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Guide to Good Practice in Research

Executive Summary

Health Research Institute of the Hospital Clínico San Carlos (IdISSC)

IdISSC
INSTITUTO de INVESTIGACIÓN SANITARIA
Hospital Clínico San Carlos

Index

1. PRESENTATION

The aim of this Guide to Good Practice in Research is to provide the Health Research Institute of the Hospital Clínico San Carlos with a common documentation that can be shared and respected by all the professionals who make up the Institute and that includes the rules of action and ethical principles relating to the research activity carried out at the Institute, from the planning and development of the research activity to the recording and communication of the same.

Therefore, the Guide to Good Practice in Research is the commitment of the Institute's scientific staff to research quality and integrity.

2. GUIDE TO GOOD PRACTICE IN RESEARCH

This Guide to Good Practice in Research of the Health Research Institute of the Hospital Clínico San Carlos aims to be a document with recommendations that promote the quality and integrity of the research carried out at the Institute. The recommendations of the **European Code of Conduct for Research Integrity (ALLEA)** have been included for reference:

Good research practices are based on fundamental principles of research integrity. They guide researchers in their work as well as in their engagement with the practical, ethical, and intellectual challenges inherent in research. These principles are:

• Reliability in ensuring the quality of research, reflected in the design, the methodology, the analysis, and the use of resources.

• Honesty in developing, undertaking, reviewing, reporting, and communicating research in a transparent, fair, full, and unbiased way.

• Respect for colleagues, research participants, society, ecosystems, cultural heritage, and the environment.

• Accountability for the research from idea to publication, for its management and organisation, for training, supervision, and mentoring, and for its wider impacts.

Good research practices in the following areas are described below:

- Researcher values and research environment
- Training and supervision of research staff in training
- Research planning and development
- Review, evaluation, publication, and dissemination of results

2.1. Researcher values and research environment

The main researcher values that should be present in good research practices are the following:

- Integrity
- Transparency
- Leadership and cooperation

The main characteristics defining each of these values are described below:

Integrity

Researchers should be honest about their own actions and those of other researchers. This value encompasses the full spectrum of research-related activities, including experimental design, data generation and analysis, application for funding, publication of results, and acknowledgement of all direct or indirect contributions from colleagues, collaborators, and others.

Plagiarism and falsification of results is considered to be professional malpractice in research and may be grounds for sanction. When applying for research grants, all information submitted by applicants is expected to be clear and accurate and in line with this Guide to Good Practice in Research.

In addition, researchers are also expected to declare and manage in accordance with this code of good practice any actual or potential conflicts of interest that may arise.

Transparency

While recognising the legitimate interest of individual researchers in pursuing their professional development, the Institute encourages researchers to be as open and transparent as possible in sharing and discussing their work with other members of the Institute or the public.

Once the results have been published, researchers are expected to make the relevant research results available to other colleagues upon request, provided that there is no ethical conflict over the results and that industrial and/or intellectual property rights over the results allow it.

Leadership and cooperation

Area directors and senior researchers have the responsibility to promote a working environment consistent with this code of good research practice, which encourages mutual cooperation, the development of individual skills and the free exchange of scientific knowledge.

These leaders must also ensure proper direction of research, supervision, and training of researchers.

2.2. Training and supervision of research staff in training

In order to achieve the ultimate goal of research excellence, the Institute develops a unique and integrated Training Plan for the different members of the Institute. This Plan has the following main objectives:

- **To promote the development of training activities in R&D&I** in accordance with a reference quality policy that contributes to their continuous improvement, which implies that the efficiency of their development must be planned, measured, and evaluated.
- To establish a **training offer** for the Institute's staff **that is adapted to the needs of staff** in training at all levels (from pre-university training to specialised continuing education for its most experienced and consolidated professionals).
- To contribute significantly to the training of its professionals in order to **keep their skills up to date**, tackle new projects, improve results, internal processes, etc. In other words, to contribute to excellence through the training of the people who make up the institution.
- **To promote the development of research** through the organisation of sessions, seminars, conferences, congresses, etc. involving professionals with different profiles (both from the entities that make up the Institute and from other entities), contributing to the intensification of relations between basic and clinical research groups.
- **To strengthen the existing research training offer in the entities that make up the Institute**, with special interest in training in basic, pre-clinical and clinical research methodologies.

Supervisors and mentors are expected to advise and supervise the entire research process, including the drafting of hypotheses, methodology, application for funding, recording and analysis of data, and assessment of any ethical issues that may arise. The training and development of young researchers is central to the Institute's quality and integrity policy. For this reason, the Institute relies on the institutions that make it up, which have a strong teaching component for the correct direction of research and supervision of all persons linked to the Institute for their training as scientific researchers or technical research assistants.

Trainees who are regularly engaged as researchers at the Institute will have a supervisor/tutor to support them in meeting the learning objectives and expectations initially set.

2.3 Research planning and development

2.3.1 Definition of the research protocol

The research protocol is the planning stage of an investigation. It is also the researcher's basic document, whose specifications enable him/her to guide the process of carrying out the work of a scientific research project with the greatest possible detail, precision, and clarity.

The research protocol should clearly and precisely state the objectives and research plan. The content should be sufficiently detailed and complete for anyone to be able to conduct such research with similar results, or to assess the validity and reliability of the study steps.

The basic components or contents that a research protocol should contain are: Title, Data on researchers and participating institutions, Abstract, Problem statement, Theoretical or conceptual framework, General and specific objectives, Methodological design, Bibliographical references, Timeline, and Resources.

In addition to all this, the research protocol must be clear, simple, and written in a way that its content can be understood by the project evaluators, the researchers, and the technicians involved in its execution.

2.3.2 Regulatory requirements in the conduct of research

Research projects must respect the fundamental principles established in the Declaration of Helsinki, in the Council of Europe Convention on Human Rights and Biomedicine, in the UNESCO Universal Declaration on the Human Genome and Human Rights, as well as comply with the requirements established in Spanish legislation in the field of biomedical research, personal data protection and bioethics.

Any research protocol involving the use of institutional computer files, the creation of databases containing information on individuals or any other processing of personal data must comply with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC and with Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights, as well as any other applicable data protection regulations and the procedures and directives in this area that, where appropriate, are approved by the entity of the Institute in which the corresponding investigation is carried out.

The regulatory requirements for conducting research projects are detailed below:

- **Human research**

Projects involving research on human subjects or the use of biological samples of human origin must comply with the provisions of Law 14/2007 of 3 July 2007 on Biomedical Research (hereinafter Law 14/2007 of 3 July 2007) and other relevant legislation in force.

The rights, safety and welfare of the study subjects are the most important considerations and must take precedence over the interests of science and society. Before initiating a study, foreseeable inconveniences and risks should be considered in relation to the anticipated benefit

to the individual trial subject and to society. Research should be initiated and continued only if the anticipated benefits justify the risks.

Studies must be scientifically reasonable and described in a clear and detailed protocol, which has received prior review and a favourable opinion/approval from the Clinical Research Ethics Committee.

Freely given informed consent must be obtained from each subject prior to their participation in the study.

The confidentiality of records that could identify subjects must be protected, respecting privacy and confidentiality rules, in accordance with relevant regulatory requirements as well as applicable data protection legislation.

All study data should be recorded, managed, and stored in a manner that allows for accurate reporting, verification, and interpretation.

The medical care that subjects receive and the medical decisions that affect them should always be the responsibility of a qualified physician or, where appropriate, a qualified dentist or other qualified personnel.

Each individual involved in the conduct of a study must be qualified by education, training, and experience to perform their work.

Systems and procedures must be carried out to ensure the quality of each aspect of the study.

Projects involving research on human subjects, whether prospective or retrospective, or the use of biological samples of human origin, or personal data, require a favourable report issued by the Clinical Research Ethics Committee or by an Ethics Committees for Research with medicinal products (RECmp), as appropriate, and, where applicable, depending on the type of study to be carried out, authorisation from the Spanish Agency of Medicines and Medical Devices and the corresponding Autonomous Community.

Projects involving clinical trials must comply with the provisions of Royal Decree 1090/2015, of 4 December, which regulates clinical trials with medicinal products, the Ethics Committees for Research with medicinal products, and the Spanish Clinical Trials Register.
Projects involving clinical investigations relating to medical devices shall comply with Regulation (EU) 2017/745.

Research projects involving the use of human stem cells or cell lines derived from them, as well as research projects involving the use of cells and tissues of human origin in the field of regenerative medicine must comply with the provisions of Law 14/2007 of 3 July on biomedical research and Royal Decree 2132/2004 of 29 October, which establishes the requirements and procedures for requesting the development of research projects with stem cells obtained from surplus pre-embryos and in Royal Decree 1527/2010, of 15 November, which regulates the commission of guarantees for the donation and use of human cells and tissues and the registry of research projects, as well as the rest of the legal regulations in force.

Projects involving research with human tissues and cells must comply with the provisions of the current text of Royal Decree-Law 9/2014, of 4 July, which establishes the quality and safety standards for the donation, collection, testing, processing, preservation, storage, and distribution of human tissues and cells, and approves the coordination and operational rules for their use in humans.

Any research protocol involving the collection and/or storage of biological samples shall ensure the confidentiality of donors, regardless of the degree of identification in which the samples are stored. Where non-anonymised samples are retained for genetic testing, consent shall be renewed each time new analyses are intended, provided that they are different from those foreseen in the first protocol.

The principal investigator and collaborators of a research project on human subjects shall follow faithfully and only what is provided for in the research protocol, especially with regard to obtaining informed consent from the participating subjects and the confidentiality of data, samples, and results.

Research involving invasive procedures or involving biological samples of human origin

They must be conducted in accordance with ethical principles originating from the Declaration of Helsinki, which are consistent with Good Clinical Practice and relevant regulatory requirements.

According to Law 14/2007 on Biomedical Research, they need the approval of a REC (the need for uniformity of criteria and a single opinion is also included in multicentre studies) and the contracting of liability insurance if they involve invasive procedures that involve a higher than minimal risk. It is up to the evaluating REC to make this assessment.

The treatment of samples in the research project will have to follow the requirements established in RD 1716/2011, which regulates the different treatment regimes for biological samples included in the research: project, biobank, or private collection.

Research staff shall undertake not to transfer data or biological samples to other projects or other researchers, or to make any use other than that for which consent was obtained, without the authorisation of the donors or the corresponding REC.

Research for genetic purposes

All research protocols involving the collection, processing and/or conservation of biological samples for genetic analysis shall comply with the provisions of the Biomedical Research Act and other applicable regulations and, especially, when the legislation so provides or, where applicable, it is possible and has been required, the patient shall be informed of the data arising

from the project. Whenever biological samples are intended to be used for purposes other than those foreseen at the time of donation or under terms different from those of the initial consent, a new specific, express, and written consent must be requested.

- **Animal research**

Projects involving animal experimentation must comply with the provisions of current legislation and, in particular, with the current text of Law 32/2007, of 7 November, on the care of animals in their exploitation, transport, experimentation and slaughter, and Royal Decree 53/2013, of 1 February, which establishes the basic rules applicable to the protection of animals used in experimentation and other scientific purposes, including teaching.

Projects involving the use of genetically modified organisms must comply with the provisions of Law 9/2003 of 25 April 2003, which establishes the legal regime for the contained use, voluntary release and commercialisation of genetically modified organisms, and with the current text of Royal Decree 178/2004 of 31 January 2004, which approves its Regulations.

Any research protocol involving animal experimentation shall never be implemented without the approval of the Animal Experimentation Ethics Committee (CEEA), of the corresponding authorised body and, where appropriate, of the competent body of the corresponding Autonomous Community.

The use of animals in experiments may only take place for the following purposes:

a) Fundamental research

b) Translational or applied research, and scientific methods for any of the following purposes:

1. The prevention, prophylaxis, diagnosis, or treatment of diseases, ill health or other anomalies, or their effects on human beings, animals, or plants

2. The assessment, detection, regulation, or modification of physiological conditions in humans, animals, or plants

3. Animal welfare, in particular the improvement of production conditions of animals kept for agricultural purposes

c) The development and manufacture of pharmaceuticals, food, feed and other substances or products, and the testing of their quality, efficacy and safety, for any of the purposes referred to in point b)

d) The protection of the natural environment in the interest of human or animal health or welfare

e) Research aimed at the conservation of species

f) Higher education or training for the acquisition or upgrading of professional skills

g) Forensic and legal medicine

Experiments may only be carried out by competent persons in accordance with the provisions of the applicable legislation on animal experimentation.

A procedure should not be carried out if another method or testing strategy for obtaining the desired result, which does not involve the use of live animals, is recognised in EU legislation.

Where there is a choice between different procedures, those most likely to provide satisfactory results and which meet the greatest number of the following requirements will be chosen:

a) using as few animals as possible

b) involving animals with the least capacity for pain, suffering, distress, or lasting harm

c) causing the least pain, suffering, distress, or lasting harm.

Wasteful duplication of procedures should be avoided, and alternative methods should be applied where possible. The animals ultimately used in experiments must be properly always cared for.

Experiments should be conducted under general or local anaesthesia unless the latter is more traumatic to the animal than the experiment itself or is incompatible with the purpose of the experiment.

- **Research with biological agents**

Projects involving the use of biological agents must comply with the provisions of Law 31/1995, of 8 November, on the Prevention of Occupational Hazards, and the Royal Decrees that develop it in terms of risks related to exposure to biological agents.

2.3.3 Responsibilities of researchers

As stated in the European Code of Conduct for Research Integrity, ALLEA:

- Researchers consider the latest state-of the-art in developing research ideas.
- Researchers design, carry out, analyse, and document research in a careful and well-considered manner.
- Researchers make proper and conscientious use of research funds.

In any application for research funding, the person responsible for the report is at the same time responsible for the veracity of the resources committed.

In the preparation of a personal CV, the author is responsible for the accuracy of its contents. As proof of this, it is advisable to sign the curriculum vitae document.

Researchers publish research results and interpretations in an open, transparent, honest and accurate manner, and respect the confidentiality of data or findings when legitimately requested to do so.

Researchers report their results in a way that is compatible with the standards of the discipline and, where applicable, can be verified and reproduced.

The principal investigator, in collaboration with the other researchers, should develop a plan for communication and publication of the possible results of the research.

In addition, applications for grants for new research projects should be avoided as far as possible if this would lead to a delay in the publication of the results of completed projects.

Because the process of data collection in clinical research is complex and not always repeatable, the principal investigator and collaborating staff involved in the research protocol must pay particular attention to ensure that the protocol reflects the quality of data collection and data custody.

2.3.4 Collaborative projects

Whenever a collaborative research project is carried out, it is advisable to formalise a protocol that sets out the terms under which the different groups from the same centre or different centres agree to collaborate.

The principal investigator and collaborating staff of research projects, not being responsible for the clinical treatment of those potentially involved, have an obligation not to interfere in any matter determined by the medical staff responsible for those subjects.

As stated in the European Code of Conduct for Research Integrity, ALLEA:

- All partners in research collaborations take responsibility for the integrity of the research.
- All partners in research collaborations agree at the outset on the goals of the research and on the process for communicating their research as transparently and openly as possible.
- All partners formally agree at the start of their collaboration on expectations and standards concerning research integrity, on the laws and regulations that will apply, on protection of the intellectual property of collaborators, and on procedures for handling conflicts and possible cases of misconduct.
- All partners in research collaborations are properly informed and consulted about submissions for publication of the research results.

2.3.5 Documentation, storage and custody of data, records, and biological or chemical material resulting from investigations

Any research protocol should, whenever possible, include a specific plan for the collection of data, records, and biological or chemical material resulting from the conduct of the research, as well as for their custody and preservation.

The principal investigator and his/her collaborating staff must collect any and all details observed in the experiments and observations of the research. All information, whatever it may be, should be permanently written down and entered into logbooks or *ad hoc* case report forms that may be established. So much so, that any intermediate or final data must correspond to that of the original documents, as would be the case of the patient's clinical history in clinical trials. Experiments and observations should include the number of persons involved and the time and circumstances of their conduct. Errors, negative, unexpected, or discordant results should never be ignored. Corrections must be clearly traceable and there must be a systematic identification of the person making the corrections.

Any documentary record of data or any sample forming part of a bank of biological or chemical material in the course of an investigation should be permanently accessible to all members of the research team. There is a mutual obligation between them with regard to the information, processing and interpretation of the data obtained.

All documentation (logbooks and case report forms among others) and biological or chemical material obtained in the course of a research project is the final property of the Institute, where it must remain duly guarded in accordance with the criteria of the corresponding entity of the Institute to which the principal investigator of the project belongs.

As stated in the European Code of Conduct for Research Integrity, ALLEA:

- Researchers, research institutions and organisations ensure appropriate stewardship and curation of all data and research materials, including unpublished ones, under secure protection for a reasonable period of time.
- Researchers, research institutions and organisations ensure that access to data is as open as possible and as closed as necessary, and, where appropriate, in line with the "FAIR" (findable, accessible, interoperable, and reusable) principles for data management.
- Researchers, research institutions and organisations provide transparency about how to access or make use of their data and research materials.
- Researchers, research institutions and organisations acknowledge data as legitimate and citable products of research.
- Researchers, research institutions and organisations ensure that any contracts or agreements relating to research outputs include equitable and fair provision for the management of their use, ownership, and/or their protection under intellectual property rights.

3. REVIEW, EVALUATION, PUBLICATION, AND DISSEMINATION OF RESULTS

3.1 Communication of results

Authorship of scientific papers

As a general rule, the order of the signing authors should be guided by the following:

- The first and last authors are those persons recognised by the rest of the group as the most important for the conception and development of the research and who have written the first draft of the article prior to its publication.
- The last author should be the one who bears ultimate responsibility for the research protocol.
- The rest of the authors can be ordered according to the importance of their contribution or simply in alphabetical order.
- There is a right to justify the order of signatures in a footnote.

It may be the case that two or more authors have shared the same effort in the development of the research and preparation of the manuscript. In these cases, and subject to acknowledgement by the rest of the group, the authors may be considered as first/last authors, and this must be explicitly reflected in the publication of the original.

The institutions to which the authors belong and those in which the research has been carried out should be mentioned.

The sources of funding that have provided funds (in part or in full) for the development of the research shall be included.

All contributions from formal collaborations or other contributions directly or indirectly supporting the research work that do not involve scientific authorship should be appropriately acknowledged. Failure to do so would be considered misappropriation of intellectual authorship.

The acknowledgements section should include contributions limited to functions such as fundraising or similar. Any contribution must be accompanied by an explicit acknowledgement of the assistance provided. This will include the services of support transversal units that have been required for the implementation of the research project.

For publications of multicentre studies involving a large number of participants, collective authorship and the designation of an Editorial Board may be accepted. In the case of a nominal list of authors, the order should be established according to objective criteria such as the number of patients contributed to the study. Individual centres can negotiate independently with the Editorial Board for separate publication of the particular contribution.

In all cases, the Area Director may review the writing before it is sent for publication and may offer advice and recommendations as appropriate. It will always retain the right to compel

authors to include an exclusion of liability statement that will save its own or the department's personal liability.

The affiliation procedure in publications deriving from the research activity of IdISSC members must expressly mention the Institute.

Publishing practices

Publication of results is essential if scientific knowledge is to be used effectively and in the public interest. The publication makes results available to the scientific community for verification, contrast and replication, and initiates a process of developing new results from the initial ones.

Communication and dissemination of research results to the media should follow their scientific publication. This would only be justified on public health grounds. In such cases, the authors will consider the possibility of having the results reviewed in parallel, as a matter of urgency, in a scientific journal, or they will agree on the scope of this exceptional communication with the editors of the journals in which they have planned their final publication.

The researcher with overall responsibility for the research programme should authorise the publication of the content (completeness of results, adequate peer review, adequate protection of intellectual property rights) and its place of publication.

Non-publication, delay in publication or overstating the relevance of results for clinical practice and health policy is considered an unethical and unlawful practice.

The publication of negative results or results that fall short of expectations is an unavoidable part of research.

If an error in a study undermines the value of its findings, a correction note should be issued as soon as possible.

The publication of the results of research involving individuals is an ethical and legal imperative.

Appropriate acknowledgement should be given to any contributions from formal collaborators or others who assist the research in a way that is directly related to the research, avoiding unwarranted references.

Acknowledged persons have the right to decline to be named, and the authors will seek their written permission.

In the final publication of the results, mention should be made:

- The centres to which the authors belong.
- The centres where the research was carried out.
- The independent ethics committees that have overseen the research protocol.
- Basic information on the ethical/legal acceptability of the study protocol, as well as a description of the scientific method used.

Any financial support or other sponsorship received, with identification of such support, must be acknowledged in conference papers or other types of presentations prior to publication.

Researchers should demand that their scientific output be evaluated in terms of content and not only in quantitative terms.

Quality must take precedence over quantity. It is not considered good scientific practice the proliferation of publications with multiple authors in order to increase quantity.

Redundant or duplicate publication is considered an unacceptable practice. Authors should not publish the same data in different journals.

Fragmented publication in small blocks would only be justified by a legitimate need to advance findings by publishing preliminary data.

As stated in the European Code of Conduct for Research Integrity, ALLEA:

- All authors are fully responsible for the content of a publication, unless otherwise specified.
- All authors agree on the sequence of authorship, acknowledging that authorship itself is based on a significant contribution to the design of the research, relevant data collection, or the analysis or interpretation of the results.
- Authors ensure that their work is made available to colleagues in a timely, open, transparent, and accurate manner, unless otherwise agreed, and are honest in their communication to the general public and in traditional and social media.
- Authors acknowledge important work and intellectual contributions of others, including collaborators, assistants, and funders, who have influenced the reported research in appropriate form, and cite related work correctly.
- All authors disclose any conflicts of interest and financial or other types of support for the research or for the publication of its results.
- Authors and publishers issue corrections or retract work, if necessary, the processes for which are clear, the reasons are stated, and authors are given credit for issuing prompt corrections post publication.
- Authors and publishers consider negative results to be as valid as positive findings for publication and dissemination.
- Researchers adhere to the same criteria as those detailed above whether they publish in a subscription journal, an open access journal or in any other alternative publication form.

IdISSC Annual Activity Report

The Institute draws up an *Annual Activity Report* that compiles and describes its research activity.

Systematic and regular mechanisms for assessing the quality of research activity should be developed in order to drive improvements in innovation and development.

3.2. Peer review

As stated in the European Code of Conduct for Research Integrity, ALLEA:

- Researchers take seriously their commitment to the research community by participating in refereeing, reviewing and evaluation activities.
- Researchers review and evaluate submissions for publication, funding, recruitment, promotion, or reward in a transparent and justifiable manner.
- Reviewers or editors with a conflict of interest withdraw from involvement in decisions on publication, funding, recruitment, promotion, or reward.
- Reviewers maintain confidentiality unless there is prior approval for disclosure.
- Reviewers and editors respect the rights of authors and applicants, and seek permission to make use of the ideas, data or interpretations presented.

3.3. Industrial and Intellectual Property Rights

The industrial and intellectual property of a work must be considered prior to its application for publication or presentation at scientific meetings.

All industrial and intellectual property generated by members of the Institute in projects funded by the Institute are the property of the Institute. This is also true for temporary employees who carry out their research through the Institute.

Intellectual property can only be properly protected if the researcher keeps accurate, complete, and up-to-date records. This is necessary not only to demonstrate good research practice but also to deal effectively with questions that may arise about the authorship of the research and the results obtained.

In the event of the possibility of patentability of a research result, the research team shall reach an agreement establishing the rights acquired by each member of the team on industrial property rights.

Because research activity is a cooperative process involving many people with common scientific interests, the Institute's researchers have an obligation to cooperate with the scientific community by sharing research results (knowledge, know-how, reagents, data, samples, or materials generated) with accredited scientists within a reasonable time after the results have been published.

In this respect, the IdISSC has an internal procedure which, in collaboration with the Innovation Unit, specifies the steps for the Protection and Transfer of Industrial and Intellectual Property Rights (FIB-PO-06-PNT-01).

3.4. Conflict of interest

Conflict of interest refers to all situations in which a person's judgement of the primary interest of scientific knowledge is influenced by a secondary interest, such as financial, academic, political, or personal gain.

Being in a conflict-of-interest situation does not inherently present any ethically unacceptable behaviour, as long as the objectivity and integrity of the design, conduct, interpretation, and publication of the research has not been compromised.

Attention should be paid not only to actual conflicts of interest, but also to perceived and potential conflicts of interest. The way one is perceived to act can influence the attitude of others and discredit the Institute as a whole.

All members of the Institute are expected to recognise when they are in a conflict-of-interest situation, declare it to their superiors, and handle it in a legally and ethically correct manner.

4. BREACH OF RESEARCH INTEGRITY - MALPRACTICE

As stated in the European Code of Conduct for Research Integrity, ALLEA, it is of vital importance that researchers master the knowledge, methodologies and ethical practices related to their field. Non-compliance with good research practice is irreconcilable with professional responsibilities and damages research processes, impairs relationships between researchers, undermines trust in and credibility of research, results in a loss of resources, and may expose research subjects, users, society, or the environment to unnecessary harm.

Research misconduct is traditionally defined as fabrication, falsification, or plagiarism (the so-called FFP categorisation) in proposing, performing, or reviewing research, or in reporting research results:

• Fabrication is making up results and recording them as if they were real.

• Falsification is manipulating research materials, equipment or processes or changing, omitting, or suppressing data or results without justification.

• Plagiarism is using other people's work and ideas without giving proper credit to the original source, thus violating the rights of the original author(s) to their intellectual outputs.

These three forms of non-compliance are considered particularly serious insofar as they distort the research record. There are further violations of good research practice that damage the integrity of the research process or of researchers.

In addition to direct violations of the good research practices set out in this Code of Conduct, examples of other unacceptable practices include, but are not confined to:

• Manipulating authorship or denigrating the role of other researchers in publications.

• Re-publishing substantive parts of one's own earlier publications, including translations, without duly acknowledging or citing the original ('self-plagiarism').

• Citing selectively to enhance own findings or to please editors, reviewers, or colleagues.

• Withholding research results.

• Allowing funders/sponsors to jeopardise independence in the research process or reporting of results so as to introduce or promulgate bias.

• Expanding unnecessarily the bibliography of a study.

• Accusing a researcher of misconduct or other violations in a malicious way.

• Misrepresenting research achievements.

• Exaggerating the importance and practical applicability of findings.

• Delaying or inappropriately hampering the work of other researchers.

• Misusing seniority to encourage violations of research integrity.

• Ignoring putative violations of research integrity by others or covering up inappropriate responses to misconduct or other violations by institutions.

• Establishing or supporting journals that do not comply with the quality control of research ('predatory journals').

In its most serious forms, unacceptable practices are punishable but, at the very least, every effort should always be made to prevent, deter, and avoid them through training, supervision and mentoring, and by developing a positive and collaborative research environment.

The following principles should be incorporated into all research processes.

Integrity

• Investigations are fair, comprehensive, and conducted expediently, without compromising accuracy, objectivity, or thoroughness.

• The parties involved in the procedure declare any conflict of interest that may arise during the investigation.

• Measures are taken to ensure that investigations are carried through to a conclusion.

• The proceedings are conducted confidentially in order to protect those involved in the investigation.

• Institutions protect the rights of 'whistle-blowers' during investigations and ensure that their career prospects are not endangered.

• General procedures for dealing with breaches of good research practice are publicly available and accessible to ensure their transparency and uniformity.

Fairness

• Investigations are conducted in accordance with proper procedures and in a manner that is impartial to all parties.

• Persons accused of research misconduct are given full details of the allegation(s) and allowed a fair process for responding to allegations and presenting evidence.

• Action is taken against persons for whom an allegation of misconduct is upheld, which is proportionate to the severity of the violation.

• Appropriate restorative action is taken when researchers are exonerated of an allegation of misconduct.

• Anyone accused of research misconduct is presumed innocent until proven otherwise.

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- Royal Decree 2132/2004 of 29 October, which establishes the requirements and procedures to apply for the development of research projects with stem cells obtained from surplus pre-embryonic stem cells.
- BIO-Ethics and Research at CIMA.
- UK Medical Research Council “Good Research Practice”.
- Office of Research Integrity, U.S. Department of Health & Human Services.
- Guidelines for Investigators in Scientific Research; University of Medicine & Dentistry of New Jersey.
- Good Scientific Practice; Biotechnology and Biological Sciences Research Council.
- Code of Good Scientific Practice. Illinois Institute of Technology.

- Code of Good Scientific Practice, Instituto de Investigación Sanitaria de Aragón (Aragon Health Research Institute)
- Code of Good Scientific Practice, Instituto de Investigación Sanitaria del Hospital Ramón y Cajal (Institute for Health Research of the Ramón y Cajal Hospital)
- Code of Good Scientific Practice, IMIM (Municipal Institute of Medical Research, attached to the Pompeu Fabra University)
- Protocol against harassment at work, sexual and gender-based harassment (FIBHCSC).
- SOP of Protection and Transfer of Industrial and Intellectual Property Rights in the IdISSC (FIB-PO-06-PNT-01).