IMIBIC Code of Responsible Practices and Research Integrity

IMIBIC
INSTITUTO MAIMÓNIDES DE INVESTIGACIÓN BIOMÉDICA DE CÓRDOBA
Junta de Andalucía
UNIVERSIDAD D CÓRDOBA

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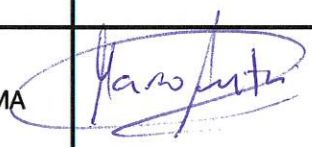
FIRMA			

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A. INTRODUCTION

The need for scientific research staff to accredit their research experience, together with other personal motivations, can lead to inappropriate decisions that result in scientific fraud. In order to ensure that research projects comply with current ethical and legal standards, institutions dedicated to promoting and funding research have set up various independent committees to guarantee the quality and rigorousness of the scientific practice carried out within them. However, it must be borne in mind that the guarantee of adequate research ultimately rests on the commitment of the research staff themselves.

In recent years, research-related institutions have developed so-called 'Codes of Good Scientific Practice'. Likewise, these institutions should create a **Research Integrity Committee** and establish standardised procedures for the appropriate management by this committee of the conflicts and dossiers generated by non-compliance. This Committee will be made up of research staff and other professionals from the Institute, Hospital Reina Sofia and the University of Cordoba, with a demonstrable reputation and experience in legal aspects of biomedical research, appointed by the Research Integrity Committee. The Committee will proceed to conduct an investigation of the claim of misconduct, which must be processed within a **maximum period of three months** (unless there are justified extensions). After conducting the investigation, it shall prepare a final report, proposing, if appropriate, possible actions to be taken with the researcher or group involved or measures necessary to restore their reputation in the most appropriate manner.

B. PURPOSE AND SCOPE

Research is the core mission of IMIBIC, essential to meet the needs and demands of society. This commitment to research excellence is based on an explicit recognition of integrity in research, in accordance with the constitutional principles of autonomy and the duty of public administrations to serve the general interest. The Code reflects IMIBIC's desire to achieve its scientific and social objectives in accordance with Human Rights and current legislation, maintaining the highest standards of integrity.

The Code promotes good practices in the research function, covering all IMIBIC staff and the external entities involved, in order to ensure that the relationships between these actors favour the generation and exchange of knowledge. It establishes a commitment to the continuous improvement of research quality, the prevention of inappropriate conduct and the protection of the rights of all participants in research activity. Its application is limited to the conduct of research, without interfering in the choice of topics, methodologies or scientific approaches.

All researchers are obliged to transmit these principles and good practices to the persons whose research activities they coordinate or supervise, prohibiting any practice that calls them into question.

C. GENERAL ETHICAL PRINCIPLES

Impartiality, Fairness and Transparency: IMIBIC will guarantee the impartiality of its researchers vis-à-vis external interests and will avoid conflicts of interest in the evaluation and selection of personnel, promoting fairness in the distribution of tasks and the recognition of contributions. Likewise, transparent procedures will be adopted for calls for projects, grants and recruitment, and will require open disclosure of funding sources and any circumstances that may compromise the integrity of the research.

Honesty and Responsibility: IMIBIC researchers must express the objectives, methods and results of their research rigorously, truthfully and exhaustively, guaranteeing their originality and reliability, and giving fair recognition to all authors. Misuse of IMIBIC's resources, name or reputation for private purposes will not be permitted. Research staff shall perform their work competently and in accordance with the terms agreed with funders, and IMIBIC will provide appropriate training and supervision to ensure professional development.

Respect and Freedom: Researchers shall respect human rights, human dignity and autonomy, paying special attention to vulnerable groups, animal welfare, and protection of the environment and cultural heritage, in accordance with current regulations and IMIBIC provisions. Participation in research will be guaranteed to be free and informed, respecting the freedom of thought and expression of researchers, within the limits of available resources and intellectual property.

Accountability: Researchers are accountable to their employers, funders and society, especially when public funds are used, and must use them efficiently. IMIBIC will implement the necessary mechanisms for public accountability of research results and use of funds.

D. RESPONSIBLE PRACTICES

1. ***Research planning***

a. Elaboration and Approval of Research Protocols: All research conducted at IMIBIC must be formally formulated in a written protocol prior to its initiation, which must

be publicly accessible through a repository or in a scientific publication. This protocol must be clear, precise and detailed in its objectives, research phases and general plan, showing the relationship between the different stages. Prior to its execution, the protocol must be submitted for review and approval by the competent accredited bodies, who will evaluate its scientific quality, its compliance with ethical requirements, and its conformity with the applicable regulations.

b. Modification of Research Protocols: During the course of a project, if the need arises to modify the initial approach or approach not foreseen in the protocol, a supplementary protocol must be drafted before proceeding with the implementation of the project. Any such modification will also require prior authorisation from the relevant ethics committees and, where appropriate, the funding body. Likewise, any incorporation of new investigators to the team must be notified to the corresponding entities, specifying their responsibilities in the research.

c. Conditions and Use of Research Facilities: IMIBIC will guarantee suitable conditions for research, providing the resources, facilities, equipment, security means, and opportunities necessary for the development of research projects and training in this area. Any research that uses facilities or equipment that are not for the exclusive use of IMIBIC will require prior authorisation from the person in charge of said facilities or equipment. In collaborative research with other research groups, it will be necessary to establish in writing the terms of the collaboration, signed by the heads of each party.

d. Treatment of Biological Samples and Sensitive Data: All research protocols must contain a specific plan for the collection, custody, preservation, and partial or total transfer of data, records, and biological or chemical materials derived from the execution of the research. This plan must comply with applicable regulations on personal data protection, biosafety, and ethical use of human and animal biological samples, as well as hazardous or protected materials.

e. Use of Products in Research and Healthcare Equipment: Protocols involving the use of products in research, healthcare equipment, or external facilities must comply with the Standards of Good Manufacturing and Distribution Practices and be approved by the person responsible for the facility or equipment concerned. The safety and efficacy of the products used must be supported by clinical data obtained in accordance with ethical and methodological criteria established in current legislation.

f. Transparency and Publicity of Information: IMIBIC is committed to maintaining transparency in research by providing up-to-date public information on research projects, contracts and agreements, including the teams involved, the objectives to be achieved, the funding received, and the funding entities. This policy of transparency reinforces the integrity and responsibility of IMIBIC in its research work.

g. Projects under Special and Emergency Conditions: In situations requiring urgent research due to safety or public health reasons, the initiation of activities must also be supported by a protocol, albeit a simplified one. In addition, any research project using facilities for animal experimentation must comply with specific regulations regarding the registration of animals used, guaranteeing their protection and welfare, and ensuring that the persons conducting the experiments are competent or under the responsibility of trained professionals.

2. Recording, custody, access, availability and ownership of data and material resulting from investigations

a. Collection and Preservation Plan: All IMIBIC research protocols should include a detailed system for the collection, custody, and preservation of data and materials obtained during the conduct of the study.

b. Data Recording and Storage: It is mandatory to document all data, tasks, and results in secure physical or digital notebooks or logbooks, which should be available for external review. IMIBIC will provide the necessary resources to guarantee the custody and preservation of the documentation, assuming the corresponding costs.

c. Access and Custody of Information: Participating investigators must have access to the study records, and IMIBIC may request them through an institutional officer. Custody of the data and records will be the responsibility of the principal investigator of the project.

d. Ownership and Use of Data and Samples: The logbooks and their contents are the property of IMIBIC, with the possibility of copying for researchers who change institutions, under the supervision of the principal investigator. The transfer of information or materials, in case of change of responsible, will be supervised by the competent authority of IMIBIC.

3. Development of the research

a. Responsibility and Regulations in Research: IMIBIC researchers must ensure that their research is relevant and does not duplicate previous studies. It is mandatory to respect current legislation and IMIBIC regulations. Furthermore, geographical, intersectorial, transdisciplinary and virtual mobility must be encouraged in order to increase scientific knowledge. Researchers must seek continuous professional development by updating their knowledge and skills. The institution must guarantee safe working conditions in compliance with current regulations.

b. Research Involving Human Subjects and Medical Devices: All research involving human subjects must be registered in a public database before commencing and obtain the approval of the Cordoba Provincial Research Ethics Committee. Research must prioritise the safety and rights of participants, and the benefits must justify the risks. Research involving medical devices, medical devices and biological samples must comply with applicable legislation, including the Biomedical Research Act.

c. Research with Biological Agents, Human Cells and Tissues: Handling of biological agents must be carried out in accordance with occupational safety regulations. Research with mesenchymal cells, tissues of human or pre-embryonic origin must comply with specific regulations and the corresponding Royal Decrees. The procurement and treatment of material of embryonic origin must be approved by the Guarantees Commission and comply with the laws on biomedical research.

d. Research with experimental animals and genetically modified organisms: Projects using experimental animals must follow the regulations in force and have the approval of the Ethical Committee for Animal Experimentation of the Junta de Andalucía. Research with genetically modified organisms must also comply with the regulations in force.

e. Use of Facilities and Equipment: Any research using own or external health facilities or equipment requires the approval of the person in charge of these facilities. The use of IMIBIC or Queen Sofia University Hospital facilities by third parties requires authorisation. The acquisition of equipment will be governed by the institute's regulations and may be carried out through the Central Purchasing Office or by the researcher.

f. Biological Data and Sample Management: Any research protocol should include procedures for the collection, processing, storage, and release of data and biological or chemical samples, ensuring compliance with data protection regulations. Records should document all activities, errors and unexpected results. Retention of data and samples shall be for a minimum of ten years, and transfer to third parties must comply with a transfer protocol that ensures anonymisation of the data.

g. Project Completion and Final Report: At the conclusion of each project, a final report will be prepared documenting results, incidents, changes and personnel involved. This report will be incorporated into the project documentation and sent to the corresponding funding agency, thus ensuring transparency and compliance with ethical and legal requirements.

4. Protection of results and intellectual property

a. Ownership of Research Results: All physical or digital media considered primary sources, as well as biological or chemical materials obtained during a research project, are the property of IMIBIC, Reina Sofia University Hospital and/or University of Cordoba, unless otherwise stipulated in the regulations or in a contractual agreement. Likewise, the intellectual property, knowledge, know-how, data and materials generated by IMIBIC members in projects funded by IMIBIC are the property of the institution. Their registration, storage and custody correspond to the principal investigator. In research involving samples, analyses or opinions of third parties, it is recommended that a prior communication and authorship plan be established.

b. Retention of Data and Samples: All primary and original information generated in a research project should be retained for a minimum of 10 years from the first publication of the results, unless otherwise provided by law. In the case of clinical trials, documentation and data should be retained for 25 years from the clinical trial closure visit. Biological samples should be retained only for as long as they are necessary for the purposes for which they were collected, unless the source subject expressly consents.

c. Intellectual Property Rights and Protection of Results: Research results with potential interest for commercial exploitation should be adequately protected. If the results may lead to inventions or applications susceptible of protection, the person responsible for the project must inform the IMIBIC Management through the Innovation Unit. The ownership and exploitation rights of the research activity correspond to the funding entities, always respecting copyright. The results must not be published or presented until the protection process has been completed. The Technology Transfer Office (OTT-SSPA) and the Research Results Transfer Office (OTRI) provide services for the protection and commercialisation of developed technologies.

d. Transparency and Confidentiality in the Transfer of Knowledge: In the exchange or transfer of knowledge with private entities, the public interest must prevail, guaranteeing the transparency of the agreements. IMIBIC will establish the necessary rules to protect the intellectual freedom of its researchers and to avoid disproportionate or harmful confidentiality commitments for the institution, as well as unjustified restrictions in the publication of the results obtained.

e. Intellectual Property Agreements with External Entities: When IMIBIC research staff participate in projects promoted by external entities, and contribute to their design and execution, agreements will be established to share the intellectual and industrial property of the results obtained. The promoting entity may have exclusive use of the results for a period of ninety days in order to assess their commercial interest. In the case of participation limited to the collection of data or provision of

technical services, the conditions of communication and publication will be mutually agreed.

f. Legal and Contractual Obligations: Researchers must comply with applicable national and sectoral legislation and practices, including intellectual property regulations and the requirements and conditions imposed by funders. The institution must ensure that research staff obtain the benefits from the exploitation of their R&D&I results through adequate legal protection of their intellectual property rights, as well as protect the rights of IMIBIC in all research carried out at the institution or by its staff.

g. Protection and Use of Documentation and Results: Documents submitted for evaluation are considered confidential and privileged information, and therefore may not be used for personal gain until publication. Results with potential commercial interest must be protected in accordance with applicable regulations, ensuring appropriate management of intellectual property rights. All research protocols must include confidentiality clauses that protect the integrity of the information and data obtained during the research.

5. Publications and communication of results

a. Honesty and Rigour in the Publication of Results: IMIBIC researchers must publish the results of their research in an honest, open and transparent manner, ensuring that all the necessary conditions of quality and rigour have been met. Publication must be made, except in justified cases, in recognised scientific journals with adequate peer review, unless intellectual property considerations or commercial reasons make it advisable to delay publication. Failure to publish relevant results or unjustified delay may be considered a serious misconduct.

b. Authorship Rights and Requirements: Authorship of publications must be based on creative and significant contributions only. The inclusion of 'honorary', 'guest' or 'ghost' authors is not permitted. The persons responsible for the research will make public in advance the general criteria for establishing the order of authorship and reflecting appropriately the contribution of each author. In any case, it is intended that the order of authors should be established by consensus. Ideally, the specific contribution of each author should be stated in the publication itself. All co-authors are responsible for ensuring compliance with ethical requirements on authorship, ensuring that no one is unfairly included or excluded.

c. Order of Authors and Corresponding Author: The order of authors in a publication should reflect the magnitude of their contribution: the first author is the one who has put the most effort into the research and written the first draft; the last, or senior, author takes final responsibility for the research protocol; the other authors may be

ordered according to the importance of their contribution or alphabetically. The corresponding author is responsible for the editorial process and all future interactions with other researchers related to the publication.

d. Shared authorship: When two or more authors have devoted the same effort in the development of the research and preparation of the manuscript, both authors can be considered as first authors, and the contribution of both authors must be explicitly reflected in the original publication as 'equal contribution' or 'contributed equally'. The same criterion can also be applied in the case of intermediate and senior authorship, as well as for corresponding authors.

e. Transparency and Procedures in Multicentre Studies: In multicentre research involving multiple investigators, collective authorship and the appointment of an editorial board is acceptable. The person in charge of correspondence will be responsible for editorial and future interaction with other investigators. In case of multi-centre studies, clear criteria for participation and designation of authors must be established, ensuring transparency and fair recognition of all participants.

f. Acknowledgements and Acknowledgements: All contributions from contributors who do not meet the criteria for scientific authorship, but who have directly or indirectly supported the research, must be appropriately acknowledged in the acknowledgements. Contributions must be mentioned with precision, respecting the right of the persons or institutions mentioned to decline their mention.

g. Citations and References: The work of others who have influenced the research should be appropriately acknowledged. Bibliographical references should be precise, being limited to published works, in press or personal communications, with prior authorisation.

h. Affiliations: In all publications, IMIBIC researchers must explicitly mention their affiliation to IMIBIC, the Reina Sofia University Hospital and the University of Cordoba, thus ensuring the proper visibility of the institutions in the international scientific community. To this end, they will follow the corresponding bibliographic designation established by IMIBIC.

i. Protection of Results and Confidentiality: Commercially exploitable results must be protected prior to publication. Disproportionate or harmful confidentiality commitments for IMIBIC must be avoided and the intellectual property rights of all parties involved must be respected. Public disclosure of results should be made in a comprehensible and honest manner, avoiding any exaggeration of their importance or applicability.

j. Duplicity of Publications: Publication of the same work in different journals or of substantial parts of it, including translations, will only be permitted with the prior consent of the editors and provided that appropriate reference to the first publication is included. In the CVs of researchers, these related articles should appear as a single publication. Likewise, the same paper shall not be submitted simultaneously to more than one journal for publication.

k. Guidelines for Correction and Withdrawal of Publications: In case of errors in a study that affect the value of its conclusions, authors should publish a correction note as soon as possible. Withdrawal of publications must be managed in accordance with the ethical and professional standards in force, always guaranteeing scientific integrity and public confidence in the research conducted by IMIBIC.

6. Conflicts of interest

a. Declaration and Management of Conflicts of Interest: IMIBIC research staff must visibly declare in publications any conflict of interest that may affect the objectivity, integrity or interpretation of the results, especially when there is a relationship with any entity whose products or services are related to the object of the research. Likewise, potential conflicts must be reported to the research coordinators and, where appropriate, to the corresponding management, when there are reasonable doubts about the impartiality of the researcher's judgement or professional performance due to financial, family, political or any other interests.

b. Objective Evaluation and Challenge: The review of manuscripts, projects, protocols and reports at IMIBIC must be carried out under strictly scientific criteria, avoiding influences of personal opinions or conflicts of interest, such as direct links with the authors or direct competition. Conflict of interest recusal procedures will be established, which must be based on justified causes and managed with discretion and confidentiality, preserving the rights and honour of all parties involved.

c. Conflict of Interest Complaint Procedure: IMIBIC will implement, through its Research Integrity Committee, an appropriate procedure in accordance with international, national and regional standards to address complaints and protect the rights of individuals or institutions that may be affected by conflicts of interest, ensuring the integrity of the research process and the reputation of the institute.

7. Responsibility towards trainee researchers

One of the main objectives of IMIBIC is to encourage and favour the professional development of its staff. For this reason, IMIBIC must guarantee trainee researchers

the correct direction of research and supervision in their training as scientific researchers or research support technicians.

a. Assignment and Responsibility of Tutors: All researchers in training linked to IMIBIC must be assigned to a tutor, who will be responsible for supervising and guiding their professional development. The mentor must set and meet the training objectives, and ensure that trainees receive the guidance and support necessary for successful development.

b. Duties of the Mentor: The mentor must maintain regular personal supervision of the trainees' tasks, provide regular meetings to evaluate progress and ensure participation in scientific updating. He/she must also prevent trainees from performing tasks unrelated to their project and familiarise them with the relevant legal and ethical standards. The number of people in charge of a single tutor should be appropriate to his/her responsibilities and the complexity of the research.

c. Supervision and Guidance of Trainees: Tutors, supervisors or mentors must ensure that the research process is adequately supervised, ensuring that the training objectives are met. In the event that changes to the conditions of the training programme are required, both the trainee and the mentor must submit a detailed request to the relevant committee.

d. Rights and Obligations of Trainees: Trainees have specific rights and obligations that must be respected and managed by the mentor. IMIBIC must ensure that admission standards and conditions for training are clear and based on criteria of merit and ability, guaranteeing professional development and the integrity of the training process.

8. Collaboration with other researchers and institutions

a. Coordination in International Projects: In collaborative research projects, especially international ones, the parties involved should agree at the outset on the conditions of ownership, access, storage and dissemination of data and research results.

b. Collaboration with Developing Countries: IMIBIC will promote scientific collaboration with institutions in developing countries, maintaining the same good practices established in this Code for all research.

c. Compliance with International Regulations: IMIBIC researchers must adhere to the research regulations and practices of the foreign countries with which they collaborate, provided that these are compatible with this Code and the applicable

ethical and legal regulations. Any foreseeable legal problems must be reported to IMIBIC before starting the research.

d. Data Management and Funders: Publicly funded data should be made accessible to the international scientific community in full and at low cost, respecting data protection and intellectual property regulations. In cases of private funding, agreements will be promoted that balance the dissemination of data with their possible commercial exploitation. Coordinators of projects with multiple funders must ensure that they comply with all conditions set by the funding bodies without conflicts between them.

E. IMPLEMENTATION OF THE CODE OF RESPONSIBLE PRACTICES AND INTEGRITY IN RESEARCH

This Code of Responsible Practices and Integrity in Research, approved by the IMIBIC Board of Trustees, is mandatory for all researchers hired by or assigned to the Institute. Its implementation covers all the Institute's research staff. The Code will be periodically disseminated among the Institute's professionals and is available on the Institute's website.

The IMIBIC Research Integrity Committee will be in charge of the evaluation and monitoring of the Code, including the review of its content and the proposal of necessary modifications to adapt it to the reality of the Institute or to new regulatory frameworks. Likewise, the Committee shall be responsible for the management and resolution of possible conflicts related to the scope of the Code.

Any person who has knowledge or a well-founded suspicion of a breach of this Code may report it through the whistle-blowing channel available on the Institute's website.

F. CURRENT REFERENCE REGULATIONS

- Law 14/2007, of 3 July, on biomedical research.
- Law 32/2007 of 7 November 2007 on the care of animals during their exploitation, transport, experimentation and slaughter.
- Circular No 7/2004 of the Directorate General for Pharmacy and Medical Devices on the authorisation procedure for clinical research involving medical devices.
- European Code of Conduct for Research Integrity, ALLEA - All European Academies, 2018.
- Regulation (EU) 2016/679 of 27 April 2016.
- Royal Decree 1344/2007 of 11 October 2007 regulating the pharmacovigilance of medicinal products for human use.

- Order SCO/256/2007 of 5 February 2007 establishing the principles and detailed guidelines for good clinical practice and the requirements for authorising the manufacture or importation of investigational medicinal products for human use.
- Circular No 15/2002 of the Spanish Medicines Agency on communication procedures on pharmacovigilance of medicinal products for human use between the Pharmaceutical Industry and the Spanish Pharmacovigilance System for medicinal products for human use.
- Regulation (EU) 536/2014.
- Royal Decree 53/2013, of 1 February, establishing the basic rules applicable to the protection of animals used in experimentation and other scientific purposes, including teaching.
- Organic Law 3/2018 of 5 December on the Protection of Personal Data.
- RD1716/2011, of 18 November, which establishes the basic requirements for the authorisation and operation of biobanks for biomedical research purposes and the treatment of biological samples of human origin, and regulates the operation and organisation of the National Register of Biobanks for biomedical research.
- Law 41/2002, of 14 November, basic law regulating patient autonomy and rights and obligations regarding clinical information and documentation.
- Spanish Research Ethics Committee, Report on authorship and affiliations of scientific and technical works 2023.
- World Medical Association Declaration of Helsinki (Fortaleza, 2013).

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