CODE OF ETHICS AND GOOD RESEARCH PRACTICES

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Content

1. INTRODUCTION

This Code of Ethics and Good Research Practices sets forth the ethical and quality criteria and best practices that will guide the research conducted by the Biomedical Research Institute of Málaga and Nanomedicine Platform, IBIMA Plataforma BIONAND.

The code contains a series of recommendations aimed at ensuring compliance of the research conducted at the institute with current ethical and legal standards, as established by the ALLEA European Code of Conduct for Research Integrity.

The principles set forth in this guide are applicable to all professionals who conduct research at the institute and the different centers that form part of it. Researchers should consider it a personal commitment in order to guarantee best scientific practices.

To ensure adequate dissemination of this Code of Ethics and Good Research Practices, the document will be accessible to all researchers on the IBIMA Plataforma BIONAND website.

2. PRINCIPLES OF THE CODE OF ETHICS

The IBIMA Plataforma BIONAND's Code of Ethics and Good Research Practices is based on a series of **fundamental principles** of integrity in the research conducted at the institute that should guide researchers in their work. These principles are:

- **Professionalism** and rigor in the practice of research.
- **Reliability** to ensure quality research, reflected in the design, methodology, analysis, and use of resources.
- **Integrity** in developing, conducting, reviewing, reporting, and communicating research in a transparent, fair, complete, and impartial manner.
- **Respect** for colleagues, research participants, society, ecosystems, cultural heritage, and the environment.
- **Responsibility** for research, from the idea to publication; for its management and organization; for training, supervision, and mentoring; and for its impact in its broadest sense.

The research conducted at the institute shall comply with the provisions of the applicable ethical and legal standards, bearing in mind that:

- All research involving the participation of human beings, use of human biological samples, or personal data must be reviewed by a research ethics committee (REC), as set forth in the Law on Biomedical Research.
- All animal research must be reviewed by an animal experimentation ethics committee.
- All projects must comply with the applicable legal regulations, both on the national and regional level, and must receive the pertinent administrative authorization if necessary.

3. GOOD RESEARCH PRACTICES

3.1 Research Environment

The Biomedical Research Institute of Málaga and Nanomedicine Platform (IBIMA Plataforma BIONAND) is organized as a multidisciplinary research space. At its core are the Regional University Hospital of Málaga and the Virgen de la Victoria University Hospital, but it is open to all public primary care and hospital healthcare centers in the province of Málaga. Together with the University of Málaga, these centers conduct and synthesize basic, clinical, and public health research, promoting translational research and research on nanomedicine.

The institute's mission is to develop and promote a multidisciplinary scientific space for R&D&I of excellence in the field of biomedicine and nanomedicine aimed at industrial transfer and the translation into clinical practice in Málaga.

The institute has been accredited since January 2015 as a Health Research Institute, in accordance with Royal Decree 279/2016, of June 24, on the accreditation of biomedical or healthcare research institutes.

Its R&D&I Management System has been certified since 2016 in accordance with UNE 166.002:2021. It has received the European recognition "HR Excellence in Research," awarded to research institutions that implement the 40 principles of the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers in its human resources policies and practices (C&C), encouraging transparent practices in the recruitment and promotion of researchers.

The IBIMA Plataforma BIONAND Institute has implemented the Responsible Research and Innovation strategy as its centers, which are based on citizen participation, equality, ethics, science education, open access, and governance. In its institutional open science policy, approved by its Board of Directors, the institute states its intention to promote open access to the science it produces. The institute is involved in the open science movement and is committed to the main international declarations as well as related European initiatives on open access.

3.2. Training, Supervision, and Mentoring

The training and development of young researchers is a primary concern within the institute's quality and integrity policy.

The lead investigators of the research groups, expert investigators, and/or supervisors will mentor new team members and provide them with specific guidance and training to properly design, develop, and structure their research as well as foster a culture of research integrity.

Personnel in training who form part of the institute will have a person in charge/tutor to ensure compliance with the learning objectives and expectations set.

Regarding the training of research personnel, the institute will develop a training plan for all institute members. One of this plan's objectives is to promote training on ethics and good scientific practices to ensure that all researchers are aware of the codes and standards applicable to them and are rigorously trained on the design, methodology, and analysis of research.

3.3. Research Procedures

All research projects must be explained in detail in a research protocol. The creation and submission of the research protocol will be the responsibility of each project's Principal Investigator. In the case of projects submitted to obtain any type of funding, the protocol shall coincide with the application report. The research protocol shall clearly and precisely state the research objectives and plan. At minimum, it must contain the following:

- Title.
- Research team.
- Summary.
- Working hypothesis.
- Background and justification.
- General and specific objectives.
- Methods.
- Timeline and distribution of tasks.
- Resources available and required as well as their justification.
- Ethical and gender-related aspects.
- Communications and dissemination plan.
- Data management plan.

The research protocol must be clear, simple, and written in such a way that its content is understood by the project evaluators, researchers, and technicians involved in its conduct. Any amendments to the study protocol must follow the established authorization and external review processes.

In order to ensure adequate traceability of the documentation, the protocols must be identified with a version and a date so that there is a record of the successive changes and versions submitted to the corresponding evaluators and calls.

Access to research protocols may be restricted for confidentiality reasons, although secrecy of all or part of a protocol will not be allowed.

In research projects that require the collaboration of different groups from a single center or from other centers, it will be the responsibility of the principal investigator and the project's coordinating bodies to sign a protocol that includes the terms of said collaboration (justification of the collaboration; distribution of responsibilities and tasks; procedures for custody, storage, distribution, and anonymity of the data or samples obtained; commercial implications and issues related to funding and conflict resolution; results communication plan; and all that is considered appropriate).

3.4. Safeguards

It is the **researchers' responsibility** to:

- Know and comply with the ethical, legal, and safety requirements applicable to their research project(s).
- Guarantee the safety of individuals participating in the research, both support personnel and study subjects, and to minimize the adverse consequences that could arise from said participation.
- Ensure the confidentiality of research participants' personal and clinical information according to current regulations.
- Optimize the use of resources and the correct maintenance of the equipment they are responsible for.
- Report any possible conflicts of interest identified in the investigation.
- Ensure the veracity and updating of the information on their curriculum vitae.

It is the **institute's responsibility** to:

The IBIMA Plataforma BIONAND Institute and its scientific bodies undertake the following functions and responsibilities:

- Know of and facilitate the conduct of research carried out in its environment and guarantee that its infrastructure complies with legal requirements and has the pertinent authorizations.
- Ensure that research projects meet quality criteria and comply with this code's standards.
- Update the code to adapt it to applicable legal standards.
- Act as a mediating body in ethical conflicts, conflicts of interest, or suspected research misconduct.
- Ensure follow-up on the processes that lead to the corresponding administrative authorization, depending on the research project's nature.
- Inform the management bodies of the centers that form part of the institute of the different research projects that are conducted in its surroundings and obtain their agreement if necessary.

3.5. Practices and data management

The research projects conducted at the IBIMA Plataforma BIONAND institute respect the fundamental principles set forth in the Declaration of Helsinki, the Oviedo Convention on Human Rights and Biomedicine, and the UNESCO Universal Declaration on the Human Genome and Human Rights and comply with the requirements established in Spanish legislation in the field of biomedical research (Law 14/2007, of July 3, on Biomedical Research). Any research protocol that involves the use of institutional computer files or the creation of databases that contain information related to individuals must comply with Organic Law 3/2018, of December 5, on Personal Data Protection and Guarantee of Digital Rights and the EU General Data Protection Regulation 2016/679.

Specifically, the need for the following will be taken into account:

- Obtain a favorable report from the REC/DREC prior to starting the research.
- Obtain the subject's express written informed consent prior to his/her participation in the research.
- Have civil liability insurance in case of research with invasive procedures, if applicable.
- Follow the specific standards in the event of particularly vulnerable subjects and if performing genetic analyses.
- Projects that involve animal experimentation will be conducted in accordance with the applicable regulations and will require a prior report from the Animal Experimentation Ethics Committee.

Researchers and the IBIMA Plataforma BIONAND Institute will ensure that access to their research data will be as open as possible and, if appropriate, compatible with the "FAIR" (findability, accessibility, interoperability, and reusability) principles. They will make use of the institutional repository of their Autonomous Community, RiSalud, or any other they consider suitable for open access to the research results, acting with transparency regarding how to access or make use of their data and research materials.

3.5.1 Data, records, and biological or chemical material resulting from research

The protection of personal privacy and the confidential processing of personal data resulting from biomedical research will be guaranteed in accordance with the provisions of current legislation. The same guarantees shall apply to the biological samples that are a source of personal

information. Specifically, it will be taken into consideration that:

- The principal investigator and his/her collaborating personnel must guarantee the proper custody and storage of the data and biological or chemical material resulting from the research during the period legally established for each type of project. In the event that personal data are collected, it is the principal investigator's responsibility to ensure compliance with current regulations, consulting his/her institution on the necessary procedures.
- Every research protocol must establish standard procedures for data and biological or chemical material collection, recording, custody, and storage to ensure consistent and accurate data. Any interim or final data must correspond to the original documents.
- Copies of the most relevant software used will be kept in order to be able to retrieve the original data in the future if necessary.
- It is advisable to assess the suitability of biological samples derived from research being incorporated into the Andalusian Health System Biobank, an aspect that should be taken into account when obtaining informed consent. For this provision, the approval of the Biobank managers must be obtained prior to collecting the samples.
- If the biological samples collected are intended to be kept for future research, the principal investigator, in compliance with RD 1716/2011, will ask the patient to sign the informed consent form for the Andalusian Biobank Network.

The entity responsible for storing all documentation and biological or chemical material resulting from research is the IBIMA Plataforma BIONAND institute and the healthcare center.
Biological or chemical data and materials resulting from research may be **transferred** to third-party researchers provided that they have a protocol with a favorable assessment, both from a methodological and ethical point of view, and that any restrictions on their future commercialization are respected. Such a transfer will only be possible with the express consent of the source subject under the terms set forth in RD 1716/2011.
The transfer may be limited for reasons of availability, competitiveness, or confidentiality.
If a researcher changes centers and intends to take data obtained from the course of his/her activity, the center's management will provide him/her with a photocopy of all or part of the logbooks, a copy of the existing electronic information, a photocopy of the case report forms, or aliquots of the biological or chemical material available.

Nominal biological samples (coded samples and identified samples) are those that, from an ethical point of view, identify the person from whom they originate and therefore, they must be processed with the same ethical criteria and practices as research on human subjects.

Researchers who intend to transform identifiable samples into anonymous samples must obtain the consent of the sample owner and provide sufficient written assurances about the procedure to the research ethics committee, including a description of the procedure, to ensure subjects are protected from possible disclosure of confidential information.

The subject is responsible for expressly authorizing and determining the destination and uses of his/her biological samples for research purposes (regardless of whether they were obtained for healthcare or research purposes).

Any new use of identified biological samples requires the authorization of the person who provided it; the person who obtained and stored it; and, in any case, of the research ethics committee.

It is necessary for the subject to authorize investigators to access to clinical and analytical data relating to him/her.

The subject must be correctly informed about the possible benefits and risks for him/her and, if applicable, his/her family, the social or age group to which he/she belongs, and third parties.

In cases in which it is foreseeable that a protocol will pose a risk to a particular group, said risk must be described in the informed consent process.

In retrospective studies of nominal samples in which previously stored samples are studied, the researcher is obliged to respect the will of the subjects who provided these materials if they have expressed it. If they have not done so, the research ethics committee will assess whether it is possible to dispense with consent and approve the corresponding study. For this purpose, the committee shall consider whether the criteria of exceptional situations envisaged in the applicable regulations are met.

In research projects, it is possible to use samples obtained in the healthcare setting if the patients have given their consent, even if the objectives of these projects were not known at the time the samples were obtained. In this case, the research ethics committee must determine whether such advance consent is valid for each specific project. Consent should be obtained after informing the donor as explicitly as possible about the potential uses, including the most sensitive ones (genetics, reproductive biology, neuropsychiatry, etc.), they may be used for. The donor may determine whether the samples must be anonymous or identifiable.

When the samples were initially obtained for diagnostic or therapeutic purposes, their use for research may in no case compromise those purposes. The priority for the patient's interest after

the biopsy is the anatomic pathological study in order to establish the diagnosis and prognosis of his/her lesion. Therefore, the histopathological examination takes precedence over any other possible use. The reasons for doing so are both ethical and in the interest of quality of care.

If the source subject or his/her family needs them for health reasons, they may use the samples so long as they are available and are not anonymized.

Once consent to participate in a research protocol has been obtained, pathologists and investigators must agree to fulfill their corresponding specific purposes while respecting the freely expressed will of the patient. The pathologist must protect the patient's medical-healthcare interests; the researcher must ensure that the subject's willingness to participate in the research is respected.

Even when patients are invited to donate surplus samples obtained for their clinical care, which are normally discarded, their right to grant or withhold consent and to authorize the types of uses of the samples must be strictly respected. They will be informed that their refusal to consent to the presumed use of their biological samples in research projects will in no way affect their clinical care. In this case, consent for research uses must be requested only after the samples necessary for clinical care have been obtained.

Since the conditions for obtaining research samples may vary from one protocol to another, specific rules are not established herein, but rather must be determined by the interested parties for each specific situation.

The donor has the right to revoke consent, in whole or in part, at any time. The effects of this revocation, including the possibility of destruction or anonymization of the sample, will not extend to data resulting from research that has already been conducted.

Both the sponsor and the investigator must submit a written commitment to the research ethics committee to destroy the biological samples after completion of the studies unless the subject has given his/her authorization for their storage.

3.5.2 Research projects using stem cells obtained from excess pre-embryonic stem cells

Research projects whose conduct entails the use of frozen human pre-embryos left over from assisted human reproduction techniques must meet the following conditions:

- Identity and professional qualifications of the principal investigator and all project participants.
- In cases in which the projects entail or include the development of cell lines from embryonic stem cells, the number, origin, and center of origin of the pre-embryos donated for these purposes that will be used in the project, including the informed consent form of the corresponding progenitors both for the intended use and for other purposes, will be required.
- Material and human resources as well as resources available for conducting the project.
- General information and current state of scientific knowledge in the research project's field.
- Justification and objectives of the project, including, among others, accreditation of its relevance and scientific excellence as well as the impossibility of conducting the planned research in an animal model.
- Description of the project and its phases and timelines, including specification of its restriction to the basic science scope or its extension to the clinical scope of application.
- Description of the project's financial conditions and budget as well as a declaration and commitment to the non-profit nature of the project.
- Written commitment to provide the corresponding public authority with data that will make it possible to identify and know the conservation of cell lines that may be obtained as a result of conducting the project for the purpose of creating a registry of cell lines.
- Commitment to cede cell lines that may be obtained in the conduct of the project free of charge for the conduct of other projects.

3.5.3 Research for genetic purposes

The collection, processing, and/or storage of biological samples for genetic analysis shall comply with the provisions of the Law on Biomedical Research and other applicable regulations. Without prejudice to the provisions of personal data protection legislation, the following information must be received in writing:

- Purpose of the genetic analysis for which you consent.
- Place of analysis and destination of the biological sample at the end of the analysis, be it the dissociation of the sample's identifying data, its destruction, or other destinations, for which the consent of the source subject will be requested in the terms provided for in this law.
- Individuals who will have access to the results of the analysis when they will not be subject to dissociation or anonymization procedures.
- Warning about the possibility of unexpected discoveries and their possible significance for the subject as well as the subject's ability to take a position in regard to being notified of receiving notice of them.
- Warning about the implications the information obtained may have for their relatives and the suitability of the subject himself or herself communicating such information to them, if applicable.
- Commitment to providing genetic counseling once the results of the analysis have been obtained and evaluated.

3.5.4 Good practices in research on human beings: Clinical Trials

For the conduct of drug clinical trials managed by biomedical research foundations and conducted in public healthcare centers of the Community of Andalusia, a standardized agreement template is required that incorporates into the previously established template the legislative amendments following the publication of Royal Decree 1090/2015, of December 4, which regulates drug clinical trials, drug research ethics committees, and the Spanish Clinical Studies Registry; 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 and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation); and Organic Law 3/2018, of December 5, on Personal Data Protection and guarantee of digital rights as well as the rest of the regulations in force on the protection of personal data that may be applicable.

The incorporation of these legislative amendments in a centralized manner facilitates the coordination and legal certainty of the research process regarding drug clinical trials. In addition, the new regulations are intended to give an important boost to drug clinical research, simplifying administrative processes and streamlining the conduct of simultaneous multicenter studies throughout Europe. It improves the delimitation of participating agents' responsibilities, increases the safety of the trial subjects, and in turn increases the efficiency of the evaluation and communication processes involved.

3.5.5 Good practices in animal research

The institute's compliance with good practices and current national and European legislation follows the European Directive 2010/63/EU, which has been transposed into national legislation through Royal Decree RD 53/2013, which establishes the basic rules applicable for the protection of animals used in experimentation and other scientific purposes. Following the current regulation of Order ECC/566/2015, personnel who handle animals for scientific and research uses must have adequate knowledge, skills, and attitudes for caring for animals. In addition, all necessary resources must be available for the proper handling of animals with respect to facilities, husbandry, welfare, and veterinary care.

Projects that involve animal experimentation must comply with the provisions of current legal regulations and in particular with Law 6/2013, of June 11, amending Law 32/2007, of November 7, on the care of animals with regard to their exploitation, transportation, experimentation, and slaughter, in addition to the aforementioned legislation.

No research protocols that involve animal experimentation will be conducted without the approval of the University of Málaga Ethics Committee on Animal Experimentation (CEUMA, for its initials in Spanish).

The use of animals in experimentation is only permitted when it pursues the following purposes:

- Basic research.
- Translational or applied research and scientific methods for any of the following purposes:

- The prevention, prophylaxis, diagnosis, or treatment of disease, poor health, other abnormalities, or their effects in humans, animals, or plants.
- The assessment, detection, regulation, or modification of physiological conditions in humans, animals, or plants.
- Animal welfare, in particular the improvement of production conditions of animals raised for different purposes.

¬ The development and manufacture of pharmaceuticals, food, feed, and other substances or products as well as the performance of tests to verify their quality, efficacy, and safety for any of the purposes indicated in the second paragraph.

¬ The protection of the natural environment in the interest of human or animal health or welfare.

¬ Research aimed at species conservation.

¬ Higher education or training for the acquisition or improvement of professional skills.

¬ Forensic and legal medicine.

Experiments may only be performed by or under the responsibility of competent individuals and care must be taken to ensure the protection of animals used for experimental and other scientific purposes, including teaching, and in particular that the animals used are given adequate care; that they are not caused unnecessary prolonged pain, suffering, distress, or injury; that any unnecessary duplication of procedures is avoided; and that the number of animals used in procedures is kept to a minimum, using alternative methods to the extent it is possible.

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

3.5.6 Good practices in research with genetically modified organisms (GMOs)

Projects that involve the use of genetically modified organisms must comply with the provisions of Law 9/2003, of April 25, on the confined use, voluntary release, and commercialization of genetically modified organisms and Royal Decree 178/2004, of January 30, approving the general regulations for its enactment and the regulation is enacts.

3.6 Collaborative work

All partners collaborating on an investigation are responsible for its integrity.

Whenever a collaborative research project is conducted, it is advisable to sign a protocol that includes the terms under which the different groups from the same center or different centers agree on the joint collaboration. In addition to the requirements for a research protocol, this agreement must also include:

- Unambiguous wording on all aspects of the research plan envisaged within the framework of the joint collaboration.
- Explicit distribution of the responsibilities, rights, and duties of the participating groups or centers, both in respect to the tasks to be carried out and the results to be obtained, including the determination of the custody and storage of the data or samples obtained.
- Criteria for updating the conduct of studies among the different participating groups or centers.
- A preliminary draft of the plan for the presentation and dissemination of the results through any means.
- Procedures for the storage and distribution of data and samples as well as for safeguarding confidentiality.
- All that is considered relevant in addition to possible commercial implications, issues related to funding, and its finalization.

As they are not responsible for the clinical treatment of subjects potentially involved, the principal investigator and collaborating personnel on research projects have the obligation not to interfere in any matter determined by the medical personnel responsible for said subjects.

3.6.1 Research projects sponsored by industry or other for-profit entities

The following considerations should be taken into account with regard to the sponsorship of research by private entities that is conducted in the public sector:

a) Industry has an urgent need to conduct certain types of research in public institutions, especially in terms of experimental and technological development.
b) Industry-sponsored research is advisable and necessary, since it promotes technology transfer and can provide important financial resources.
c) In scientific relations with industry, the necessary limits must be established to prevent compromising the principles and purposes of intellectual freedom.
d) Scientific personnel who benefit from public money and credibility always have the obligation to develop findings in accordance with public interest.

The totality of the data, the trial results, as well as all works and industrial and/or intellectual property rights derived from it are the property of the sponsor and the parties are subject to the provisions of any applicable legislation. This circumstance will not prevent the principal investigator and the institute's managing foundation from using the results in their professional activities, safeguarding the industrial and/or intellectual property rights of the sponsor and respecting the protocol's provisions.

In accordance with the provisions of RD 1090/2015, the sponsor undertakes to publish the results obtained, whether positive or negative, once the trial has been completed. This publication will take place in publicly accessible scientific media, preferably in scientific journals. If the final trial results have not been submitted for publication by the sponsor, the principal investigator may publish said data, discoveries, or inventions for professional purposes and in scientific journals and publications, mentioning the sponsor at minimum. The publication shall be made according to the following criteria: trials with non-marketed products: in the first year after their authorization and marketing in any country; post-marketing trials: in the year following completion of the trial unless publication in a peer-reviewed medical journal is committed to or if it contravenes national legislation.

The sponsor must receive a copy of the text proposed for publication and/or dissemination for its review. This must be in accordance with the provisions of the protocol or, if nothing is indicated, at least forty-five (45) days before the date of submission to the scientific journal and at least twenty (20) days before in the case of an abstract. In any case, the principal investigator may only use these data with the express written authorization of the sponsor.

All agreements of a financial nature between the sponsoring entity and the researcher or research group as well as any other type of remuneration established in direct or indirect relation to the research must be included in a single agreement between the sponsor and the institution the researchers belong to. Financial agreements must be accessible to the bodies, committees, and individuals responsible for the matter agreed on.

3.7. Publication and dissemination

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

The publication of research results is an ethical imperative whereas not publishing, a delay in publication, or exaggeration of the importance of the results for clinical practice or health policy are considered unacceptable practices.

The publication of negative results or results that differ from those expected is also an unavoidable part of research.

Plagiarism and the falsification of results are unacceptable and may be grounds for sanction. In the event of an error in a study that under- or overvalues its conclusions, a correction must be published as soon as possible.

In projects with funding, the regulations established by the funding agencies on the dissemination and communication of results must be respected.

Individuals mentioned in the acknowledgments section of a publication have the right to decline to be mentioned. Therefore, it is necessary to inform them beforehand.

Once the results have been published, researchers are expected to provide relevant data and research materials upon request from other colleagues, provided that there is no ethical conflict regarding the data, materials, or intellectual or industrial property rights.

In publications and the scientific dissemination of the results, the following shall be explicitly stated:

- The centers to which the authors belong.
- The centers where the research was conducted.
- The independent ethics committees that supervised the research protocol.

- Basic information on the ethical/legal acceptance of the study protocol.
- Any financial support or other type of sponsorship received.
- In order to ensure the proper identification of scientific papers published, institute members should always include the institute's name in their signature, regardless of their place of work.
- It is also advisable to report all these details in communications to conferences or other types of presentations prior to publication.

The communication and dissemination of research results to the news media prior to their appearance in a scientific publication or patent would only be justified for public health reasons. In these cases, the authors will weigh the possibility of having the results reviewed in parallel, in an urgent manner, by a scientific publication or they will agree on the scope of this exceptional communication with the editors of the publications in which their definitive publication is envisaged.

Redundant, duplicate, or fragmented publication is considered unacceptable, except in the case of a legitimate need to advance discoveries by publishing preliminary data. Publications with multiple authors whose purpose is to increase the amount of scientific production of its signatories are also considered unacceptable.

The investigator with overall responsibility for the research project will be the person who must authorize the publication of the content (integrity of the results, adequate peer review, adequate protection of intellectual property rights) and its place of publication.

3.7.1 Authorship of scientific papers

The condition of authorship of a research work implies having contributed substantially to the design or conduct of the experimental work, the analysis and interpretation of the data, or the preparation of the resulting communications and publications.

Participation in obtaining resources or providing routine data do not justify scientific authorship, but should be recognized in the acknowledgments section.

It is unacceptable to base the status of author solely on an employment relationship or hierarchical position.

It is recommended to detail the contribution and signing order of each of the presumed authors at the time the study protocol is submitted.

The following rules are recommended to establish the order of the signing authors:

- The first author is the person recognized by the rest of the group as the most important

individual in the conception and conduct of the research and has written the article's first draft prior to its publication.

- The last author should be individual ultimately responsible for the research protocol.
- The rest of the authors can be ordered according to the importance of their contribution or simply in alphabetical order.
- Authors have the right to justify the signing order in a footnote.
- If several authors have made the same effort in conducing the research, as recognized by the rest of the group, both authors can be considered first authors. This should be explicitly reflected in the original publication.

Internal drafts, reports, working or technical reports, and any other written document addressed to third parties must include the authors of the research in the same terms in which they would be included if it were a scientific publication.

In multicenter studies with participation of a large number of people, collective authorship and the designation of an editorial committee will be accepted. In the case a nominal list of authors, the order should be established according to objective criteria.

In the case of projects in collaboration with other research groups, it is recommended that prior commitments be made regarding communication, authorship, and patents.

The IBIMA Plataforma BIONAND Institute has an **attribution policy** that is mandatory for its members. It includes the proper identification of institute researchers' scientific production as well as the correct way to indicate use of research support platforms.

3.7.2 Industrial and/or Intellectual Property Rights and exploitation of results

The possibility that results obtained from research may be susceptible to commercial exploitation (patents, utility models, etc.) must appear in the research protocol in the section on the results dissemination plan.

The principal investigator is obliged to inform the institute of the possible patentability of the project results and to manage the publication of results taking into account this possibility.

The ownership and exploitation rights resulting from the research activity shall correspond, if applicable, to the entity/entities funding said activity, respecting copyright in all cases.

In order to properly protect intellectual and industrial property, the researcher will provide the necessary information to maintain an accurate, complete, and updated record of the data.

In the case of patents, it is the principal investigator's responsibility to reach an agreement with the rest of the researchers on the authorship rights of the intellectual and/or industrial property.

Research personnel must respect the IBIMA Plataforma BIONAND Research Institute's intellectual and industrial property policies. If the results obtained in a research project may lead to inventions or applications that are potentially susceptible to protection due to their commercial interest, researchers should contact the institute's Innovation Support Unit in order to receive the necessary advising and support for their potential protection and exploitation.

3.7.3 Dissemination of Results

The **dissemination** of research results to the general public should be done in an honest and understandable manner, avoiding changes or exaggerations in the impact or importance of the results. The information must be verified, truthful, and appropriately discussed for the target audience using accessible, understandable language to avoid misinterpretation of the results.

It must be possible to clearly identify membership at the institute and in no case adopt positions that could compromise the institute's image. In case of public activities in which personal opinions are given, it is necessary to make it clear that they are personal and do not represent the entity.

Institute personnel should rely on the organization and its communications and outreach experts to speak on behalf of the institute.

Likewise, all institute personnel undertake to comply with the dissemination criteria set forth in funded projects, taking responsibility for ensuring that the organizations involved are correctly mentioned and that publishing requirements for logos and corporate identity elements are complied with.

3.7.4 Conflicts of Interest

A conflict of interest is defined as a situation in which a person's actions may be influenced by a secondary interest, whether of a financial, professional, academic, political, or personal nature.
A conflict of interest situation does not inherently entail any ethically unacceptable behavior, so long as it is made public and does not compromise the objectivity and integrity of the design, conduct, interpretation, publication, and evaluation of the research.
All institute members are expected to recognize when they find themselves in a conflict of interest situation, report it to their superiors, and handle it in an ethically correct manner.

In the case of research funded by for-profit entities, all agreements reached with the sponsor must be included in a contract or agreement that expressly states the financial and intellectual and industrial property agreements. These agreements must be accessible to the institutions and individuals who are responsible for this matter.

3.8. Review, evaluation, and editing

In general terms, researchers should seek to have their scientific output evaluated in terms of content and not only in quantitative terms, following the current trend set forth in the framework of the San Francisco Declaration on Research Assessment (DORA).

On the other hand, the evaluations conducted by the Institute are mainly based on peer review. Peers may examine and critique a manuscript submitted for publication, a report that requests an individual or collective grant, a clinical or experimental protocol submitted for review by an ethics committee, or a report to be made during an on-site visit.

Individuals who agree to participate as experts in the review process must observe the following rules:

- The information must be treated with the utmost confidentiality and may not be shared or used for personal gain.
- Reviews must be objective, based on proven scientific criteria.
- Any invitation to participate in an expert review should be declined if there is any real or potential conflict of interest.

When the advisors called as experts do not feel that they are sufficiently expert in the subject matter to be critiqued, they should clearly report this.

4. BREACH OF RESEARCH INTEGRITY

It is vitally important that researchers master the knowledge, methods, and ethical practices related to their field. Breach of good research practices is irreconcilable with the professional duties and harms research processes; impairs relationships among researchers; undermines confidence in and the credibility of research; wastes resources; and may expose research subjects, users, society, or the environment to unnecessary harm.

4.1. Research misconduct and other unacceptable practices

Research misconduct is commonly defined as invention, falsification, or plagiarism in the proposal, conduct, or presentation of research results.

Invention refers to making up results and recording them as if they were real.

Falsification refers to manipulating research materials, equipment, or processes or the unjustified changing, omitting, or deleting data or results.

Plagiarism refers to using the work and ideas of others without properly citing the original source, thus violating the original author(s)' rights regarding their intellectual production.

In addition, there are other breaches of good research practices that undermine the integrity of research process or researchers, such as:

- Manipulating authorship or denigrating the role of other researchers in publications.
- Republishing substantial portions of one's own previous publications, including translations, without acknowledging or properly citing the original ("self-plagiarism").
- Selectively citing to improve one's own results or to please editors, reviewers, or peers.
- Retaining research results.
- Allowing sponsors to compromise independence in the research process or in the presentation of results in order to introduce bias.
- Unnecessarily inflating a study's bibliography.
- Maliciously accusing an investigator of misconduct or other wrongdoing.
- Misrepresenting the achievements of the research.
- Exaggerating the importance and practical relevance of the results.

- Inappropriately delaying or hindering the work of other investigators.
- Using one's own professional experience to encourage breaches of research integrity.
- Ignoring alleged breaches of research integrity by third parties or covering up inappropriate reactions to misconduct or other breaches by institutions.
- Establishing publications or provide support to publications that do not comply with the research quality control process ("abusive publications").

The most serious forms of unacceptable practices are punishable, but before reaching this extreme, every effort must always be made to prevent, deter, and avoid these practices through training, supervision, mentoring, and by developing a positive and collaborative research environment.

4.2. Ethical principles against fraud

The anti-corruption policy of the institute and its managing foundation, FIMABIS, sets forth that all employees of the institute and any third party acting for it or on its behalf must not have any interest or commitment that conflicts with or prevents them from performing their work duties in an ethical and proper manner. Furthermore, all work must be conducted in strict compliance with such ethical standards and applicable legislation. The institute and the foundation consider integrity and transparency as essential and have a zero-tolerance policy for any corrupt practices.

Likewise, employees of the foundation that manages the institute and of any third party acting on its behalf shall not make contact or under any circumstances, directly or indirectly, authorize payments of any kind to any of the foundation's suppliers for the purpose of obtaining an improper advantage or unduly influencing any decision making process. The concept of "payments" includes payments or promises of payment, in kind and/or in cash, as well as any other offer of goods or services.

5. IMPLEMENTATION OF THE CODE OF ETHICS AND GOOD RESEARCH PRACTICES

This Code of Ethics and Good Research Practices, approved by the IBIMA Plataforma BIONAND Institute Board of Directors, shall be adopted by all its professionals. Therefore, its implementation extends to all researchers hired by or belonging to the institute.

The code is periodically disseminated to all the institute's professionals through its newsletters and is available on its website.

The **Internal Scientific Committee** will be the body responsible for its evaluation and follow-up, reviewing its content and proposing any changes that may be required to bring the document in line with the reality of the institute or any new regulatory framework.

Likewise, the **Internal Scientific Committee** shall be responsible for the management and resolution of possible conflicts related to this matter.

Depending on the seriousness of the facts to be addressed, the committee may create an analysis working group that will review the details and facts of the researcher's or group's misconduct. This committee will comprise researchers and other institute professionals with a reputation and demonstrable experience in the field of action in which the complaint has been made as well as in the legal aspects of biomedical research such that the optimal professional profiles are available to resolve the situation.

Anyone who has knowledge or a reasonable suspicion of any breach of this Code of Ethics and Good Research Practices can report it through the **whistleblower channel** on the institute's website https://ibima.eu/es/canal-de-denuncias/.

6. REFERENCE STANDARDS

The following are key documents that should be known and followed by all agents involved in biomedical research:

- World Medical Association's Declaration of Helsinki (Fortaleza, 2013).
- European Code of Conduct for Research Integrity, ALLEA - All European Academies, 2018.
- Spanish Research Ethics Committee, Report on authorship and attributions of scientific and technical works 2023
- Instrument ratifying the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, signed in Oviedo, April 4, 1997. Published in BOE 20-10-1999
- Good Clinical Practice Guidelines (CPMP/ICH/135/95).

- Regulation (EU) 536/2014.
- RD 1090/2015 regulating clinical trials with medicinal products.
- Order SCO/256/2007, of February 5, establishing principles and detailed guidelines for good clinical practice and the requirements governing the authorization of the manufacture or importation of investigational medicinal products for human use.
- Law 14/2007, of July 3, on biomedical research.
- RD 1716/2011, of November 18, establishing the basic requirements of authorization and functioning of biobanks for biomedical research and the management of human biological samples, and regulating the functioning and organization of the National Registry of Biobanks for biomedical research.
- Regulation (EU) 2016/679 of 27 April 2016.
- Organic Law 3/2018, of December 5, on the Protection of Personal Data and Guarantee of Digital Rights.
- Law 41/2002, of November 14, basic law regulating patient autonomy and the rights and obligations on matters of clinical information and documentation.
- Royal Decree 1344/2007, of October 11, regulating the pharmacovigilance of medicines for human use.
- Memo No. 15/2002, from the Spanish Medicines Agency, on communication procedures for pharmacovigilance of medicinal products for human use between the pharmaceutical industry and the Spanish Pharmacovigilance System for medicinal products for human use.
- Memo No. 7/2004 from the General Directorate of Pharmacy and Medical Devices, on the authorization procedure for clinical research with medical devices.
- Royal Decree 53/2013, of February 1, establishing the basic rules applicable to the protection of animals used in experimentation and other scientific purposes, including teaching.
- Law 32/2007, of November 7, on the care of animals with regard to their exploitation, transportation, experimentation, and slaughter.