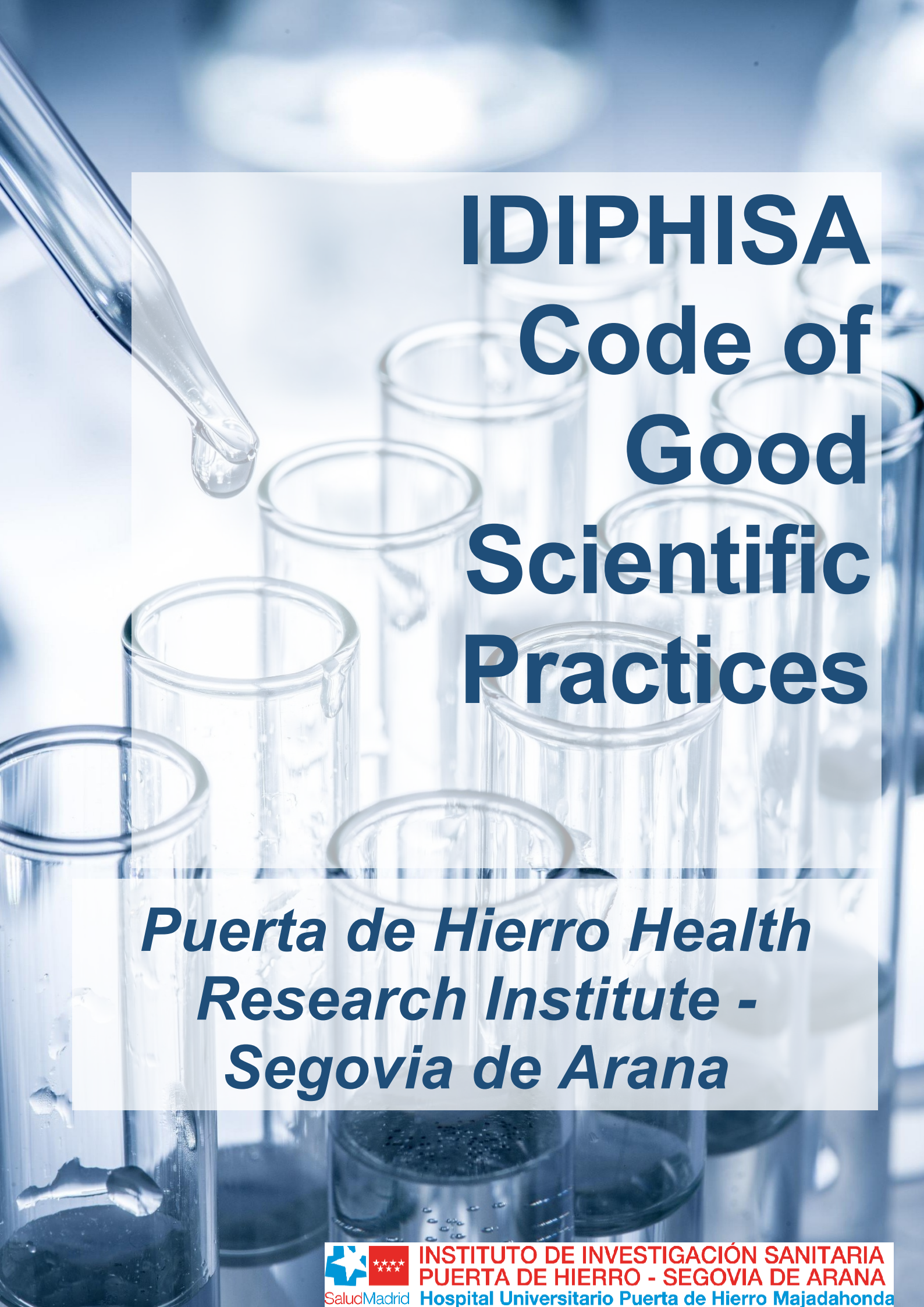

IDIPHISA Code of Good Scientific Practices

Puerta de Hierro Health Research Institute - Segovia de Arana

SaludMadrid
INSTITUTO DE INVESTIGACIÓN SANITARIA
PUERTA DE HIERRO - SEGOVIA DE ARANA
Hospital Universitario Puerta de Hierro Majadahonda

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1 PRESENTATION

The Instituto de Investigación Sanitaria del Hospital Universitario Puerta de Hierro Majadahonda - Segovia de Arana, hereinafter IDIPHISA, was constituted on September 28, 2012 and has subsequently been updated with successive maintenance agreements. The IDIPHISA's member entities are: the Community of Madrid through the Regional Ministry of Health and General Directorate of Research, Teaching and Documentation, the Madrid Health Service with the University Hospital "Puerta de Hierro Majadahonda" hereinafter, HUPHM) as the basic core and the University Hospital Infanta Cristina (hereinafter, HUIC), the Autonomous University of Madrid and the Foundation for Biomedical Research of the University Hospital Puerta de Hierro Majadahonda (managing entity of IDIPHISA). In accordance with the provisions of RD 279/2016, of June 24 , on the accreditation of biomedical research institutes or health.

IDIPHISA is conceived as a space dedicated to promoting, developing and integrating research of excellence in health sciences, with special attention to cooperative, transversal and multidisciplinary research that promotes translational research aimed at improving the health of citizens, which implies a constant improvement in health care activities and therefore improves the quality of life of the population.

With this general objective we ensure that R&D&I projects meet the necessary requirements and focus on priority areas. The system has a set of procedures that should help the achievement of objectives and the correct allocation of the resources involved.

This Code of Ethics and Good Scientific Practices establishes the ethical and quality criteria that will guide the research activity developed by IDIPHISA. The Good Research Practices are based on fundamental principles of integrity in research. They guide researchers in their work, as well as in their commitment to the practical, ethical and intellectual challenges inherent to research.

The "Codes of Good Scientific Practice" (hereinafter CBPC) are a set of rules, recommendations and commitments that scientific personnel, research grant-awarding bodies and even scientific societies use to promote the quality of research and prevent problems of conflicts of interest. The generation of new scientific knowledge developed in basic or clinical research, thanks to its dissemination, and its application will lead to a clear improvement in the fields of healthcare practice, teaching and the training of new scientists in the health sciences.

This CBPC must be adopted as an individual commitment by all IDIPHISA personnel, in order to improve the quality and integrity of the research, adapting the following principles in the development of their scientific and research activity, which allows to obtain an adequate quality in the work and adapting to the current regulations o Law 14/2007, of July 3, 2007, on Biomedical Research.

The premises on which the CBPCs are based are:

- Reliability in ensuring the quality of the research, which is reflected in the design, methodology, analysis and use of resources.
- Honesty in developing, conducting, reviewing, reporting and communicating research a transparent, fair, complete and impartial manner.
- Responsibility for research, from idea to publication, for its management and organization, for training, supervision and mentoring, and for its impact in its broadest sense.
- Respect for life, the law and the public interest, justifying any work proposal, with special sensitivity if it involves people, animals and the environment itself.

This IDIPHISA Code of Good Scientific Practice will be available on the Institute's website.
https://investigacionpuertadehierro.com/

2 OBJECTIVES

The present Code of Ethics and Good Scientific Practices includes the ethical conduct and quality performance that will guide IDIPHISA professionals in the development of their research activity, from the generation of the idea, planning and development of the research, to the recording and communication of results. For this reason, it will be disseminated among all its members, for their knowledge and implementation.

The main objectives are:

- Promote that researchers develop their research in compliance with the best standards of rigor, transparency, honesty, responsibility, leadership and cooperation.
- Motivate and lead, through the principal investigators (PI) or area coordinators or group leaders, the entire team that develops its research activity in IDIPHISA, encouraging in turn the emergence of leaders within the development of all processes and activities carried out.
- To promote the development of research personnel and their skills, in order to achieve a more effective and efficient performance. The training actions that are considered necessary will be planned and developed taking into account the existing economic availability.
- Guarantee to funding agencies that the funds they allocate to IDIPHISA research projects will be managed as efficiently as possible within a framework of good research practice.
- Maintain its commitment to , leading projects whose main objective is to have a direct impact on society and its state of well-being: prognosis, diagnosis, prevention, treatment of the disease and quality of life.
- Guarantee the rights of the subjects that participate in research projects (Research Ethics Committee - CEI), as well as giving dignified treatment to the animals that are the object of experimentation (Animal Experimentation Ethics Committee - CEEA).

3 RESEARCH PERSONNEL

Research practice is an attitude of mind translated into an attitude toward work. It is about how researchers plan and conduct research, record and protect data, and communicate and exploit results. Ensuring the quality and integrity of research practice requires that all staff, regardless of their position, are properly trained and supervised in their research work. The complexity of today's scientific research increasingly requires teamwork and collaboration, often with a multidisciplinary approach and across institutional boundaries.

3.1 RESEARCH TEAMS

Group or area leaders, as well as other researchers, are responsible for promoting a work environment consistent with this Code of Good Scientific Practice, which stimulates 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.

Researchers must ensure that the research complies with ethical, legal and safety requirements and in accordance with the terms and conditions defined in the calls for proposals, research protocols and agreements between IDIPHISA and funding agencies. Researchers are responsible for:

- Know and comply with ethical, legal and safety requirements applicable to research projects.
- They must ensure the safety of the persons participating in the research, both support personnel and study subjects, and minimize the adverse consequences that could result from such participation.
- They must ensure the confidentiality of personal and clinical information of research participants in accordance with applicable regulations.
- They will be responsible for optimizing the use of resources and the correct maintenance of the equipment in their charge.
- The researcher is responsible for the veracity and updating of the data contained in his/her Curriculum Vitae.
- Declare possible conflicts of interest in the research.
- Communicate those research results susceptible of protection by means of patents or other forms of industrial or intellectual property. The ownership of these will correspond to the signatory entities with which the researchers have their labor relationship, taking into account the current regulations of their Institution.

3.2 TRAINEES

The training and development of young researchers is a central issue within IDIPHISA's quality and integrity policy. Therefore, the Institute has the duty to ensure the proper direction of research and supervision of any person linked to the Institute for training as a scientific researcher or research technician.

To achieve the objective of research excellence, a fundamental axis in the Institute is the training and recruitment of new researchers at all levels: biomedical science students, predoctoral, postdoctoral and MIR. With new researchers, the aim is to promote their training in basic, clinical and translational research methodology. To this end, trainees attend regular meetings such as the weekly face-to-face accredited research sessions (organized by the Training Committee), and are offered attendance at research training courses offered by the Hospital, the Foundation or external courses and conferences.

On the other hand, the scholarship holders linked to the Institute as researchers will have a person in charge/tutor to ensure that the learning objectives and expectations initially established are met in a timely manner.

Trainees should:

- To assume a commitment with his/her own training as a researcher and with the objectives of the project/group in which his/her research work is framed, dedicating the necessary time and effort to achieve the proposed objectives.
- Follow the advice and recommendations of the directors and tutors, always informing them of the results achieved and the initiatives they propose for the progress of the research.
- Undertake to make proper use of the material means and facilities at its disposal, and to value and facilitate management and administrative tasks and participate in scientific activities, seminars, conferences, forums and other activities related to the development of its own work as a researcher.
- To keep the due confidentiality on the results of the research and on those subjects that involve studies with clinical data of patients.

3.3 WORK ENVIRONMENT

IDIPHISA will provide all research personnel with the technical means and physical spaces within its reach to guarantee the success of the research work. Also, researchers will be trained in issues related to occupational safety and health in their jobs, as indicated in Law 31/1995, of November 8, 1995, on Occupational Risk Prevention. Similarly, it will guarantee to the workers in its service the periodic monitoring of their state of health according to the risks inherent to the work, always respecting the right to privacy and dignity of the worker and the confidentiality of all information related to their state of health.

On the other hand, IDIPHISA has protocols such as the "Equality and Diversity Plan" which guarantees non-discriminatory, safety, health and environmental conditions. Also, IDIPHISA signed and sent to the European Commission in March 2018 the declaration of commitment to the principles of the "***Charter for European Researchers***" and the "***Code of Conduct for the Recruitment of Researchers***".

The HRS4R strategy ("*Human Resources Strategy for Researchers"*) is a tool launched by the European Commission to support universities and research institutions and research funding organizations in the implementation of the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers, which to contribute to the development of an attractive European labor market for researchers. In July 2019, IDIPHISA was awarded the HRS4R Seal.

IDIPHISA is committed to creating a work environment that respects the human rights and dignity of all people, as well as a clear and decisive attitude towards

The company's commitment not to tolerate sexual and labor harassment. These ethical principles are essential elements to guarantee the researcher's intellectual development, growth and competitiveness.

In this sense, it will promote equal opportunities and equal treatment between both sexes, for which it will undertake actions to provide technical and scientific training to all researchers and the rest of its staff, recognizing the contribution of the value of diversity and promoting the professional development of all its personnel, through values of respect and equality, without discrimination of any kind for reasons of gender, age, race, religion, opinion or any other personal or social condition.

4 PROTOCOLS AND PROCEDURES FOR RESEARCH

The research protocol is a document that details the planning of an investigation. It provides an overview of the aspects of the study before the study begins and should be described with sufficient precision and clarity, including the objectives and research plan, to enable another researcher to conduct the research with similar results.

4.1 PROTOCOL DESIGN

All research projects, whether internal to IDIPHISA or submitted to external funding agencies, will be prepared following a written "research protocol", the preparation and presentation of which will be the responsibility of the principal investigator.

For proper planning and development of research, researchers must ensure that they are up to date and well informed of the legislation and regulations governing their professional activity, and that they scrupulously comply with ethical principles and good practices, especially with regard to research involving humans, animals and their potential impact on the environment.

Prior to its initiation, all biomedical research must be previously formulated in a written protocol. Such a protocol provides an overview of the aspects of the study before starting it and should clearly describe what is to be investigated, how it will be done, how long it will take to achieve the objectives and under what circumstances it will be carried out.

Research project protocols should take into account at least the following aspects in the project design phase:

- Identification of Principal Investigator and collaborators
- Justification of the request.
- Bibliographic review
- Establishment of working hypotheses.
- Elaboration of objectives (primary, secondary).
- Selection of study variables.
- Sample size or population.
- Statistical methodology.
- Data collection and archiving.
- Calendar with the planning of tasks, chronogram.
- Justified budget
- Reports from the pertinent committees, if necessary.
- Dissemination planning (publications, congresses,...)

IDIPHISA has the following committees for the review of research protocols:

a) Committee on the Ethics of Investigation with Medicines (CEIM) / Ethics Research Committee (CEI): if the protocol directly involves persons, material or data of human origin. Responsible for ensuring the protection of the rights, safety and well-being of patients participating in clinical research projects and for providing public assurance in this respect, by issuing an opinion on the study protocol, the suitability of the investigators and the adequacy of the facilities, as well as the methods and documents to be used to inform study participants in order to obtain their informed consent. Its scope of competence includes clinical trials with

The company is not responsible for any research project that involves the direct participation of human beings or in which samples of human origin or their personal data are used.

b) Animal Experimentation Ethics Committee (CEEA): if the protocol involves the use of animals for animal experimentation. In charge of guaranteeing the welfare of animals used as experimental models in research.

c) Biological Safety Committee (CSB): if it involves the use of biological material such as infectious agents, genetically modified organisms or animals. In addition, the Occupational Health and Prevention Service of IDIPHISA and the Hospital Universitario Puerta de Hierro Majadahonda must be informed.

d) Research Commission. This commission, depending on the requirements of the call, may prioritize which projects are to be presented in such calls. It is made up of researchers selected from the different centers that make up the IDIPHISA. In charge of promoting, assessing, disseminating and coordinating IDIPHISA's research activity, facilitating the establishment of collaborations between basic and clinical researchers of the different specialties.

5 ETHICAL REQUIREMENTS IN RESEARCH

5.1 RESEARCH WITH PEOPLE

Before initiating a research study involving human subjects, the risk/benefit of the study should be analyzed. It should only be initiated and continued if the anticipated benefits justify the risks, taking into account the rights, safety and well-being of the research subjects.

The conduct of **research projects** involving the participation of persons, human biological samples or the use of personal data must be governed by the provisions of the regulatory framework Law 14/2007, of July 3, 2007, on Biomedical Research, Royal Decree 1716/2011, of November 18, which establishes the basic requirements for the authorization and operation of biobanks for biomedical research purposes and the treatment of biological samples of human origin, and regulates the operation and organization of the National Register of Biobanks for biomedical research, and other applicable regulations in force.

Clinical research involving medicinal products is the basis for generating knowledge that ultimately enables clinical practice to be improved for the benefit of patients. Clinical research with medicinal products includes clinical trials and observational studies, both defined in Regulation (EU) number 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use. In turn, the revised text of the Law on Guarantees and Rational Use of Medicines and Health Products, approved by Royal Legislative Decree 1/2015, of July 24, includes in its article 58 the definition of "observational study" differentiating it from "clinical trial".

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

Freely given informed consent should be obtained from each subject prior to their participation in the clinical trial. The confidentiality of records that could identify subjects should be protected, respecting privacy and confidentiality rules in accordance with the relevant regulatory requirements.

The studies must be scientifically reasonable and described in a clear and detailed protocol, and subject to the approval of the Research Ethics Committee. Each time new analyses are intended (modifications to the protocol, patient information sheet and/or informed consent, etc.), different from those foreseen in the original research protocol, the patient's consent and the IRB's authorization must be obtained again.

The research personnel must undertake to keep the personal data of the participants in the study confidential, both in the process of obtaining, processing and storing the data and in the subsequent publication of the results. All research information must be recorded, handled, and stored in a way that allows its analysis, verification, and interpretation, and assures the quality of every aspect of the study.

In general, anonymization criteria should be applied to data that could lead to the identification of participants, except when the characteristics of the study require another procedure, duly justified. The current personal data protection law must be complied with. Specifically with the provisions of the additional provision 17 of the Organic Law 3/2018 on Data Protection that regulates research with health data.

Royal Decree 957/2020, dated November 3, November 26, 2010, regulates **observational studies with** medicinal **products for human use**.

relating to the health of persons, provided that it does not meet any of the conditions required to be considered a clinical trial established in article 2.1.i) of Royal Decree 1090/2015, of December 4, which regulates **clinical trials with medicines, the Ethics Committees for Research with Medicines and the Spanish Registry of Clinical Studies.**

The purpose of observational studies with drugs should be to complement the information already known about the drug without interfering with routine clinical practice. Such studies should guarantee the patient's informed consent, confidentiality, identify sources of funding and make the results of the study public.

Clinical investigations with medical devices cover many and varied types of devices, materials, products and apparatus of different nature, including medical software. The essential requirements that the products must meet are established and in Spain they are classified according to three Royal Decrees that transpose the corresponding EU directives and the Law on Guarantees and Rational Use of Medicines and Medical Devices.

These Royal Decrees are:

- Royal Decree 1591/2009, of October 16, 2009, regulating medical devices, which transposes Directive 93/42/EEC. Royal Decree 1662/2000, of September 29, 2000, on medical devices for in vitro diagnostics, which transposes Directive 98/79/EC.
- Royal Decree 1616/2009, of October 26, 2009, which regulates medical devicesactive implantable , transposing Directive 90/385/EEC.

The legislation on medical devices, when defining the essential requirements that products must meet, refers to the need for this compliance to be demonstrated by means of clinical evaluation. This means that the safety of the products and the benefits they offer must be supported by clinical data obtained with ethical and methodological criteria that are included in an annex to the legislation itself. The assessment of the benefit/risk ratio must also be supported, in order to determine whether the risks are acceptable in relation to the benefits provided.

Active implantable medical devices are a type of medical device whose two fundamental characteristics are, on the one , that they are intended to be totally or partially introduced into the human body in order to remain implanted in it, and on the other hand, that their functioning depends on electricity or any other source of energy other than that generated by the human body or by gravity.

Clinical research is one of the crucial steps in the development of new implants or new applications, so the conditions under which such research must be carried out, its authorization procedure and the information to be kept, made available or recorded in the corresponding files and databases are crucial.

5.2 STUDY WITH BIOLOGICAL SAMPLES

IDIPHISA has its own Biobank that holds collections of biological samples of human origin for biomedical research purposes, organized as a technical unit with criteria of quality, order and destination. Following the current regulations, the Biobank is governed by RD 1716/2011 of November 18, which articulates the authorization system for the constitution and operation of Biobanks, and the basic requirements of its organization, with special emphasis on the need for express written consent for the collection and use of samples, on the obligation to respect the right to privacy and informational self-determination, and on the gratuity of the entire process of treatment of samples. The aim is to make available to the scientific community the biological material necessary for research in optimal conditions that ensure the competitiveness and excellence of the research.

Among other structures that IDIPHISA has, we have the Technical Support Units for Research, whose main objective is to provide quality technological support to the Institute's researchers in essential areas of biomedical research that, due to their complexity or cost, cannot be undertaken by individual groups. Thus, in addition to providing technological support by highly qualified personnel, promoting quality research, the performance of the equipment is improved and resources are made profitable by improving their efficiency.

Although the main objective of these units is to provide internal service to the institute's groups, they are also open to collaborations with groups from other public and private institutions. We currently have 4 units that cover important areas in Biotechnology such as Confocal Microscopy, Cytometry, Sequencing and Cell Cultures.

5.3 ANIMAL RESEARCH

The directive to which animal research RD 53/2013, of 1 February, establishing the basic rules applicable to the protection of animals used for experimental and other scientific purposes, including teaching, has meant an important advance in animal welfare, not only because it adapts the minimum general requirements to scientific advances, but also because it extends the scope of application of the protection standards to cephalopods and certain fetal forms of mammals, and because it establishes as a general principle the promotion and implementation of the "three Rs principle", i.e. the "replacement, reduction and refinement" of procedures, encouraging the use of alternative methods to experimentation on live animals.

Animals may be used when their use is justified by the purpose pursued, always evaluating its opportunity in terms of its potential benefits. It may only take place when absolutely necessary, there being no other possible alternatives for scientific research, to study aspects such as the prevention of diseases, their effects, diagnosis and treatment in man, and other living beings. Likewise, and in accordance with the above, for the development of pharmaceutical products and other substances or products to verify their quality, efficacy and safety.

The personnel involved in the projects (design, handling and care) must have the specific education and training that provides them with the required qualification, as established in current legislation.

In the planning of animal research, the Ethical Committee for Animal Experimentation (CEEA) of IDIPHISA will be used as an advisory body. The existence of the CEEA is a necessity deriving from Community regulations, and from Spanish legislation on the protection of animals used for experimental and other scientific purposes in Royal Decree 53/2013, of February 1, 2013.

The CEEA may request as much information as necessary (principal investigator, report on the research, number of animals to be used, anesthesia, analgesia, maintenance and care after the experiment, training and qualification of the personnel involved in the procedures, etc.), and a favorable report from the CEEA is mandatory for the research.

It must also ensure the protection of animals used in experimentation, 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 reduced to a minimum, applying alternative methods as far as 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.

The units destined to animal experimentation in the Institute are obliged to keep a register book in which there is a record of all the animals used, as well as the number and species of animals acquired and the establishments of acquisition and the final destination of those, once the experiment is finished. This register is kept for at least three years from the date of the last entry and is subject to periodic inspection by the competent authority.

5.4 RESEARCH ON MODIFIED ORGANISMS

Genetically modified organisms (GMOs) are understood as those in which the genetic material has been artificially altered. The regulations in Spain, for legal purposes, in LAW 9/2003, of April 25, 2003, which establishes the legal regime for the confined use, voluntary release and commercialization of genetically modified organisms, define these GMOs as any organisms, with the exception of human beings, whose genetic material has been modified in a way that does not occur naturally in mating or natural recombination, provided that techniques are used that are established by regulations.

IDIPHISA through its Biological Safety Committee will evaluate studies, requirements, procedures or any other work activity involving the handling of biological material, such as genetically modified organisms. It will analyze the safety and feasibility of the study in IDIPHISA's facilities, so that the work is carried out minimizing the risk to personnel exposed to this type of material. It will issue its technical opinion on the biosafety aspects in the different work areas, so that the physical integrity of the personnel and the environment is guaranteed and compliance with the biosafety measures issued by said committee will be reviewed.

Researchers must develop and maintain updated standard operating procedures for the handling, transport, storage and disposal of biological material that complies with current laws and safety standards. On the other hand, they must submit reports to IDIPHISA's governing and management bodies on the research activity with genetically modified organisms.

In the event of accidents, IDIPHISA's governing and management bodies must be informed and keep a record of them and propose any necessary corrective measures, as well as contacting the corresponding Occupational Risk Prevention Service.

Regarding the activities that can be carried out with genetically modified organisms, it is found that, legally, these activities fall into three categories: i) confined use; ii) voluntary release and iii) commercialization (Law 9/2003).

In the research activity carried out within the IDIPHISA facilities, the category in which this activity is included will be that of Confined Use. This category is defined as:

Contained use; genetic material is modified with confinement measures that limit contact with the population and the environment. Depending on the prior assessment of risks to human health and the environment, there are three types of activities (Law 9/2003):

- Activities of Null or Insignificant Risk; it is not necessary to communicate it to the competent Administration.
- Low-risk activities; authorization from the competent Administration is required, only if it requests more information or if the conditions of the confined use are modified.
- Activities from risk risk activities; will be essential request authorization from the competent Administration.
- High-risk activities; it will be essential to request authorization from the competent Administration.

6 CUSTODY AND PRESERVATION OF DOCUMENTATION, RECORDS, DATA, AND SAMPLES DERIVED FROM THE RESEARCH.

Researchers are obliged to collect all the data obtained from their research, which can be recorded in the data collection notebooks. 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 people, animals, etc. used in the study, as well as the protocol used. This protocol should include a specific plan for the collection of data, records and biological or chemical material resulting from the execution of the research, as well as a system for the collection, custody and preservation of data. Errors, negative, unexpected or discordant results should never be ignored. Rectifications must be clearly traceable and there must be a systematic identification of the person who makes them.

In studies with individuals, with their samples or their identified or identifiable data, the provisions of the current national data protection regulations, Organic Law 3/2018, of December 5, on the Protection of Personal Data and Digital Rights (LOPDGDD) and with Regulation (EU) 2016/679 of the European Parliament and of the Council 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, must be complied with. The data must be processed in an anonymized form, avoiding access to personally identifiable data.

The principal investigator will keep a record for tracking data log books, as well as chemical or biological material banks with a specific plan storage and collection of backup copies.

Any documentary record of data or any sample that forms part of a bank of biological or chemical material in course of research must permanently accessible to all members of the research team, and must remain properly guarded in the institution where the person responsible for the project is linked.

All documentation (record books and data collection notebooks, among others) and biological or chemical material obtained in the course of an investigation is the final property of the institution where the investigation was carried out. The institution may provide copies of the data collection notebooks to the principal investigator if, for professional reasons, he/she changes research center.

On the other hand, the primary and original information must remain stored for at least ten (10) years from the first publication of the results, except for those cases in which the law requires longer periods. In any case, the biological or chemical material stored as a result of the research may not be destroyed before ten years after the first publication of the results, except for those cases in which the law requires longer periods. It may be stored for longer periods and its destination shall require the approval of the principal investigator.

In the case of human samples, in accordance with article 61 of the Biomedical Research Law, in the event that the sample is conserved, the subject from whom the sample originates will have been previously informed in writing of the conservation, objectives, future uses, transfer to third parties and conditions to be able to withdraw them or request their destruction. However, the biological samples used in

biomedical research will be kept only as long as they are necessary for the purposes for which they were collected, unless the source subject has given his or her explicit consent for other subsequent uses.

As for data and samples shared with third , the use of biological or chemical material and computerized data resulting from research must be publicly available and may be shared by third party researchers, with the exception of cases in which restrictions derived from patents or their future commercialization have been established. The assignment shall require the qualification for its proper use by the person who made the request; the due

In this sense, in all applications for research projects/studies that so require, and in general in all applications, as a recommendation, a Data Management Plan will be included, prepared by the PI and adapted to each specific case, with the help and supervision of the Data Protection Officer.

To ensure the correct treatment of personal data, IDIPHISA research staff may contact the data protection officer of the FIBHUPHM (dpd@idiphim.org), guarantor of compliance with the RGPD in the Research Foundation. From this delegation will decide the relevance of further actions that may involve the Information Security Commission of the Regional Ministry of Health (data protection delegate:).protecciondedatos.sanidad@madrid.org

7 PUBLICATIONS, DISSEMINATION OF RESULTS AND AUTHOR

7.1 PUBLICATION AND DISSEMINATION OF RESULTS

The research staff completes the research process with the publication of the results obtained, in an accurate and transparent manner and regardless of whether or not they coincide with what was initially foreseen.

Research results should always be published, whether positive or negative data are obtained. In clinical research, the publication of results, both positive and negative, is an ethical duty that becomes a legal requirement in the drug research environment, and this is contemplated in the regulations.

Publication should be attempted in a scientific setting before dissemination to the non-health public. The publication should state the Research Ethics Committee that approved the study, as well as the funding entity, if applicable.

Fragmentation to increase the number of publications will be avoided, except in case of extension of the work or at the request of the editors.

The importance of dissemination lies in allowing scientific debate, avoiding the publication of redundant data, duplication or repetition of processes already carried out and serving as a basis for the development of new hypotheses. For this reason, the communication and dissemination of research should not be delayed, and the research staff will strive to publish the results of their research in an honest, transparent and truthful manner, including those findings that were not in line with the initial hypotheses.

The results obtained within the framework of a contract/agreement signed with public or private entities shall be disseminated in accordance with the clauses stipulated , and always in line the provisions of this code. In the project funding agreement, the type of recognition to be given to the funding agencies, or to the company if the funding is part of a private agreement, must be stated.

In oral communications on the content of research, the same criteria should be followed as for publications.

7.2 AUTHORSHIP POLICY

According to the recommendations of the International Committee of Medical Journal Editors (ICMJE), the **following criteria must be met** in order to be designated as an **author in IDIPHISA**:

1. There is a substantial contribution to the conception or design of the article or to the acquisition, analysis or interpretation of the data;
2. To have participated in the design of the research work or in the critical review of its intellectual content;
3. That they have been involved in the final approval of the version to be published;
4. The ability to be accountable for all aspects of the article to ensure that issues related to the accuracy or completeness of any part of the work are adequately researched and resolved. In publications resulting from work

multidisciplinary, each author will be responsible and liable for the accuracy or completeness of his/her contributions to the joint work.

Those who do not meet the four criteria should be acknowledged in the acknowledgements.

The persons carrying out the work should be responsible for identifying who meets these criteria and for establishing the order of authorship in the manuscript.

The **author responsible** for correspondence on a manuscript is the person who assumes responsibility for communication with the journal editor during manuscript submission, peer review, and the editorial process and is generally responsible for administrative requirements with the journal and details regarding authorship, ethics committee approval, registration of clinical trials, and declaration of conflicts of interest, although these functions may be delegated to one or more co-authors.

The **order of authors' signatures** must be established at the time the work is planned and its load.

- The **first author** is the main author of the document, the person who conceived the work, planned it and led its execution in its different phases.
- The **last author** is responsible for critically reviewing the manuscript and certifying that the article is ready for submission; this position usually corresponds to senior research staff. The contribution of the **second** and subsequent authors is more varied: writing the article, providing substantive comments, or performing specialized tasks.

When the work has been carried out by a **group of authors,** the group will decide who will be listed as author based on this policy. All members of the group designated as authors must meet the criteria for authorship, including approval of the final manuscript. They must be able to take public responsibility for the work and have full confidence in the accuracy and integrity of the work of the other authors in the group. They must also ensure that the representation of women and men participants and their recognition is fair.

Some multi-author groups designate their authorship with a **Group Name**, with or without the names of individuals. The author who assumes communication with the journal should specify the Group Name, if any, and clearly identify the members of the group and responsibility for the work as authors.

In accordance with the provisions of the *General Innovation Procedure of IDIPHISA*, any research result susceptible of industrial exploitation obtained within the framework of research carried out at IDIPHISA, must be communicated to the Innovation Support Unit of IDIPHISA by the authors belonging to the FIBHUPHM and assigned to IDIPHISA, as soon as possible and always prior to publishing or disseminating any result susceptible of being protected.

As a general rule, all scientific documents in which IDIPHISA researchers participate, regardless of their contractual relationship, must always be signed in accordance with the signature policy for IDIPHISA scientific publications:

- Researchers contracted by the hospital* or by the research foundation (FIBHUPHM): [Service or Unit/ Name of the group/ Laboratory/ Platform], Hospital Universitario Puerta de Hierro Majadahonda, IDIPHISA. Madrid, Spain
- Hospital researchers* linked to the university: Service or Unit, Hospital Universitario Puerta de Hierro Majadahonda. Department, Faculty, University, IDIPHISA. Madrid, Spain
- Researchers hired by IDIPHISA University (UAM): Department, Faculty, University, IDIPHISA. Madrid, Spain.
- Researchers belonging to networks or consortia: Include the acronym and/or full name of the Network or Consortium according to the policy established by these structures.

7.3 OPEN ACCESS / OPEN SCIENCE

Open Science is a movement promoted by the OECD countries and encouraged by the European Commission, which advocates free access by citizens to the results of scientific research, data, resources, results, thoughts, as well as the results and discoveries of scientific research to be universally accessible and without restrictions.

Open Science implies **Open Access to** publications, and much more:

- Openness of **research data** and *Linked Open Data.*
- Processes
- Methodology
- **Software**
- Scientific workflows
- **Academic social networks**
- And **peer review.**

In short, opening up science throughout the research cycle.

In our country, the Law of Science, Technology and Innovation, which includes in its article 37, under the title "Open Access Dissemination", the main aspects to be taken into account when carrying out the open dissemination of research results financed with public funds and accepted for publication in serial or periodical research publications. Therefore, it establishes the legal obligation for the Spanish scientific community to deposit in open access a copy of the articles published in the framework of their national R+D+I projects.

Horizon Europe 2021-2027 is the extension of the Horizon 2020 program. It is the European Union's flagship initiative for the promotion of research and innovation from the conceptual phase to market introduction, and complements national and regional funding. This program also aims to ensure open access to research data: in accordance with the principle "as open as possible and as closed as necessary" and establishes the mandatory data management scheme for FAIR (findable, accessible, interoperable and reusable) data.

In this framework, IDIPHISA is committed to work on an Open Science policy to improve the implementation of the national open access model, working on open access repositories of its publications and results. In this sense, IDIPHISA's Open Science policy will be developed in line with other national public access repositories in which the Instituto de Salud Carlos III is working (Repositorio Institucional en Salud, REPISALUD, https://repisalud.isciii.es/) and those of the Community of Madrid in its open science policy (Repositorio Institucional de la Consejería de Sanidad de la Comunidad de Madrid, https://repositoriosaludmadrid.es/), to ensure interoperability between them and the sharing of information.

Open Access (OA), referring to scientific literature, means access to information and its use free of charge without any kind of restriction. There are two main ways to publish in open access:

- The Golden Path. It is published in open access journals with a cost (APCs) that is normally assumed by the authors of the document.
- The Greenway. It is published in institutional repositories. In this sense, IDIPHISA facilitates the open access publication of its research staff through the Repository.

Institutional created by the Consejería de Sanidad de la Comunidad de Madrid, where, in addition to the article itself, research data can be shared.

The advantages of publishing in Open Access are:

1. Improvement of the research process, as there is greater transparency and information reaches the scientific community sooner.
2. Visibility and use of research. Facilitates dissemination and citation.
3. Impact of research. Greater repercussion in the scientific field and in society.

IDIPHISA's research staff publishes research results in Open Access when the mandates referred to, mainly, in the Law 14/2011 of June on Science, Technology and Innovation, the Horizon 2020 Framework Program and subsequent ones establish it. Sometimes, it will be necessary to take into account possible mandates within a given region or autonomous community. Most commonly, it is mandatory to publish in open access those research works carried out with the funding of a public body.

Aspects to be taken into account by authors when publishing in OA:

1. The version of the article they can publish. It is important to review the journal's editorial policy to comply with open access mandates.
2. Authorship rights. Open access publishing allows the author to control more effectively the use and dissemination of his/her research work, something that is lacking in traditional publishing, since exclusivity remains in the hands of the publisher.
3. Creative Commons licenses, which are directly related to the two previous points and allow establishing a legal framework where authors have the capacity to decide how their works can be distributed and used by third parties.
4. The costs for publishing in open access (APCc -Article Processing Charges), should be taken into account if they can be assumed (within the financing a part dedicated to publication can be stipulated) in the case of opting for publication in the golden way and not in an institutional repository.

7.4 CONFLICTS OF INTEREST

Conflict of interest is understood as all those situations in which the judgment of a person, with respect to the main interest of scientific knowledge, is influenced by a secondary interest, such as economic, academic, political or personal gain.

A conflict of interest situation does not inherently present any ethically unacceptable behavior, as long as the objectivity and integrity of the research design, development, interpretation and publication have not been compromised.

Attention should be paid not only to actual conflicts of interest, but also to perceived and potential conflicts of interest. How 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 recognize when they find themselves in a conflict of interest situation, declare it to their superiors and handle it in an ethically correct manner.

7.5 ANNUAL ACTIVITY REPORT

All research activity carried out at IDIPHISA will be summarized each year in the Institute's annual Scientific Report.

The information contained in the annual scientific report is validated with the heads of the research groups as well as with the support and/or transversal/common units. Once this process is completed, it is submitted to the corresponding bodies of the Institute and to the ISCIII. It is then disseminated and published on the IDIPHISA website, for knowledge of all IDIPHISA staff as well as the rest of the scientific community and society:

https://investigacionpuertadehierro.com/investigacion/memorias-cientificas/

Regardless of the preparation of this annual report, each service, unit, research group or research support unit belonging to IDIPHISA may publish or disseminate its activity using the guidelines contained in this Code.

7.6 INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS

In accordance with the provisions of the General Innovation Procedure of IDIPHISA, any research result susceptible of industrial exploitation obtained within the framework of research carried out at IDIPHISA, must be communicated to the Innovation Support Unit of IDIPHISA by the authors belonging to the FIBHUPHM and assigned to IDIPHISA, as soon as possible and always prior to publishing or disseminating any result susceptible of being protected.

When research personnel wish to out a research in collaboration with researchers from other entities, they must negotiate and, under contract, safeguard the information and knowledge owned by IDIPHISA. These contracts or agreements will include the assigned tasks or contributions of all parties. The obligation of secrecy and confidentiality assumed by each party, the assignment of ownership of the results generated within the framework of the project, and the possibility of their adequate and effective legal protection and the conditions of their exploitation will be established. All these obligations will have to be communicated sufficiently in advance to all the participants in the research.

See Chapter XIV, Guarantee of confidentiality and industrial and intellectual property, art. 66 and 67 of the Resolution of December 3, 2020, the Directorate General of Labor of the Ministry of Economy, Employment and Competitiveness, on registration, deposit and publication of the collective agreement of the Group of Companies of the Biomedical Research Foundations of the Health Institutions attached to the Madrid Health Service (SERMAS) (code number 28102923012020).

8 RRI (Responsible Research and Innovation)

Responsible research and innovation (Responsible Research and Innovation) requires taking into account the potential effects and impacts of R&D and innovation on society and the environment.

It is a comprehensive approach to research and innovation, which allows obtaining knowledge about the consequences of the results obtained and effectively assessing their relationship social needs and moral values. It seeks to achieve a more open science, more connected with society and to achieve more transparent, inclusive and collaborative research and innovation.

The RRI perspective is increasingly being considered as an evaluation criterion in various national and international calls for proposals. It is also an essential key in the European program Horizon Europe, the European Commission's framework program for research and innovation (2021-2027).

The 6 principles of RRI are:

1. **Science Education**

   IDIPHISA works to improve educational processes and promote scientific vocations among young people, in line with the Training Plan, the Emerging Groups Mentoring Plan and the Action Plan of the HRS4R strategy.

   The 43 research groups that make up the IDIPHISA annually welcome students at different stages of their training (end-of-degree project, end-of-master's project, pre-doctoral and post-doctoral internships for laboratory technical staff). There are agreements with different national and international universities and other research and training centers.

   The IDIPHISA proposes courses, seminars and scientific sessions for all its research staff, oriented in the different areas of knowledge, with the participation of its own research staff, other speakers of recognized prestige both nationally and internationally, patients and social forums, as well as other non-scientific actors. Furthermore, efforts will be intensified in the implementation of activities and projects for scientific dissemination and education at different educational levels, as well as in initiatives to provide rigorous and truthful information from scientific institutions to society.

   The IDIPHISA website provides information on the Institute's RRI approach.

   https://www.isciii.es/InformacionCiudadanos/DivulgacionCulturaCientifica/DivulgacionISCIII/Paginas/Divulgacion/InvestigacionInnovacionResponsableRRI.aspx

2. **Gender equality**

   IDIPHISA reiterates its commitment to the establishment and development of policies that integrate equal treatment and opportunities between men and women, without discriminating directly or indirectly on the basis of sex or other aspects (nationality, race, religion...), as well as in the promotion and encouragement of measures to achieve real equality within our organization, establishing equal opportunities as a strategic principle of our corporate and Human Resources policy, in accordance with the definition of this principle established by the Organic Law of March 22nd, for effective equality. This commitment has been put into practice through the creation of the Equality Committee and the promotion of new measures or positive actions, through the Equality and Diversity Management Plan.

Within the European framework and the Human Resources Strategy for Research (HRS4R), in March 2018 IDIPHISA signed and sent to the European Commission in March 2018 the declaration of commitment to the principles of the "Charter for European Researchers" and. the "Code of Conduct for the Recruitment of Researchers".

The HRS4R strategy is a tool launched by the European Commission to support universities and research institutions and research funding organizations in the implementation of the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers, which aim to contribute to the development of an attractive European labor market for researchers.

The charter and the code of conduct are recommendations from the Commission to the Member States, which are invited to apply them voluntarily:

- European Charter for Researchers: The European Charter for Researchers is a set of general principles and requirements that define the roles, responsibilities and rights of researchers and employers and funders.
- Code of Conduct for the Recruitment of Researchers: The Code of Conduct for the Recruitment of Researchers, which does not differ much from the standard rules governing recruitment, stresses the importance of open and transparent recruitment procedures and diverse and experienced selection committees.

The HR Excellence in Research" seal of quality awarded by the European Commission institutions that generate and support a stimulating and favorable environment for research work.

IDIPHISA welcomes and supports the recommendations of the European Commission contained in the "European Charter for Researchers" and the "Code of Conduct for the Recruitment of Researchers". It also undertakes, in accordance with its internal policies, to develop its human resources , adhering to the recommendations and principles set out in the Charter and the Code and to ensure transparency, accessibility, equity and the pursuit of excellence in the recruitment of researchers.

HRS4R at IDIPHISA. The complete procedure contains the following five steps:

1. Elaboration of a rigorous Internal Analysis.
2. Publication of the Institution's Strategy on the corporate website.
3. Evaluation and approval of the strategy by the Commission.
4. Implementation and continuous self-evaluation of the process by the institution.
5. Finally, the Commission should externally evaluate the Strategy and its deployment every four years after the start of the process.

In April 2019, both the GAP analysis and the Action Plan made by IDIPHISA were sent to the European Commission for evaluation. The IDIPHISA Action Plan can be downloaded from the following link: HRS4R Action Plan IDIPHISA

Specific HR initiatives in IDIPHISA:

https://investigacionpuertadehierro.com/iniciativas-especificas-hr-en-el-idiphisa/

Equality and Diversity Plan, you can consult in:
https://investigacionpuertadehierro.com/wp-content/uploads/2021/03/Plan-de-igualdad-

signed-.pdf with all actions related to equality and diversity.

An *Anti-Harassment Protocol"* for prevention and action sexual, gender-based, sexual orientation and gender identity and/or expression harassment and cyber-harassment has also been developed at IDIPHISA. Available at https://investigacionpuertadehierro.com/wp-content/uploads/2021/03/Protocol-against-harassment-signed.pdf

3. Ethics

To promote scientific integrity, in order to prevent and avoid unacceptable research practices, IDIPHISA has a Research Commission, a Research (CEI/CEIm) Ethics Committee and an Animal Experimentation Ethics Committee (CCEA).

The high level of competition for resources and research funding should not make us forget the compliance with ethical principles and the moral demands that should govern the entire process.

The Institute will ensure an independent review of research projects by qualified and competent experts in the field of the proposed research and research methodology by the Research Committee, the CEIm and the CEEA. The information will be treated with the utmost confidentiality and may not be shared or used for personal gain. The reviews will be objective, based on scientific criteria that can be evidenced. Compliance with applicable ethical and legal standards will be reviewed.

4. Governance Agreements

In order to provide tools to foster shared responsibility between stakeholders and institutions, governance arrangements will be promoted, which are:

- Robust and adaptable for the unpredictable development of R&D&I.
- Familiar enough to align with existing practices.
- Sharing responsibility among all stakeholders.
- To provide governance instruments to promote this shared responsibility.

5. Open Access

In this framework, IDIPHISA is committed to work on an Open Science policy working on open access repositories of its publications and results. In this sense, the Open Science policy of IDIPHISA will be developed in line with other national public access repositories in which the Instituto de Salud Carlos III is working (Repositorio Institucional en Salud, REPISALUD, (https://repisalud.isciii.es/) and those of the Community of Madrid in its open science policy (Repositorio Institucional de la Consejería de Sanidad de la Comunidad de Madrid,(https://repositoriosaludmadrid.es/), to ensure interoperability between them and the sharing of information.

6. Citizen participation

IDIPHISA will promote interaction between all the actors involved in the quadruple helix (academia, public administration, business and society) to jointly respond to current social challenges and bring science closer to the public, who will be involved in the research and innovation process from its conception to its completion.

its development and achievement of results.

All activities carried out in terms of promoting citizen participation will be disseminated through IDIPHISA's website and will be supported by the Institution.

The IDIPHISA will include a patient/society representative, in line with the new Re-accreditation Guidelines for Health Research Institutes of the ISCIII.


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