CODE OF GOOD SCIENTIFIC PRACTICE

HR STRATEGY (HRS4R)

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1. INTRODUCTION

The Code of Good Scientific Practice (CGSP) of the Carlos III National Center for Cardiovascular Research Foundation (CNIC) is a set of principles and rules for the practice of scientific activity, aimed at promoting quality research and preventing, in the field of scientific activity, malpractices of an ethical nature with legal implications. Its contents complement the legal provisions in place and have been supervised and approved by the Scientific Management of the CNIC and reviewed by the *Coordinators Advisory Group*, the CNIC *Research Office* and the *Works Council* of the center representing all employees.

This code was developed with the aim of subjecting science to ethical and legally relevant criteria which are based on the following principles:

First. Recognition of human beings as free and autonomous research subjects. The interests of science are subordinate to human beings and the society they serve as instruments of progress oriented to the common good. Scientific research must respect in all cases the individual and collective rights of the citizens.

Second. Respect for human dignity. In particular, when they are the subject of experimentation, so that their free and express consent is always sought in accordance with legally or statutorily provided procedures and protocols. Consent shall be expressed by the research subject or, in cases of extreme necessity where the research subject is not able to consent, by a related person on their behalf, according to the protocols, with complete information on and full knowledge of the risks and possible consequences that may result from misuse or misguided use of the research processes concerning the research subject.

Third. Accountability in the exercise of scientific activity. The scientist is accountable to the human being whose rights are inviolable and to other living organisms, especially experimental animals, and shall avoid their unnecessary suffering; likewise, the scientist is accountable to the environment in order to prevent its degradation.

Fourth. Transparency of research activity. The scientist shall use appropriate results communication policies and ensure the truthfulness of such results and the legitimacy of the methods and procedures used to achieve them.

Fifth. Professional development. Science has a growing impact on the economic development of societies today. A researcher's work is developed through his/her scientific career which in the CNIC is governed by the European Charter for Researchers (ECR) and the Code of Conduct for the Recruitment of Researchers (CCRR), as well as by the CNIC's Remuneration Policy and Professional Classification Plan (RPPCP). In this field of activity questions may be raised concerning the veracity of published data, ownership of discoveries, authorship of publications, training of scientists, labor practices involving subordinates, and relationships with private companies, which deserve specific treatment.

Therefore, various international organizations have developed rules, principles and recommendations that must govern biomedical research. The Declaration of Helsinki is the basic document that must be upheld by researchers in biomedicine.

Other ethical aspects of an academic nature of scientific practice have been addressed in standards accepted by the scientific community, such as the practice of "peer review" and the Vancouver guidelines for the authorship of publications. The ownership of discoveries is regulated by the laws of each country.

In parallel it has been necessary to create "ad hoc" committees as guarantors of research quality, such as Research Commissions (on the nature of the research to be carried out in the institution), Bioethics Committees (for research involving human beings) Animal Welfare Committees (for the use of experimental animals), and Biosafety Committees (for the use of infectious or genetically modified material).

The CNIC has the following research practices advisory committees:

Operating Committee (OC): advises on the research areas to be developed in the center and on the appropriateness of the different research projects. It is also responsible for settling conflicts of an ethical nature raised by the research and those pursuant to the rules of this code.

Coordinators Advisory Group (CAG): *is the forum in which all scientific areas and programs of the CNIC* are represented and that advises on all research-related matters, including any ethical issues that may arise.

Animal Facility and Animal Welfare Commission (AFAWC): ensures compliance with the legislation on animal housing and animal welfare.

Ethics Committee for Animal Experimentation (ECAE): Ensures compliance with the ethical principles of animal experimentation.

Biological, Chemical and Radiation Safety Commission (BCRSC): advises on activities related to biosafety, biocontainment, waste treatment and the use of chemicals and ionizing radiation from the points of view of personal and work safety, public health and environmental management.

Research Ethics and Animal Welfare Committee of the Institute of Health Carlos III. This is an organ external to the CNIC, within the scope of the ISCIII, whose intervention is mandatory in research involving humans.

Furthermore, the CNIC has a Committee on Occupational Health and Safety with equal participation of workers' representatives.

The existence of these committees ensures the quality and rigor of scientific practice, and for this reason the research funding agencies, in addition to assessing the scientific quality of the proposed research, require suitability reports prepared by the relevant committees before deciding to fund a research project.

The last link in the safeguards that ensure correct research from an ethical point of view resides in the personal commitment of researchers to not engage in unfair practices, falsify research results or authorship, and to respect the ethical principles of research. Research-related institutions have developed in recent years so-called "Codes of Good Scientific Practice" that include guidelines on the various ethical aspects that must be upheld by the managers and researchers of the institution.

Law 14/2007, of 3 July, on Biomedical Research states in article 12 f) that one of the functions of the Research Ethics Committees of the centers that carry out biomedical research is to develop codes of good practice in accordance with the principles established by the Bioethics Committee of Spain, as well as to manage conflicts and handle dossiers resulting from non-compliance with these codes.

To complete a structure that meets the described needs and that ensures ethically correct research, this document serves to create the **Code of Good Scientific Practice** conceived as a collective self-regulatory instrument designed to promote the ethics of scientific practice. It also entrusts the OC with the mandate to monitor compliance with the Code and to resolve conflicts arising from non-compliance, without prejudice to the intervention of the Ethics

Committee of the ISCIII in studies involving humans, which shall be subject to its own rules.

2. OBJECTIVE

The purpose of this code is to establish a set of standards and ethical principles with legal relevance to ensure that research is conducted according to international ethical standards, to prevent injury to individual rights, to contribute to animal welfare, to preserve the environment and avoid unfair practices, and to guarantee respect for authorship of publications and ownership of discoveries.

3. LEGISLATION

By way of reference and without prejudice to international regulations and treaties, to new regulations that may be adopted on the subject and to amendments to the rules in force, the following legislation is of particular relevance:

Organic Law 15/1999, of 13 December, on the Protection of Personal Data.

Law 14/2007, of 3 July, on Biomedical Research.

Law 32/2007, of 7 November, on the care of animals during their exploitation, transport, experimentation and sacrifice.

Law 14/2011, of 1 June, on Science, Technology and Innovation.

Law 24/2015, of 24 July, on Patents

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

Royal Decree 53/2013, of 1 February, establishing basic standards for the protection of animals used in experiments and for other scientific purposes, including education.

Commission Implementing Decision of 20 December 2013 correcting Annex II to Implementing Decision 2012/707/EU establishing a common format for the submission of the information pursuant to Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.

4. CODE OF GOOD SCIENTIFIC PRACTICE

TITLE I. ETHICAL CONDUCT IN SCIENTIFIC PRACTICE

Article 1. Scope of the Code of Good Practice

The Code of Good Practice in Research is for all professionals linked to the CNIC irrespective of the title of this link, including employees, trainees, visiting scientists, scientific collaborators and other natural or legal persons associated with the activity of the CNIC.

Article 2. Good practice in the use of resources

As beneficiaries of the Foundation and in accordance with its statutes, CNIC professionals shall utilize the allocated material and financial resources appropriately in accordance with the principles of effectiveness and efficiency, responsibility and proper management, so that the intended objectives can be achieved and thereby generate the greatest possible degree of confidence in the scientific community and society.

When utilizing resources, CNIC professionals shall pursue the public interest and may not use resources of the Foundation for private purposes. This is especially important given that the financial and material resources are limited and that the CNIC is a center that operates in the public sphere, with an important mission aimed at improving the health of the citizens.

Regarding Human Resources: the professionals of the CNIC and in particular the heads of the various groups, laboratories, units and departments and the management of the center assume the commitments contained in the Code of Good Governance of the CNIC and in the Code of Ethics of the CNIC, as regards respect for the constitutional and labor rights of all professionals and the promotion of mutual respect and cordiality in workplace relations.

Article 3. Misconduct when carrying out research

Abusive or misleading interpretation of data, falsification of data or evidence to generate the appearance of truth, fabricating data and discoveries, total or partial plagiarism of the work of others and other practices of a similar nature are considered misconduct in the field of scientific activity.

In order to prevent malpractices researchers must submit any new contribution to criticism by presenting results in seminars, conferences and peer reviewed publications, which will allow independent substantiation of the results by other researchers.
The CNIC professionals and especially the heads of laboratories, departments and units and the management of the Center are committed to exposing and opposing malpractices.

Article 4. Responsibilities of the management of the center

The Management of the CNIC must guarantee the professionals working there that the infrastructures meet the requirements established by law and that the center has the necessary authorizations to undertake any scientific activity that is subject to specific regulations. In addition to the procedures that regulate scientific research involving human subjects, samples or data, experimental animals, or human embryonic material, the facilities must meet the requirements that are legally required for the exposure to and use and storage of radioactive material, genetically modified organisms and any other potentially hazardous biological, chemical or radiological agent.

Article 5. Research involving human subjects

All research protocols that directly or indirectly involve the participation of human subjects or that are based on any information or biological samples obtained from human subjects must comply with Law 14/2007, of 3 July, on biomedical research, in particular with regard to having obtained informed consent of the subjects (both sick and healthy) participating in the research and with regard to having obtained the required approval of the Ethics Committee which, in case of the CNIC, is the Ethics Committee of the ISCIII.

Researchers shall be especially diligent in all matters relating to information on the purpose, side effects, potential risks and benefits of the research, shall obtain explicit, specific and written consent of the participants, and shall ensure confidentiality of data, samples and results obtained in strict compliance with the regulations on risk prevention.

Article 6. Research in humans for genetic purposes

All research protocols that involve 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 and in particular, where the law so provides or, where appropriate, if possible and so required by the patient, the patient must be informed of the data derived from the project. Whenever biological samples are intended to be used for purposes other than those agreed upon at the time of donation, or in terms different from those of the original consent, a new specific, express written consent must be requested.

Article 7. Research involving human embryonic material

All research protocols that involve the collection, processing and/or storage of biological material of human embryonic origin or functionally similar cells shall request a report from the Commission of Guarantees for the Donation and Utilization of Human Cells and Tissues, in accordance with the Biomedical

Research Act. Previously, approval by the competent Ethics Committee shall be applied for.

Article 8. Protection of personal data and guarantees of confidentiality in humans

All research protocols that involve the use of institutional computer files or the development of databases containing information on persons shall guarantee the anonymity of the participants and shall be subject to the current regulations, especially Organic Law 15/1999, of 13 December, on the protection of personal data and its implementing regulation, as well as the relevant provisions in the Biomedical Research Act. Files containing protected personal data shall be registered with the Spanish Data Protection Agency, indicating the level of protection applicable in each case. The necessary protocols shall also be developed internally to ensure traceability of access, authorized persons and data security.

Regarding the right to confidentiality, this shall be subject to the provisions of article 5 of Law 14/2007, of 3 July, on Biomedical Research, and other applicable legal provisions, under which any person accessing personal data in the course of their medical care-related functions and/or biomedical research-related functions shall be subject to the obligation of secrecy. This obligation shall persist even after termination of the research or activities.

Article 9. Insurance against harm in Interventions on human subjects

Any project involving an intervention on human subjects (monitoring, stress testing, imaging or collecting fluid samples) shall be subject to the provisions of article 18 of the Biomedical Research Act regarding the compensation of damage. To this effect the insurance needed to meet such compensation shall be taken out.

Article 10. Research involving human biological samples

According to the Biomedical Research Act, all human samples used for research shall be accompanied by an informed and express consent of the persons affected, to be used in the research or line of research. Consent requested for diagnostic testing does not allow the use of the sample for research. For research, express informed consent is required. The two consents can be combined in a single document. Whenever biological samples are intended to be used for other purposes than those agreed upon at the time of donation, or in terms different from those of the original consent, a new consent must be requested.

Article 11. Storage of human biological samples for research

If samples are intended to be stored for future research, express informed consent for storage shall be solicited, in addition to consent for their use in the project or research line. Samples taken before the Biomedical Research Act may only be used in accordance with the second transitional provision of that Act.

Article 12. Research on experimental animals

All research procedures involving experimentation on animals must comply with the provisions of Royal Decree 53/2013, of February 1, and other applicable legal provisions establishing the basic rules for the protection of animals used in experiments and for other scientific purposes, including teaching.

Article 13. Research involving genetically modified organisms

All research procedures involving experimentation with genetically modified organisms must comply with Royal Decree 178/2004, of 30 January, which approves the general Regulation for the development and implementation of Law 9/2003, of 25 April, by which the legal regime is established regarding the confined use, voluntary liberation and commercialization of genetically modified organisms, and other legal provisions that may be applicable.

TITLE II. RELATIONS BETWEEN THE COMPONENTS OF THE WORKING GROUP

Article 14. Supervision of researchers in training

From the entry into force of this code and in line with the European Charter for Researchers, personnel in training conducting doctoral studies shall be employed on a group contract basis in the category of pre-doctoral researcher in accordance with the *CNIC's Remuneration Policy and Professional Classification Plan* (RPPCP) and shall be assigned to the pre-doctoral program of the CNIC whose legislative content follows this precept. Cases which require a link of educational nature different from an employment contract, because they involve fellowships or aids received from an external source of financing, are excepted. In any case, these external pre-doctoral researchers shall enroll in the pre-doctoral program of the CNIC.

1. Mentorship assignment

Anyone who is linked to the CNIC through a pre-doctoral researcher contract or an external training fellowship shall be assigned a research mentor, without prejudice to the thesis supervisor and the university tutor, if applicable.

2. Responsibilities of the mentor

The mentor defines the objectives and assumes responsibility for the education of the trainee. The mentor advises and guides the trainee in order that the training expectations are met in accordance with the original intentions and in the time allotted, and must provide the trainee with the best possible conditions for his or her future scientific career. The total number of trainees mentored by a single person should be appropriate and compatible with the extent of the mentor's obligations and commitments.

3. Rights and obligations of research trainees

Trainees hired by the CNIC on an employment basis have the rights and obligations established by labor laws or those laws, if any, that may be applicable to the relationship established. In any case, the primacy of the training objective aimed at the completion of the doctoral thesis shall be taken into account. In the case of trainees holding a fellowship, the conditions established in the corresponding call shall apply. The mentor must be especially diligent to restrict the work of the trainees to those activities that have an educational content.

4. Obligations of the mentor

The specific obligations of the mentor are:

a) to maintain working contacts in person and on a regular basis with the trainees for whom they are responsible to supervise the assigned tasks

b) to promote regular collegial meetings to discuss the progress of the assigned tasks and to contribute to the keeping up to date of the scientific and methodological development of the trainees

c) to keep the trainees up to date regarding existing legislation that affect scientific activities

5. Monitoring of research trainees

The Pre-doctoral Researcher's Office (PRO) and the OC are the supervisory bodies for monitoring research trainees.

In the case that an individual in training or a mentor wishes to apply for a change in the conditions of their training program (change of subject, change of mentor, change of center), the person concerned shall submit a document to the OC in which the causes of their application are detailed.

In case of conflict between the pre-doctoral researcher or trainee and his or her thesis director, mentor or supervisor, the OC is competent to take the necessary measures to resolve the conflict after having received a report of the Pre-doctoral Researcher's Office, in the case of doctoral students.

Article 15. External staff participating in research projects

The CNIC shall ask express acceptance of the rules contained in this code of all professionals linked to the center through an external relationship.

Said acceptance shall be a "sine qua non" requirement to participate in research projects at the CNIC.

TITLE III. RESEARCH PROJECTS

Article 16. Supervision of research projects

Supervision of research projects shall be carried out by the competent committee considering the nature of the project, in order to ensure compliance with the current legislation on biomedical research, research on humans, research on experimental animals and other related legislation referred to in this code, and with laws that in the future may be implemented and be applicable for the same purpose.

Article 17. Prohibition of secret research

Carrying out secret projects in whole or in part is prohibited, without prejudice to the required defense of the rights of invention or industrial property rights derived from the research, trade competitiveness or the confidentiality of scientific results. Violation of this prohibition constitutes professional malpractice, without prejudice to its legal consequences.

Article 18. Use of external facilities and equipment

All research projects that involve the use of health care facilities or equipment, either belonging to the research group or to others, or of any research facility or equipment that is not for the exclusive use of the research group, shall require prior consent from the head of the institution, center, facility or equipment to be used. The use of facilities of external centers or of special shared facilities shall be formalized between the two institutions with the appropriate permission or credentials of the visiting scientist. Likewise, the use of facilities of the CNIC by persons not belonging to the CNIC, even if they are linked to it through collaborative projects, must have the appropriate authorizations. It is presumed that such authorization exists when the person holds a visiting scientist badge. The use of any equipment of the center always requires the knowledge and authorization of those responsible for it.

Article 19. Collaborative projects

When it is foreseen that different groups from centers other than the CNIC will participate in a research project, the necessary measures shall be adopted by researchers and institutions to ensure compliance with the requirements contained in the preceding paragraphs. In any event, authorization of the management of the CNIC shall be required, and the researchers and centers must ensure that they acquire it.

IV. RECORD-KEEPING, DATA RETENTION AND SAMPLE PRESERVATION

Article 20. Plan for the collection and retention of data

All research projects must provide systems for the collection of data, records and biological or chemical material arising from the research, and a plan for their safekeeping and conservation. In the event that the project considers studies involving human subjects, human samples or data identifying human beings, a plan must be designed to protect the data in accordance with Organic Law 15/1999, of 13 December, on the Protection of Personal Data, its implementing Regulation and other implementing provisions. There must also be a plan for collecting informed consents, where appropriate, and for ensuring the confidentiality of the results obtained with human samples, in accordance with article 5 of the Biomedical Research Act and other provisions that may be applicable.

Article 21. Recording of data and alterations

Without exception, all data arising from experiments or research observations must be recorded. This information must remain permanently recorded in databases, record books, or any other appropriate format, in a condition that facilitates external review. The records must also include changes, errors, and negative, unexpected, or conflicting results as well as an indication of the person who made or observed them. Furthermore, the records must include the equipment and procedures used.

Article 22. Retention of collected data

The necessary means and infrastructure must be provided for correct custody and retention of all resulting documentation and biological or chemical material.

In the case of data recorded on electronic media, a specific plan shall be included for the preparation and physical storage of backup copies. For security purposes, personal data recorded on any medium shall be kept safe in accordance with the data protection protocols of the center.

Article 23. Custody and access to collected data

All individuals who belong to the research group must be able to access information on the data obtained and their interpretation. The person in charge of the research shall have a single register of all the different data collection instruments and of the samples under custody; it must be possible to make this register accessible to third parties. To this end, the necessary measures shall be taken to ensure good practice regarding access to that information, including strict compliance with the safety regulations applicable to the type of data.

Transfer of personal data to third parties shall be governed by the provisions of the Organic Law on the Protection of Personal Data, the Biomedical Research Act and their implementing provisions.

Article 24. Ownership of data

All primary documentation and biological or chemical material obtained in the course of a research project carried out in the CNIC or by persons linked to the CNIC is the property of the CNIC Foundation. Their recording, storage and safekeeping are at the discretion of the person in charge of the project and are his or her responsibility, without prejudice to compliance with applicable regulations that must always be guaranteed. Should the person in charge of a project change institutions, the process of change and possible transfers of knowledge, materials or equipment derived from the research project shall be carried out under the responsibility, supervision and approval of the management of the center.

Article 25. Data and samples shared with third parties

After their publication, data and materials resulting from a research project must be publicly available and in a condition to be shared with third parties, except in cases where restrictions have been established on the basis of possible future commercial use. Such provision shall require prior knowledge of the intended use by the person making the request, and that the research group is aware of the request, that there is a transfer agreement with the approval of the individual in charge of the research, and that the person making the request is willing to pay possible costs of production and shipping. Transfer may be restricted for reasons of availability, competition or confidentiality.

Material or data obtained from persons must be used according to the Organic Law on the Protection of Personal Data and its implementing regulations. Thus, information shall be used in such a way that it is not possible to identify the source subjects; otherwise, specific transfer consent of the donors shall be required.

Article 26. International Data Transfer

International transfer of data made in the context of research projects shall be submitted for approval to the management of the CNIC, and strict compliance shall also be ensured with the provisions of the applicable legislation on the protection of personal data; if required, a report or consent of the Spanish Data Protection Agency shall be obtained.

Article 27. Data retention

All primary original information stored as a result of any research project must be retained for at least five years from the date of the first publication of the results, except in those cases for which the law allows shorter periods or requires longer periods. The use of information, samples or biological material for any purpose other than the initial project shall always require the approval of the person in charge of the research project and compliance with the regulations on informed consent.

Article 28. Preservation of human samples

In accordance with article 61 of the Biomedical Research Act, in the event that the sample is preserved, the source subject shall be informed in writing of the storage conditions, objectives, future uses, assignment to third parties and conditions for withdrawing or asking for destruction of the sample. However, biological samples used in biomedical research shall only be stored for as long as necessary for the purposes for which they were collected, unless the source subject has granted explicit consent for other future use. What was indicated in the preceding paragraph is applicable to data identifying samples that have not been anonymized.

V. RULES FOR PUBLICATION

Article 29. Obligation to publish

Publication of results of clinical studies in which human subjects have participated is an ethical imperative.

Article 30. Unpublished results

The failure to publish results of clinical studies or the excessive delay in publishing them may constitute professional malpractice without prejudice to the legal consequences that may derive from it relating to the embezzlement of public or private resources associated with research projects.

Article 31. Publications that include personal data

Research results may only be published with the express prior consent of the source subjects if it is not possible to publish these results without identifying the persons who participated in the project or who provided biological samples.

Article 32. Negative results

In clinical studies and certain epidemiological studies it is equally necessary to publish negative results or results that differ from those anticipated in the research project.

Article 33. Duplicate Publication

Duplicate publication is considered to be malpractice. Secondary publication is only acceptable under the terms established in the guidelines of the Vancouver Group (see the criteria for acceptable secondary publication in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication. Updated February 2006. International Committee of Medical Journal Editors (http://www.icmje.org/)).

Article 34. Bibliographic references to third parties

Both in publications and in patent applications or utility models, it is necessary to cite all work directly related to the research and, in turn, to avoid unjustified or honorary citations. Reference to the work of third parties must sufficiently acknowledge the value of that work.

Article 35. Acknowledgements

The Acknowledgements section of a publication must follow strict principles. The persons or institutions mentioned have the right to deny permission to be mentioned. Some journals require that written authorization be obtained from individuals acknowledged. The same practice applies to references to "personal communication".

Article 36. Institutional affiliation and acknowledgement of support

In all definitive publications of results, the following must be declared explicitly:
1. the institutions or centers to which the authors belong or belonged, and where the research was undertaken;
2. the independent ethics committees who supervised the research protocol and the specific permission obtained, only when legally required;
3. details of all subsidies, grants or financial sponsorship received, in particular funding by the Pro-CNIC Foundation. When referring to persons of the CNIC, "National Center for Cardiovascular Research Carlos III (CNIC)" must be mentioned explicitly.

Article 37. Presentation in the media

The presentation of results in the mass media must always include an informative explanation or a part of the presentation that has been adapted for non-specialist audiences. In such public presentations, the names of the authors must always be linked to their institutions and, whenever possible, financial support and aids received shall be mentioned, in particular funding by the Pro-CNIC Foundation. Communication and dissemination of research results to the media prior to peer review or prior to acceptance for publication or presentation to the scientific community is considered malpractice.

Article 38. Urgent reporting

Early or premature dissemination or publication of results is only justified in exceptional cases for reasons related to public health. In such cases, the authors must ensure that the results will be simultaneously under rapid review by a scientific publisher. Moreover, the editors of the journals in which the definitive publication of the results is intended must be informed of the scope of the prior communication.

Article 39. Use of publications for purposes of research assessment

In assessments of individuals or groups in which scientific publications are analyzed, and in initial or periodic assessments carried out in the CNIC for the purposes of scientific promotion, evaluation shall always be based on the current and future quality and importance of the scientific output.

Article 40. Peer Review

1. The concept of peer review. This term is understood to mean all requests to an individual in their position of expert to undertake a specific assessment, examination, or criticism of a manuscript submitted for publication, an individual or group grant proposal, a clinical or experimental protocol subject to assessment by an ethics committee, or a report arising from an on-site visit to a laboratory or center.

2. Conflicts of interest. Reviews must be objective, that is, based on scientific criteria. Reviews must be declined when there is a conflict of interest, e.g. because there is a direct link between the reviewer and the authors or because the reviewer is in direct competition with the authors. Conflicts of interest are grounds for abstention by the reviewer.

3. Use and fate of documentation submitted for assessment. Reports and written documents that are subject to review are always confidential and privileged information. Consequently, such documentation:

a) may not be used for the benefit of the reviewer until the information has been published;
b) may not be shared with other colleagues without the explicit permission of the senior researcher, editor or agency;
c) may not be retained or copied without the express permission of the senior researcher. Good practice requires that the material be destroyed or returned once the review process is completed.

VI. AUTHORSHIP OF SCIENTIFIC ARTICLES, PUBLICATIONS AND THESES

41. Conditions for authorship

Authorship conditions do not depend upon belonging to a particular profession or upon hierarchical position, nor upon the nature of the employment relationship, but rather on the kind of contribution made to the research.
To fully meet the criteria for authorship of a publication or patent, the person must meet the standards of each publication. In a broad sense and without prejudice to the specificities of each publication, researchers are considered authors if their contribution consists of:
a) having made a substantial contribution to the creative process, that is, to the conception and design of the study, or to the analysis and interpretation of the data;
b) having contributed to the preparation of the resulting communications, reports, or publications;
c) being able to present in detail his or her contribution to the research project and to discuss the main aspects of the overall research.

Authors must accept the final draft of the original manuscripts submitted for registration or publication.

Article 42. Persons who provide data, cases or samples

Mere participation in obtaining resources or in data collection, such as, for example, the provision of routine data, experimental subjects, or samples does not necessarily justify the condition of author, although such involvement should be recognized in the Acknowledgements section. In studies involving the use of samples, analyses, or expert opinions provided by third parties, it is advisable to establish a prior plan relating to communication and authorship in which the potential intellectual contribution to the project is taken into account along with any other elements relating to rights to authorship.

Article 43. Honorary authors and ghost authors

Any person linked to a research group who requests inclusion as an author *ex officio*, on the basis of their hierarchical position or professional relationship, violates the principles of academic freedom and commits an act of abuse of authority. Conversely, the omission of names of any persons who have made proven contributions to the research is an act of misappropriation of intellectual property on the part of the other authors.

Article 44. Inclusion of authorship in reports

The preparation of memoranda, work reports, technical reports, or any other written document for the attention of third parties must always indicate the authors of the research, the center or centers with which they are affiliated, and the support received, in the same way as if the document were a scientific publication or patent.

Article 45. Order of authorship

As a general rule, the order in which authors appear in scientific publications shall be as follows: a) the first author is the person who has made the greatest contribution to the study and has prepared the first draft of the article; b) the senior author who directed and/or has final responsibility for the research project appears as the last author; and c) the remaining authors may appear in order of importance or in alphabetical order if they made equal contributions to the study.

Article 46. Shared first authorship

When two or more authors have made an equal contribution to the same study and have shared main responsibility for the preparation of the manuscript, they shall be considered as equal first authors. This condition shall be stated explicitly in the publication of the article. The same criteria shall be applied to intermediate or senior authors.

Article 47. Curriculum vitae

In the preparation of a personal *Curriculum vitae*, the author is responsible for the accuracy of its content and exempts the public CNIC Foundation from any liability arising from the lack of veracity of the data.

Article 48. Doctoral theses

The execution, reading and publication of a doctoral thesis on research carried out in the CNIC is subject to the criteria developed in this Code of Good

Scientific Practice. Research protocols must comply with current legislation and specifically:
1. Conform to the reports of the relevant Committees before starting the scientific work when so required.
2. Where appropriate, the name of the thesis supervisor, the laboratory of the CNIC in which the research was done and the Committees that authorized the protocols and the presentation shall be stated explicitly and in detail in the dissertation.
3. Data obtained and records made while carrying out the thesis work must meet the provisions of this code regarding data registration and ownership.
4. Publications arising from the thesis shall comply with the requirements of development and authorship detailed in the relevant sections of this code.

VII. PROTECTION OF INTELLECTUAL AND INDUSTRIAL PROPERTY

Article 49. Protection of results with possible commercial interest

If the researcher responsible for the project considers that the research results could lead to inventions or applications that may be amenable to protection because of their commercial interests, he/she must communicate this to the management of the center. From that moment, a patent application process can be initiated through the Office for Transfer of Research Results of the CNIC, in accordance with the internal application procedure derived from Royal Decree 55/2002, of 18 January, on the use and assignment of the inventions of public research bodies, in accordance with the provisions of Law 24/2015, of 24 July, on Patents. Information obtained in scientific seminars held in the CNIC is confidential and attendees must maintain and ensure this confidentiality for the purposes of protection of authorship and industrial property.

Article 50. Industrial Property

When research personnel who participate in a project promoted by industry make essential contributions to its design and execution, the necessary agreements will be established with the promoting organization to share the corresponding industrial property rights in accordance with the applicable effective legislation and the internal regulations regarding the participation of researchers in the economic outcomes of the exploitation of such rights. All agreements concerning industrial property require the mandatory report of the State Legal Service, without prejudice to the legally required authorizations. Agreements solely addressing distribution of participation or allocation of quotas may be exempt.

Article 51. Intellectual property

When a research group offers a technical service or when research staff participate exclusively in the collection of data as part of a protocol developed

by a third party, the conditions for communication and publication of the results obtained shall be established by mutual agreement with the promoting entity, always taking into account the principles indicated in the rules on "authorship of scientific articles" of this document. All agreements concerning intellectual property require the mandatory report of the State Legal Service, without prejudice to the legally required authorizations. Agreements solely addressing distribution of participation or allocation of quotas are exempt.

VIII. RELATIONS WITH THIRD PARTIES

Article 52. Relations with other entities

Every collaborative partnership with another entity or company involving economic benefits for the parties, shall be formalized through an agreement, contract or management order, as appropriate, which includes the background, the object of the agreement, the timetable, the equipment, the staff involved and the scientific project subject of the agreement. These instruments shall be subject to the mandatory report of the State Legal Service, except in cases in which a legal instrument of identical characteristics was authorized previously. In any case, the researchers and the centers shall adopt the necessary precautions to ensure compliance with the rules set out in this Code.

Article 53. Transparency and primacy of public interest

When knowledge and technology are exchanged with or transferred to private entities, public interests must always take precedence; therefore, all agreements must be made with full transparency.

The management of the CNIC shall establish the necessary safeguards to protect the intellectual freedom of researchers, avoid disproportionate confidentiality commitments or unjustified restrictions on the publication of results or any other abuse of position or rights, always in the framework of the current applicable legislation.

IX. FUNCTIONS OF THE OPERATING COMMITTEE

Article 54. Mission

One of the objectives of the OC is to promote awareness and internal implementation of the Code of Good Scientific Practice. The OC acts independently and is oriented towards promoting research quality and contributing to the preservation and promotion of ethical conduct in research.

Article 55. Functions

The functions of the OC relating to ethical contents are:

1. To ensure observance of the Code of Good Scientific Practice and compliance with its regulations.
2. To act as an advisory arbitration body in the case of uncertainties or conflicts that may arise in relation to research integrity, at the request of the interested parties or as instructed by the management of the CNIC.
3. To inform and raise awareness among the scientific community of the CNIC of the events, needs, and guidelines relating to the ethical aspects of biomedical research.

Article 56. Relations with other Committees

The OC shall work closely with other committees of the CNIC, especially with the CAG as the main advisory body to the OC. For the development of advisory expert opinions regarding ethical conflicts or research on experimental animals, a report from the Animal Facilities, Transgenesis and Animal Welfare Commission or from the Animal Experimentation Ethics Committee shall be mandatory, without prejudice to the intervention of the Research Ethics and Animal Welfare Committee of the Institute of Health Carlos III when required. In any case, the final resolution of the matter presented corresponds to the OC.

Article 57. Advisory arbitration in case of conflict

1. Prior to the consultation and to guarantee the independence of its members, the possible conflicts of interest of the participating members with the people involved in the consultation shall be analyzed. Members who may be affected by conflicts of interest may not participate in drawing up the expert opinion and meetings relating to the conflict.
2. The OC shall analyze the documentation received for arbitration in conflicts and may request the presence of the interested parties before issuing the advisory report.
3. Reports may also be requested from other authorities of the CNIC or from other committees that may be related to the matter in dispute. In this respect, a report from the State Legal Service may be applied for through the management bodies of the CNIC.
4. The OC shall issue a non-binding decision that shall be communicated to the individuals concerned; these latter persons can appeal and present new arguments in the reasonable period that the OC has established in its decision. After the deadline for submission of claims has passed, the OC shall issue its final decision for adoption of the final resolution of the dispute in question.

Article 58. Guarantee of procedures

In relation to its functions mentioned above, the OC shall guarantee at all times the diligence of its activities, the independence of its procedures, the anonymity and confidentiality of personal data and information received, the reliability of the information generated, the impartiality of its considerations, and the fairness of its resolutions, as well as the opportunity to appeal against those decisions and the period for appeal.

Article 59. Communication

Communication with the OC shall be by email addressed to any of its members. Where appropriate, an electronic signature or other legally valid method of signature can be used.

Article 60. Dissemination of the Code of Good Scientific Practice

The OC shall ensure that the CGSP is known, accepted and adopted by all staff of the CNIC.
The OC assumes responsibility for distributing the CGSP to all personnel of the center.
The HR Department shall provide a copy of the CGSP to all new members when they join the CNIC.
The CNIC shall include a link to the contents of the current CGSP on the intranet so that it will be readily available and can be freely consulted. When appropriate, it shall be published on the website of the CNIC.

Article 61. Updates of the Code of Good Scientific Practice

The CNIC shall provide a copy of the CGSP to all new members who join the center, be they employees, students or collaborators, as part of the welcome information. The OC shall oversee the regular review, analysis and discussion of the contents of the CGSP within the framework of postgraduate studies and activities undertaken by trainee scientists affiliated with CNIC centers. The Training Department of the CNIC shall also include information on the contents of the CGSP in postgraduate courses or similar training activities.

X. CONSULTATION OF WORKERS' REPRESENTATIVES

Article 62. Consultation of workers' representatives

The CGSP has been submitted for consultation and comment to the *Works Council* of the CNIC, which represents all employees of the center.

5. REFERENCES

1. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine:Convention on Human Rights and Biomedicine. Council of Europe 1997.
3. Universal Declaration on Bioethics and Human Rights, UNESCO, Paris, 2005.
4. Ethical Principles for Medical Research Involving Human Subjects, Declaration of Helsinki of the World Medical Association, 1964 and subsequent amendments.
5. Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979
6. Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. N Engl J Med 1997; 336:309-315.
7. Best Practices for Ensuring Scientific Integrity and Preventing Misconduct. Organization for Economic co-operation and Development. Global Science Forum. http://www.oecd.org/37/17/4018803
8. First World Conference on Research Integrity: Fostering responsible research. (Lisbon, Portugal, September 2007). http://icsu.org/5-abouticsu/PDF/WC_final>_report
9. Code of Good Scientific Practice. Barcelona Biomedical Research Park. http://prbb.org/eng/part01/p06.htm
10. Guide to Good Practice in Research in Health Sciences. Published by the Institut Catalá de la Salut, 2003.
11. Code of Good Scientific Practice. Institute of Health Carlos III
12. Code of Good Scientific Practice. CSIC