substantial errors be detected after publication, research staff must proceed to correct them or, where necessary, retract the work, in accordance with the relevant editorial policies and the principles established by the Committee on Publication Ethics (COPE).

The results of publicly funded research must be published without undue delay, except in cases where it is necessary to protect intellectual or industrial property, in compliance with Law 20/2015 of 24 July on Patents and Law 17/2022 of 5 September on Science, Technology and Innovation. As set out in the regulations governing these grants, the results shall be published in Open Access media, to ensure the free dissemination of results obtained from activities supported by public funds.

Where contracts or agreements exist with public or private entities, the dissemination of results shall be carried out in accordance with the stipulated clauses, whilst always ensuring compliance with ethical principles and scientific transparency.

Research staff must refrain from creating unfounded expectations or exaggerating the clinical or social applicability of findings, whether in publications, public presentations or in the media.

Communications aimed at the general public must adopt a clear, accessible approach, always mentioning institutional affiliation and, where possible, the grants and funding received.

In the case of opinion pieces, it must be made clear that the views expressed are the sole responsibility of the authors.

Mention of INCLIVA and acknowledgements

It is mandatory to mention affiliation with INCLIVA in any dissemination of results, in accordance with the *Guide to Signatures and Affiliations for Research Staff*, the aim of which is to ensure that research activity is visible, identifiable and quantifiable.

Regarding the acknowledgements section of a publication, the individuals or institutions mentioned therein have the right to decline such mention; therefore, they must be informed in advance. Some journals require written authorisation from those individuals who are to be included in the acknowledgements.

Intellectual and Industrial Property

In compliance with the laws applicable to the management and protection of knowledge in the field of industrial and intellectual property, such as Law 24/2015 of 24 July on Patents, Royal Legislative Decree 1/1996 of 12 April approving the consolidated text of the Intellectual Property Law and its amendments, as well as Law 1/2019 of 20 February on Trade Secrets, a regulation resulting from the transposition of Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016, on the protection of undisclosed know-how and business information (trade secrets), and the internal regulations in force or any other applicable legislation, the results generated within the framework of INCLIVA's research activities, such as publications, data, computer programs, inventions or any other product eligible for protection, are considered intellectual or industrial property owned by INCLIVA, unless otherwise established by specific agreements.

It is the responsibility of research staff to inform the Innovation Support Unit of any results that may be eligible for protection prior to any oral or written disclosure, such as publications, conference presentations, theses, master's dissertations or meetings with external personnel, amongst others, in order to assess their potential for exploitation and the feasibility of their registration and, where appropriate, to ensure their adequate legal protection or to put in place measures to safeguard their confidentiality.

In collaborative or third-party funded projects, contracts shall be drawn up clearly stipulating the ownership and exploitation rights of the results generated, as well as confidentiality obligations.

INCLIVA will promote training and awareness-raising among research staff regarding intellectual and industrial property, including aspects related to the protection of results, licences, technology transfer and commercial exploitation.

6.2. Authorship Policy

Scientific authorship should be attributed solely to those individuals who have made a substantial contribution to the research work. This policy is in line with the recommendations of the Carlos III Health Institute (ISCIII), the International Committee of Medical Journal Editors (ICMJE) and other leading international bodies on scientific publication ethics.

Criteria for authorship

An author is recognised as having made a substantial contribution to at least one of the following aspects:

- The conception or design of the work, or the acquisition, analysis or interpretation of the data.
- The drafting of the article or the critical review of its intellectual content.
- The final approval of the version to be published.
- Taking responsibility for all aspects of the work, ensuring that issues relating to the accuracy or integrity of any part of the work are properly investigated and resolved.

Furthermore, all authors must have participated in the work sufficiently to take public responsibility for its content. To this end, wherever possible, authors should include an 'Authors' Contribution Statement' in the final publication to describe the responsibilities and contributions of each author.

Order of authorship in scientific publications

In general, the following recommendations regarding the order of authorship in scientific publications should be followed:

- The first author is directly responsible for carrying out the activities that lead to the publishable results. Normally, they are also responsible for drafting the first version of the publication.
- The last author is the intellectual lead for the publication and has directed the activities that led to the publishable results.
- The remaining authors (from the second to the penultimate position) may be listed alphabetically or in order of contribution to the development of the scientific publication.

In the event that two or more authors have contributed equally to the development of a publication (particularly in the case of the first or last author), and provided the publisher permits it, this shall be indicated in the text of the publication itself.

Ethical conduct in scientific publications

Authors must declare any conflicts of interest, as well as the sources of funding for the research or publication.

Authors and publishers issue corrections or retract publications where necessary; retraction procedures are clear, the reasons for retraction are specified, and authors are given credit for publishing corrections after publication.

Authors recognise that negative results may be as relevant for publication and dissemination as positive results.

Authors are accurate and honest in their communication with colleagues, policymakers and society at large.

Authors are transparent in their communication, dissemination and public engagement regarding the assumptions and values that influence their research, as well as the strength of the evidence, including any remaining uncertainties and gaps in knowledge.

Authors follow the same criteria detailed above, whether they publish in a subscription journal, an open-access journal or any other form of publication, including preprint servers.

Improper authorship practices

The following practices shall be considered unacceptable:

- Honorary authorship: the inclusion of individuals who have not made a significant contribution.
- Ghost authorship: the exclusion of individuals who have contributed.

The mere fact of having provided funding, supervised the group or played a managerial role does not justify inclusion as an author.

Recommendations and tools for responsible authorship

- The use of the CRediT (Contributor Roles Taxonomy)[7] is recommended for the detailed identification of each author's role.
- The order of authorship should be established by consensus from the start of the project.

[7] https://credit.niso.org/

- The use of persistent identifiers such as ORCID is recommended.
- Contributions must be documented in writing in cases of multiple co-authorship.

Resolution of authorship disputes

In the event of disagreement among the authors, dialogue and mediation within the research team will be encouraged. If no agreement is reached, the dispute will be referred to INCLIVA's Good Practice Committee, which will assess the situation objectively and in accordance with the established criteria.

Institutional commitment

INCLIVA is committed to promoting transparency and ethics in the attribution of authorship through:

- Specific training in the ethics of scientific publication.
- Dissemination of criteria and guidelines on responsible authorship.
- Regular monitoring of applicable editorial policies and good practice guidelines.

6.3. Review and evaluation

The communication and dissemination of research results must not take place unless they have been subject to review and evaluation by the Institution. This would only be justified in situations posing a risk to public health that require rapid responses (health emergencies, epidemiological outbreaks, alerts relating to the safety of medical devices or medicines, etc.), whilst also considering the possibility of the results being reviewed on an urgent basis or agreeing on an exceptional scope of communication.

Within the scientific community, the most frequently used procedure for validating written work, with the aim of assessing its quality and scientific rigour, is peer review or scientific arbitration.

INCLIVA encourages researchers to participate ethically in peer review, both as reviewing authors and in accepting reviewers' comments on their own work. Likewise, research staff must commit to these review and evaluation tasks.

It is important to bear in mind that the review must be objective and evidence-based, with no conflicts of interest.

The following aspects should be taken into account as best practices for conducting peer review:

- **Transparency**: Reviewers must declare any conflicts of interest that may influence their evaluation.
- **Objectivity**: Comments should be constructive and focus on improving the scientific quality of the work, not on personal aspects.
- **Confidentiality**: The content of the manuscript must be treated confidentially throughout the review process, respecting the rights of the authors and candidates, and permission must be sought to make use of the ideas, data or interpretations presented.
- **Rigour and timeliness**: The review must be conducted rigorously and within a reasonable timeframe, ensuring compliance with the deadlines set by the journal or the editorial board.
- **Quality**: Evaluation practices are adopted that are based on principles of quality, advancement of knowledge and impact, going beyond quantitative indicators and taking into account diversity, inclusion, openness and collaboration where relevant.

6.4. Open science

INCLIVA, in line with the principles of Plan S, the European Open Science Strategy and its own *Institutional Open Science Policy*[8] , promotes a research model based on the principles of open science. This model fosters a more transparent, collaborative, reproducible and accessible scientific practice, in which knowledge is shared not only within the scientific community, but also with society as a whole.

Open science is structured around several fundamental pillars, which reinforce one another:

- Open Access publications
- Open research data managed in accordance with the FAIR principle (Findable, Accessible, Interoperable, Reusable)
- Open code and tools
- Open and transparent peer review
- Public participation in science
- Responsible management of intellectual property

INCLIVA's commitment to open science aims to ensure that the results of publicly funded research are available without financial, legal or technical barriers, thereby maximising their scientific and social impact.

In accordance with the provisions of Law 17/2022 of 5 September on Science, Technology and Innovation, INCLIVA's research staff must publish the results of publicly funded research in open access. This requirement is already included in the evaluation indicators for health research institutes accredited by the ISCIII. This obligation extends to specific mandates of programmes such as Horizon 2020, Horizon Europe, or the requirements of national and regional funding agencies.

There are two main ways to comply with this obligation:

- Gold Route: Direct publication in open-access journals. This method may involve the payment of APCs (Article Processing Charges).
- Green Road: Depositing the manuscript accepted for publication in an institutional or subject-specific repository.

Recommendations and best practices for open access publishing

To comply properly with the principles of open science, research staff should consider:

1. Version of the manuscript permitted for open access publication.
2. Copyright: retaining the rights necessary for the dissemination of results.
3. Open licences (Creative Commons): CC-BY is particularly recommended.
4. Publication costs (APCs): it is recommended that these costs be included in project budgets. The Support Plan for Emerging Groups provides for the funding of Open Access publication costs.

The implementation of open science practices brings significant benefits:

- Greater transparency, reproducibility and scientific quality.
- Increased visibility, impact and citation of results.

[8] https://www.incliva.es/wp-content/uploads/2023/02/POLITICA-OPENSCIENCE-2020.pdf

- Facilitation of interdisciplinary collaborations.
- More effective knowledge transfer to society.
- Reduction of malpractice through more auditable processes.

INCLIVA has drawn up and implemented an Open Science policy. Research staff consult and apply this policy during the conduct and publication of their scientific activities.

6.5. Annual Scientific Report

All research activity carried out at INCLIVA will be summarised each year in the Institute's Annual Scientific Report.

This report will be distributed to all Institute staff and published on the Institute's website for dissemination and awareness among the wider scientific community and society.

Irrespective of the preparation of this annual report, each department, unit, research group or research support unit belonging to INCLIVA may publish or disseminate its activities using the guidelines set out in this Code of Good Research Practice.

Applicable legal framework

- Law 17/2022 of 5 September on Science, Technology and Innovation.
- Law 24/2015 of 24 July on Patents.
- COPE (Committee on Publication Ethics). Code of Conduct and Best Practice Guidelines for Journal Editors.
- https://www.icmje.org/news-and-editorials/icmje-recommendations_annotated_jan25.pdf
- Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities, 2003.
- Plan S: Principles and Implementation. Coalition S, https://www.coalition-s.org/.
- European Commission Recommendation on access to and preservation of scientific information (2012/417/EU).
- European Open Science Cloud (EOSC).
- Horizon Europe programme (2021–2027).
- DOAJ (Directory of Open Access Journals): https://doaj.org
- SHERPA/RoMEO: https://v2.sherpa.ac.uk/romeo
- Recommendations of the International Committee of Medical Journal Editors (ICMJE). Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. https://www.icmje.org/news-and-editorials/icmje-recommendations_annotated_jan25.pdf.

7. CYBERSECURITY AND AI

In an environment as sensitive as biomedical research, **cybersecurity** is not a technical add-on, but an essential requirement for protecting knowledge, data integrity and, above all, people's rights. For this reason, INCLIVA, as an organisation belonging to the instrumental public sector, must have a framework in place that establishes conditions of trust in the use of electronic media as part of the cybersecurity obligations set out in the National Security Scheme (ENS) and integrate these into standard practice in day-to-day work.

Accordingly, INCLIVA has updated its working processes with a series of **cybersecurity policies and procedures** to strengthen safeguards in health research.

INCLIVA has an *Information Security Policy*[9] to ensure the protection, integrity and availability of the foundation's data.

Among the actions to be taken by researchers, we refer primarily to:

Equipment and resources provided by INCLIVA

- The corporate equipment and resources provided by the foundation are for professional use only.
- They must not be used for personal purposes or to extract data from them, unless expressly authorised and for a justified reason.

Protection of Information and Personal Data

- Protect data both at rest and in transit, particularly on mobile devices and networks.
- Implement measures such as pseudonymisation and anonymisation, as well as encryption (backups, communications, files).
- Ensure that sensitive data is stored in secure environments and that communications are encrypted.

Access Control

- Apply the principle of least privilege for data access.
- Passwords must be secure, containing uppercase letters, symbols and numbers, and changed regularly, particularly if they are suspected of having been compromised.
- It is preferable to use a password manager (such as 'Keepass') rather than writing them down. The use of 'two-factor authentication' is recommended.

Training and Awareness

- Train researchers and staff in security policies and best practices.
- Promote a culture of cybersecurity and the identification of threats such as social engineering.
- Establish channels for reporting unusual behaviour.

Security Incident Management

- Have a plan in place for the detection, logging, analysis and response to incidents.
- Make backups on at least two different media and appoint a person responsible for ensuring that important information is backed up.
- Assess the causes and lessons learnt from each incident to prevent recurrence.

[9] https://www.incliva.es/wp-content/uploads/2025/05/org_1_-_ENS_POL_001_Politica_de_Seguridad_de_la_Informacion_v1.pdf

Systems and Applications Security

- Keep software and systems up to date. Use correctly licensed software from secure sources.
- Assess security throughout the application lifecycle (testing, audits, secure libraries).
- Biomedical applications must comply with specific security requirements. For further information, please contact the relevant INCLIVA specialist units (such as IT, Innovation and Data Protection).
- The use of personal email addresses for corporate communications is prohibited. Instead, one of the following addresses must be used: (1) the foundation's own @incliva.es; (2) the University of Valencia's @uv.es; (3) the Carlos Simón Foundation's @carlossimonfoundation.com / @fundacioncarlossimon.com; (4) the Valencian Regional Government's @gva.es. In communications with external parties, such as companies, they should preferably be asked to use their corporate accounts.

Monitoring and Surveillance

- Prioritise the use of secure servers by storing data in shared network folders or corporate cloud storage, such as OneDrive or SharePoint.
- The use of portable storage devices, such as USB *sticks* or USB drives, is strictly restricted, requiring prior authorisation and additional safeguards.
- Use security tools and monitor open sources.
- Particular care must be taken with external email senders or recipients when they use non-corporate accounts.

On the other hand, the incorporation of **generative artificial intelligence tools** into scientific research processes can bring agility, creativity and new analytical capabilities. However, their use also entails ethical, legal and methodological risks that researchers must be aware of and manage responsibly. The key principles for the ethical, transparent and rigorous use of these technologies are set out below.

Personal responsibility and scientific integrity

The use of generative AI does not exempt researchers from their responsibility for the content produced. Researchers must maintain a critical attitude towards the results generated by these tools, recognising that they may contain errors, biases, fabrications (known as 'hallucinations') or incorrect statements. Research integrity requires the verification and validation of information.

Transparency in the use of AI

Any significant use of generative AI tools must be declared transparently. Where AI has influenced key aspects of the research, its use must be explicitly documented, for example, in the methodology section of the article or report. This declaration must include the name of the tool, its version, the date of use, the function it performed and how it affected the development or results of the work.

Protection of privacy, confidentiality and rights

The use of generative AI must not compromise individuals' privacy, the confidentiality of ongoing research or intellectual property rights. Researchers must avoid entering personal data, unpublished work or confidential information into external tools.

Legal compliance and respect for authorship

Researchers must at all times comply with national, European and international legislation on intellectual property and data protection. AI-generated content may reproduce fragments of protected works; it is therefore essential to avoid plagiarism and to properly cite any third-party material that has influenced the results obtained. The ultimate responsibility for the accuracy of citations and the acknowledgement of sources always lies with the researcher.

The above guidelines have been drawn up in accordance with the Guidelines for the Responsible Use of Generative AI in Research[10] .

8. BREACH OF RESEARCH INTEGRITY

Scientific research carried out at INCLIVA must be governed by the highest standards of ethics, methodological rigour and professional responsibility. Research integrity is essential for generating reliable knowledge, preserving the credibility of research staff, protecting participants and ensuring public trust.

According to the Office of Research Integrity (ORI)[11] , research misconduct is defined as fabrication, falsification, plagiarism or other practices that deviate significantly from those commonly accepted by the scientific community for the design, conduct or reporting of research results. This definition excludes honest errors or differences of judgement in the interpretation of data.

Failure to adhere to good scientific practice negatively affects the quality of research, damages relationships among researchers, undermines public trust in science, constitutes an inefficient use of resources, and may cause unnecessary harm to research subjects, users, society or the environment.

Behaviours considered to be serious breaches of research integrity include:

- Fabrication: the invention of non-existent data, results or observations.
- Falsification: altering procedures, data or results with the intention of misleading.
- Plagiarism: presenting the ideas, texts, methods or results of others as one's own without proper attribution.
- Misrepresentation of authorship: including people who have not contributed to the work or excluding those who have.
- Redundant publication or unjustified fragmentation of results.
- Concealment or failure to declare conflicts of interest.
- Interference with or sabotage of another person's scientific work.
- Serious failure to preserve data, improper deletion or destruction of relevant documentation.

[10] https://research-and-innovation.ec.europa.eu/document/download/2b6cf7e5-36ac-41cb-aab5-0d32050143dc_en?filename=ec_rtd_ai-guidelines.pdf
[11] https://ori.hhs.gov/

- Inappropriate pressure on trainee staff to obtain results at any cost.

INCLIVA promotes a culture based on excellence, responsibility and transparency, encouraging continuous training in good scientific practice, open access to regulatory and ethical resources, accessible mechanisms for ethical advice and consultation, and working environments that foster collaboration and the exchange of knowledge.

In their most serious forms, unacceptable practices are punishable, but before reaching this extreme, every possible effort must always be made to prevent, deter and avoid them through training, supervision and mentoring, thereby fostering a positive and collaborative research environment.

In the event of a well-founded suspicion of possible scientific misconduct, any member of INCLIVA staff may report it confidentially and in good faith to the **Commission for Integrity and Management of Conflicts of Interest**. The Commission will assess the information received and determine whether to initiate a formal investigation. If so, an evaluation committee may be established, comprising experts in the relevant scientific field who have an impeccable professional track record, no conflict of interest, and knowledge of integrity and current regulations.

The investigation will be conducted in accordance with strict principles of confidentiality, impartiality and respect for the rights of all those involved, guaranteeing the right to be heard and to present arguments. Once the analysis of the facts has been completed, the committee will draw up a detailed report setting out its conclusions. If misconduct is established, the Scientific Directorate will inform the Executive Management and, where appropriate, the decision will be forwarded to the funding agencies, scientific journals or competent judicial authorities. Individuals accused of research misconduct will be provided with full details of the allegation(s) and guaranteed a fair process to respond to the allegations and present evidence.

If the investigation determines that the complaint was unfounded and made in bad faith, the necessary measures will be taken to restore the reputation of the person under investigation, and corrective action against the complainant will be considered. In all cases, INCLIVA will act in accordance with the principles of justice, protection of professional integrity and commitment to research ethics, presuming the innocence of any professional until proven otherwise.

INCLIVA, as an institutional commitment, will protect whistleblowers acting in good faith, guarantee the confidentiality of the processes and periodically review its procedures regarding scientific integrity, reinforcing ethics as a cross-cutting principle of research activity.

9. RESPONSIBLE RESEARCH AND INNOVATION (RRI)

INCLIVA is institutionally committed to promoting Responsible Research and Innovation (RRI), in line with the European principles of excellence, integrity and social responsibility. This strategy is implemented across all areas of the institute, with the aim of strengthening the social legitimacy of research and maximising its impact on health.

RRI at INCLIVA is structured around six key pillars: ethics, governance, gender equality, science education, open access and public engagement. These pillars are integrated in a practical way into research programmes and the management of R&D&I, with a translational approach aimed at improving the healthcare system and the well-being of the population.

Ethics

INCLIVA ensures compliance with ethical and legal principles in all its projects. Studies involving human subjects, biological samples or clinical data require the approval of the Committee on Ethics in Medicinal Research (CEIm) at the Hospital Clínico Universitario de València, recognised as the Institute's ethical review body. Furthermore, continuous training in bioethics and regulatory standards is promoted amongst research, clinical and management staff. All guidelines are set out in this Code of Good Research Practice.

Responsible governance

INCLIVA's structure promotes open, participatory governance based on continuous improvement. The Strategic Plan and the operational plans of the various departments are updated periodically, incorporating indicators of impact, quality and sustainability. The Scientific Management and advisory bodies promote transparency, peer review and the development of scientific integrity policies.

Gender equality

INCLIVA is firmly committed to gender equality as a cross-cutting principle in its research activity and organisational structure. It has an Equality Plan in place and an Equality Committee that promotes active policies to ensure equity in access, promotion and staff participation at all levels, both in the scientific and management spheres.

This commitment is reinforced by the HRS4R (Human Resources Strategy for Researchers) accreditation, awarded by the European Commission in 2019, which recognises INCLIVA's commitment to the continuous improvement of working conditions, professional development and the implementation of the principles of the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers. Among these principles, respect for equal opportunities and non-discrimination on the grounds of sex, gender or any other personal characteristic stands out.

Thanks to this strategy, INCLIVA promotes inclusive working environments, encourages the balanced participation of women and men in decision-making bodies, and ensures that recruitment and evaluation procedures are transparent, fair and merit-based. Furthermore, active efforts are being made to incorporate a sex and gender perspective into research content, with specific training for research staff in this area.

Science education and research culture

The Institute promotes a strong scientific culture among its staff, driving forward training activities, mentoring (currently in the design and implementation phase), and the promotion of good scientific practices. Through its Training Unit and in collaboration with academic institutions, INCLIVA organises workshops, conferences and courses that strengthen skills in open science, integrity, bioethics, project management and research leadership.

Open access and dissemination of knowledge

In line with national and European regulations, INCLIVA promotes open access to publicly funded scientific publications and research data, encouraging transparency and the reuse of knowledge. INCLIVA has an institutional Open Science Policy with guidelines for depositing in repositories and collaborating with open science platforms.

Citizen participation and science-society dialogue

INCLIVA bridges the gap between research and society through citizen science programmes, outreach activities and co-creative projects. Through Citizen Participation Groups in Health Research, the voices of

patients, carers and social representatives will be integrated into different stages of the research process, from identifying priorities to communicating results.

10. Updating and dissemination of the Code of Good Research Practice

The INCLIVA Management will ensure that the contents of this Code of Good Research Practice (CGRP) are known, accepted and adopted by all Institute staff. To this end, regular and ad hoc dissemination mechanisms will be established, at intervals deemed appropriate, thereby guaranteeing its effective implementation in research activities.

The CBPI will be subject to periodic review, at least once a year or whenever required by scientific advances, regulatory changes, recommendations from national or international bodies, or identified internal needs. The updating of the Code will be the responsibility of the bodies competent in matters of scientific integrity at INCLIVA, with the participation of the various professional profiles involved in research.

The Institute will ensure the Code is accessible by publishing it on its institutional website (https://www.incliva.es), making it freely available to INCLIVA staff, researchers from other institutions and the general public. This measure reflects the Institute's commitment to transparency, scientific ethics and the promotion of a culture of integrity in research.

Furthermore, the Code will be incorporated into the induction process for new staff as part of the essential information material, ensuring that, from the outset of their work at the Institute, all staff are aware of the principles and recommendations governing good scientific practice.

The Scientific Management and the heads of INCLIVA's Units will be responsible for ensuring not only awareness of the CBPI, but also its compliance in day-to-day research, fostering an environment of accountability, quality, rigour and ethical commitment.