CODE OF GOOD PRACTICES INCLIVA

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INCLIVA | VLC
Instituto de Investigación Sanitaria

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1. Introduction

This Code of Good Research Practices (CBPI) establishes the ethical and quality criteria that should guide the research activity of the activity of the research staff within the IIS INCLIVA. This code is coherent with the principle of the Responsible Research and Innovation (RRI) promulgated by the European Commission, which emphasize the importance of the implementation of actions that allow the civil society, generally more distant from science, to know and understand the usefulness of the resources managed in INCLIVA and the social benefits obtained by the advances of the research developed and the European Code of Conduct for Integrity in Research[1], which develops reliability, honesty, respect and responsibility as fundamental principles of integrity in research.

The following are a series of recommendations to ensure the adequacy of the research conducted at the institute to the ethical and legal norms in force. The principles established in this guide are applicable to all the professionals who carry out their research activity at the institute and the different entities that comprise it and are considered an individual commitment of each researcher to exercise the best scientific practices. This commitment is materialized with the signature of acceptance of this code.

This Code is intended to be an understandable and supportive document on various aspects applicable to the development of the scientific activity itself. For this reason, the following are cited, offering access to them for direct consultation.

The bases on which this CBPI is built are:

- All research involving the participation of individuals, the use of human biological samples or personal data must be approved by the Ethics Committee for Research involving Medicines (CEIm) of the Clinical University Hospital of Valencia.
- All animal research must be approved by the Animal Experimentation Ethics Committee (CEEA) of the University of Valencia and authorized by the Competent Body, which in the case of the Valencian Community is the Ministry of Agriculture.
- All projects must comply with applicable national, regional and international legislation, and must have the necessary administrative authorizations, if required.
- The results of any research should be published once they are sufficiently contrasted, respecting the confidentiality of the subjects participating in the project until that moment.

In return for the commitment of the research staff, the Management and its scientific management bodies assume the following responsibilities:

- Ensure that the research projects meet quality criteria and adhere to the standards of this CBPI.
- Update this CBPI to adapt it to the applicable legal norms.

[1] The European Code of Conduct for Research Integrity. ALLEA - All European Academies, Berlin 2018.

• Act as a mediating body in ethical conflicts, conflict of interest or suspected research malpractice.

• Ensure the follow-up of the procedures leading to the corresponding administrative authorization, according to the nature of the research project.

• To inform the management bodies of the entities that integrate the IIS INCLIVA of the different research projects that are developed in their environment and to obtain their agreement if necessary.

• Assure your staff that the infrastructures meet the requirements and that the relevant authorizations are in place to carry out any scientific practice that is subject to specific regulations.

• Meet the requirements for the use, exposure and storage of radioactive material, genetically modified organisms and any other potentially hazardous biological agents.

2. Regulatory and legal framework for scientific practice

Research staff should be aware of and comply with the ethical, legal and safety requirements applicable to their research project(s) and ensure that the research conducted conforms to these ethical criteria.

2.1 General reference regulatory framework

- Law No. 14/2007 of July 3, 2007, on biomedical research. (Spanish Ley 14/2007 de 3 de julio, de investigación biomédica).
- Organic No. Law 3/2018, of December 5, 2018, on Personal Data Protection and the guarantee of digital rights. (Spanish Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales.
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation).
- Royal Decree No. 178/2004 approving the general regulations for the development and execution of Law No. 9/2003, which establishes the legal regime for the confined use, voluntary release and commercialization of genetically modified organisms. (Spanish Real Decreto 178/2004 por el que se aprueba el reglamento general para el desarrollo y ejecución de la Ley 9/2003 por la que se establece el régimen jurídico de la utilización confinada, liberación voluntaria y comercialización de organismos modificados genéticamente).
- Royal Decree No. 1090/2015 of December 4, 2015, which regulates clinical trials with medicinal products, the Ethics Committees for Research with medicinal products and the Spanish Registry of Clinical Studies (Spanish Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos).

- Royal Decree No. 957/2020, of November 3, regulating observational studies with medicinal products for human use. (Spanish Real Decreto 957/2020, de 3 de noviembre, por el que se regulan los estudios observacionales con medicamentos de uso humano).
- Royal Decree No. 53/2013, of February 1, establishing the basic rules applicable to the protection of animals used in experimentation and other scientific purposes, including teaching. (Spanish Real Decreto 53/2013, de 1 de febrero, por el que se establecen las normas básicas aplicables para la protección de los animales utilizados en experimentación y otros fines científicos, incluyendo la docencia).
- Decree No. 13/2007, of January 26, 2007, of the Consell, on the protection of animals used for experimentation and other scientific purposes in the Comunitat Valenciana (Decreto 13/2007, de 26 de enero, del Consell, sobre protección de los animales utilizados para experimentación y otros fines científicos en la Comunitat Valenciana).
- Directive 2010/63/EU of the European Parliament and the Council of 22 September 2010 on the protection of animals used for scientific purposes.
- Order ECC/566/2015, of March 20, establishing the training requirements to be met by personnel handling animals used, bred or supplied for experimental and other scientific purposes, including teaching. (Spanish Orden ECC/566/2015, de 20 de marzo, por la que se establecen los requisitos de capacitación que debe cumplir el personal que maneje animales utilizados, criados o suministrados con fines de experimentación y otros fines científicos, incluyendo la docencia).
- Communication from the commission to the European parliament, the council, the European economic and social committee and the committee of the regions a digital single market strategy for Europe.
- Council Regulation on the Community patent.
- Community Design and Community Trademark Regulations (Reglamentos de Diseño Comunitario y Marca Comunitaria).
- Community Directives on copyright and intellectual property, legal protection of databases and computer programs.
- Directive on the legal protection of biotechnological inventions.
- Law No. 24/2015, of July 24, 2015, on patents. (Spanish Ley de 24/2015, de 24 de julio, de patentes).
- Law No. 14/2011, of June 1, 2011, on science, technology and innovation. (Spanish Ley 14/2011, de 1 de junio, de la ciencia, la tecnología y la innovación).
- Law No. 2/2011, of March 4, 2011, on Sustainable Economy (Ley 2/2011, de 4 de marzo, de economía sostenible).
- Law No. 21/2014, of November 4, 2014, which amends the consolidated text of the Intellectual Property Law, approved by Royal Legislative Decree No. 1/1996, of April 12, 1996, and Law No. 1/2000, of January 7, 2000, on Civil April, and Law No. 1/2000, of January 7, of Civil Procedure. (Spanish Ley 21/2014, de 4 de noviembre, por la que se modifica el texto refundido de la Ley de Propiedad Intelectual, aprobado por Real Decreto Legislativo 1/1996, de 12 de abril, y la Ley 1/2000, de 7 de enero, de Enjuiciamiento Civil).
- Royal Decree No. 1716/2011, of November 18, establishing 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 Registry of Biobanks for biomedical research. (Spanish Real Decreto 1716/2011, de

18 de noviembre, por el que se establecen los requisitos básicos de autorización y funcionamiento de los biobancos con fines de investigación biomédica y del tratamiento de las muestras biológicas de origen humano, y se regula el funcionamiento y organización del Registro Nacional de Biobancos para investigación biomédica).

- Law No. 41/2002, of November 14, 2002, basic law regulating the autonomy of the patient rights and obligations regarding clinical information and documentation. (Spanish Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica).
- Order ECC14042013 modifying the annex of RD171616/2011- Collections. (Spanish Orden ECC14042013 por la que se modifica el anexo del RD1716/2011- Colecciones)
- Code of Good Practices applicable to biomedical research biobanks in Spain (Red Biobancos, ISCIII, May 2012).
- Answers to the most common questions about Spanish Royal Decree 1716/2011 on biobanks (version November 15, 2012, ISCIII): http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/fd-organizacion/fd-estructura-directiva/fd-subdireccion-general-investigacion-terapia-celular-medicina-regenerativa/fd-centros-unidades/Preguntas-y-respuestas-RD-1716-10- 10-2012.pdf.
- INCLIVA Innovation Guidelines.

2.2 Regulatory framework specific to scientific activity

Research involving human subjects

Any research project directly involves the participation of people, that is based on any information or uses biological samples obtained from people must comply with the provisions of Spanish Law No. 14/2007 of July 3, 2007, on biomedical research. With special diligence in everything related to information on the purpose, inconveniences and possible risks and benefits of the research, obtaining the express, specific and written consent of the participants, as well as the confidentiality of the data, samples and results obtained.

All research projects carried out at the Valencia Clinic-Malvarrossa Health Department must be evaluated by the Research Ethics Committe for Research with Medicines (CEIm), when patients are involved. In compliance with the regulations dictated in the Spanish Organic Law No. 3/2018 of December 5 on Protection of Personal Data and Guarantee of Digital Rights, Spanish Law No. 14/2007 on biomedical research and Royal Decree No. 1716/2011 on Biobanks. The requirements, as well as the necessary documentation are available at https://www.incliva.es/requisitos.

Depending on the design of the study, the applicable legislation must be taken into consideration, in that sense, when Clinical Trials with Medicines must be applied the Royal Decree No. 1090/2015 of December 4, which regulates clinical trials with medicines, the Ethics Committees for Research with medicines and the Spanish Register of Clinical Studies. For Post-Authorization Observational Studies, it should be governed by the Spanish Royal Decree No. 957/2020, of November 3, which regulates observational studies with drugs for human use.

Research for genetic purposes

Any research project involving the collection, processing and/or conversation of biological samples for genetic analysis shall comply with specific provisions of the aforementioned Spanish law No. 14/2007

on Biomedical Research. Whenever the biological samples are intended to be used for a purpose other than foreseen at the time of donation, a new consent must be requested again.

Research with human embryonic material

Any research project involving the procurement, processing and/or conservation of biological material of human embryonic origin or functionally similar cells must be request a report from the Commission of Guarantees for the Donation and Use of Human Cells and Tissues[2], attached to the Carlos III Health Institute. Previously, it must also have the approval of the Ethical Committee on Animal Experimentation (CEEA).

Assurance of harm for interventions in human beings

In accordance with the article 18 of the Spanish Biomedical Research Law, on compensation for damages and their assurance, if the project involves the performance of any intervention on human beings (monitoring, stress or imaging tests, express sample taking, etc.), prior insurance for the corresponding damages must be provided.

Research with biological samples of human origin

All samples used for research must have express consent for the research or line of research as provided for in the Spanish Biomedical Research Law. The consent requested for diagnostic tests does not allow the use of the sample for research. An express informed for research is required (the two consents can be requested at the same time in a single document, but with separated signatures to allow the donor to decide whether he/she consents only for the diagnostic use of his/her samples or, in addition, for their use in research).

According to Spanish Royal Decree 1716/2011 (Article 23.4), the document containing the consent of the source subject for the collection and use of his/her biological samples for biomedical research purposes shall be issued in the three copies. One of these will be given to the source subject, another will be kept at the centre where the sample was obtained and the third will be kept by the biobank, or by the person responsible for the collection or research, as appropriate.

Storage of biological samples for research purposes: biobanks, collections and project samples

Biological samples of human origin for use in biomedical research may be stored in a biobank or kept for use in a specific research project or as a collection for research purposes outside the organizational scope of a biobank. (article 22 of Spanish Royal Decree 1716/2011).

A biobank is defined as an establishment that houses one or more collections of biological samples of human origin for biomedical research purposes, organized as a technical unit with criteria of quality, order and destination. Informed consent for the donation of samples to a biobank is open, so that samples can be used for any biomedical research project that has been positively evaluated by a scientific committee and by an ethical committee. The IIS INCLIVA has a Biobank authorised by the General Direction of Management, Evaluation, Research, Quality and Patient Care of the Department of Health, Generalitat Valenciana and registered in the National Register of Biobanks (nº B.0000768).

[2] http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/fd-organizacion/fd-estructura-directiva/fd-subdireccion-general-investigacion-terapia-celular-medicina-regenerativa/fd-comites/comision-de-garantias.shtml

INCLIVA Biobank is part of the Valencian Biobank Network, as well as the National Biobank Network Platform.

A collection is an ordered and permanent set of biological samples of human origin preserved outside the organizational scope of a biobank, intended for biomedical research. The collection samples require a research line consent, where the team and centre/s where the projects are to be carried out are determined, and the samples cannot be used or transferred beyond what was foreseen in the initial consent (unless new consent is obtained). There must be a person in charge of the collection (natural person) who must register the collection in the National Registry of the ISCIII (collections section).

Samples retained for use in a specific project require a specific project consent that specifies the team, facility, duration, etc. Samples may only be used in that specific project and may not be transferred to third parties, except with the new consent of the source subject.

Samples taken prior to the Spanish biomedical research law may only be used in accordance with the second transitional provision of Spanish law No. 14/2007.

All informed consent documents must state the destination of the samples, which may be destruction of the sample, anonymization or free incorporation into a collection or biobank (registered in the National Register of the ISCIII), for which the specific consent of the subject will be required. (article 27, Spanish RD 1716/2011).

In the case of samples intended exclusively for research purposes, they shall be kept only as long as they are necessary for the purposes for which they were collected. Therefore, if the samples are for a specific project, limited in time, the samples and data must be destroyed at the end of the project (unless new consent is obtained for a different use: collection, biobank or new project). Storage in collections or biobanks could be indefinite. In any case, the source subject will retain the right to revoke consent at any time, and the sample would have to be destroyed immediately.

Research with animals

All research procedures involving animal research must comply with the guidelines established in the specific European, national and regional regulations. Specifically, the provisions of Spanish Royal Decree 53/2013, of February 1, establishing the basic rules applicable to the protection of animals used in experimentation and other scientific purposes, including teaching, as well as those detailed in Decree 13/2007, of January 26, of the Valencian Consell, on the protection of animals used for experimentation and other scientific purposes in the Valencian Community. It must always have the approval of the Ethical Committee for Animal Experimentation (CEEA) and be authorized by the Competent Body, which in the case of the Valencian Community, is the Ministry of Agriculture.

Research with genetically modified organisms

Any research procedure involving research with genetically modified organisms must comply with Spanish RD 178/2004. Approving the general regulations for the development and implementation of the Spanish Law No. 9/2003 establishing the legal regime for the contained use, voluntary release and commercialization of genetically modified organisms.

Interferences between the care process and research activity

When the development of the project involves patients from any of the healthcare institutions dependent on the Valencia Clinic-Malvarrosa Health Department, the research staff must inform those responsible for the healthcare process of the nature and type of the project or clinical study in which the patient is included, leaving a record of the same in the patient's clinical record.

In the event of a conflict that may distort the proper development of the care process, the corresponding Committees will be in charge of determining the final solution in each case, after evaluating all the reasonable elements of judgment available.

2.3 Protection of personal data and confidentiality guarantees

Any research project that involves the use of data that can be linked to individuals must guarantee the protection of privacy and respect for the rights and freedoms of the participants and must comply with the regulations in force, in particular the General Data Protection Regulation 2016/679 (GDPR) and the Spanish Organic Law No. 3/2018 of December 5, 2018, on Personal Data Protection and guarantee of digital rights, as well as the provisions of the Spanish Law No. 14/2007 on biomedical research.

For this purpose, INCLIVA has an institutional policy of data protection and information security, which is available at the following website https://www.incliva.es/normativa-interna

Every project should consider from its design (preparation of the protocol and other guiding documents), the flow of data from its collection to its final disposition.

Part of the good practices applied to personal data is to implement security measures relevant to the project, among which the following can be found:

1. Data location. Any file or digital database that is generated with personal data, as long as it allows the execution of the project, must remain in the environment of the computer infrastructure of the HCUV or the IIS INCLIVA, to benefit from the security measures that these networks have. If it is decided that the location of the data should be different, only a location with security measures appropriate to the type of data for the project should be selected.

2. Duty of secrecy. Any person who, in the exercise of his/her duties in connection with medical care and/or biomedical research, regardless of the scope of both, and who has access to personal data, will be subject to the duty of secrecy, which will persist even after the research or action has ceased, according to the provisions of article 5 of the Spanish Law No. 14/2007 on biomedical research.

3. Confidentiality commitments. Any person with access to personal data must have a confidentiality commitment that, in the case of staff with employment contracts linked to the HCUV and IIS INCLIVA, is found in their employment contracts.

4. Physical media. Personal data on physical media, such as informed consents that people have signed, or questionnaires, for example, must be guarded with security measures to prevent access by unauthorized persons. If the nature of the project makes it necessary to

move data from one site to another, an external hard drive with encryption measures should be used rather than the computer network.

5. Coding or pseudonymization. The files or databases prepared for the project should not contain any data that would allow direct identification of the individual, for example, his or her name, SIP or NIH. If there is consent and it is necessary for the execution of the project for the research team to know the identities of the participants, the data must be identified with a code whose correspondence with the identities must be kept in a different place from the personal data. If the research team should not know the identity of the participants, whoever performs the coding and custodies the correspondence of such codes must be a functional area other than the research team, as provided in the Seventeenth Additional Provision of the Spanish Organic Law No. 3/2018 on Protection of Personal Data.

In any case, it is the duty of the Principal Investigator (PI) to:

- Include in the protocol, or in a document linked to it, any instructions regarding the processing of personal data to be carried out in the different phases of the project.
- Provide the person whose data will be used, the information regarding the processing of these data indicated in Articles 13 and 14 of Regulation 2016/679 (GDPR), concerning the duty to inform. Always, in the most appropriate format and time according to the characteristics of each research project.
- To seek consent for the processing of personal data, or identify another legal basis as indicated in Article 6 of Regulation 2016/679 (GDPR) to carry out the processing of personal data.
- To inform the Data Protection Unit of INCLIVA, of the cases in which the project involves the sending of personal data outside the territory of the European Union for any reason, including the cases of sending to project partners and those of the provision of professional services related to such data.
- Not to carry out any processing of personal data prior to obtaining a favourable report from a research ethics committee.
- Apply appropriate security measures to the data collected for the project to prevent any unauthorized access or use.
- To foresee the data collection system, the research, as well as the plan for its custody and preservation, for example, in a Data Management Plan.
- Adequately conserve the records and/or research data collection notebooks for the period established by the legislation in force. The necessary means and infrastructures must be foreseen for a correct custody and conservation of the different documentation and resulting biological or chemical material. In the case of data recorded on electronic media, a specific plan for backup copies and their physical location should be included.
- Have a single record of the different data collection instruments (notebooks, databases, etc.) and of the custody of samples, access to which must be made available to third parties.
- Appropriately coding patient data and/or corresponding biological samples, when required, to maintain confidentiality and security to protect the identity of patients.
- Ensure that personal data, as well as clinical samples, are not, under any circumstances, the direct or indirect subject of commercial transactions for profit, this not being understood as the repercussion of handling, management and processing costs necessary for the project.

2.4 Good laboratory practices and personal protection

Good laboratory practices

- It is recommended that all research personnel involved in clinical research be trained in the Good Clinical Practice (GCP) guidelines, which provide international ethical and scientific quality requirements for the design, conduct and reporting of clinical studies involving human subjects.
- Non-clinical studies intended for health safety or environmental testing, the results of which are intended for submission to the competent regulatory authorities, shall be conducted according to the principles of Good Laboratory Practice.

Personal protection

- To work in the laboratory, it is necessary to follow a series of rules and recommendations regarding personal habits (prohibition of eating and smoking, keeping the workplace clean and tidy, use of personal protective equipment, etc.) as well as for handling products.
- Staff must be responsible for optimizing the use of resources as well as the correct maintenance of the equipment and material in their charge.
- Basic research uses many techniques with different physical, chemical and biological elements. There are several technical guides published by the Ministry of Labor based on Royal Decrees for work with biological or chemical agents available to anyone who requires them.
- Likewise, any person who must perform research with animal models must have the necessary training and accreditation to do so, according to Spanish order ECC 566/2015.

3. Research project report

Before initiating any research, technological development or innovation, it must be previously formulated in a written project report, indicating whether it directly involves people, research animals, material of human embryonic origin, etc.

The report must present an experimental design consistent with its objectives and must include the background, objectives, methodology, work plan and schedule, available and necessary resources, the participating team and the economic report.

Any research must be authorized by the corresponding Committees. No study may be initiated without express written approval for its development. All projects developed within the scope of INCLIVA must be formally notified through the established channels and must have the notifications and authorizations specified in the procedure for the presentation of projects.

4. Publication of research results

4.1 Criteria for publication

Commitment to scientific dissemination publication of research results is an ethical imperative. Non-publication of research results, unjustified delay or exaggeration of the importance of the results for clinical practice or health policies is considered an unacceptable practice and may constitute a serious misconduct for misuse of resources. Likewise, negative results or results that differ from expected results are an unavoidable part of the research and, therefore, their publication should be facilitated as much as possible.

INCLIVA, in line with European policies, joins the commitment to open science in the modern field of information and communication technologies. The goal for the INCLIVA Open Science Institutional Policy is to develop an open and collaborative scientific activity for the benefit of society. Open Science encompasses all aspects of the research cycle, such as open and unrestricted access to content generated by scientific research, Open Data, Open Peer Review, citizen science and open education.

Scientific integrity

Research results should not be published until they have reached a sufficient degree of scientific rigor and quality to guarantee the integrity of the work performed. The results obtained must be properly contrasted before publication.

Plagiarism and/or falsification of research results are not acceptable and are grounds for sanction. In the event of an error in a study that under- or overstates the conclusions, a correction note should be published as soon as possible.

In the case of opinion articles, it should be noted that these judgments are personal and not those of the institution.

Confidentiality and protection of research results

In accordance with the commitment to scientific integrity and without prejudice to INCLIVA's commitment to scientific dissemination, research should be kept confidential until the necessary requirements for publication are met.

Likewise, in accordance with the Spanish Law of 24/2015, of July 24, on Patents, they must keep confidential and inform INCLIVA, through its Innovation Support Unit, of all findings, discoveries and results susceptible of protection, and collaborate in the protection and transfer processes.

Content

It is unethical to submit for publication as one's owned the work done in whole or in part by another person/s (plagiarism or misappropriation), to falsify data or results of the research process and to suppress or alter information relevant to the understanding of the project or its results (scientific fraud).

Nor is it ethically acceptable to publish the same work (redundant or repeated publication) or part of the same work (partial publication) in more than one scientific journal, except when the nature of the work justifies it (in the case of a compilation review).

All scientific publications must include the name of the institution(s) where the research work has been carried out. The publication of the results should preferably be made in accredited scientific journals, and the scientific results should not be published prematurely.

Fragmented or duplicate publication

Fragmented publication of a unitary investigation is not acceptable, being justified only for reasons of length or except in the case of a legitimate need to advance findings by publishing preliminary data. Nor is it considered acceptable to include in the authorship researchers whose contribution to the results described is questionable, to increase their scientific production.

Mention to INCLIVA and ownership of the research results.

It is mandatory to mention INCLIVA's membership in any dissemination of the results. On the other hand, according to the Spanish Law of 24/2015, on Patents, the ownership of inventions made by INCLIVA's research staff corresponds to the institute.

Acknowledgements

The persons or institutions mentioned in the "acknowledgements" section of a publication have the right to decline to be mentioned, so it is necessary to inform them beforehand. Some journals require written authorization from those who are to appear in the acknowledgements.

Publications that include personal data

If it is not possible to publish the results of a research study without identifying the participants or those who provided biological samples, such results may only be published with their prior express consent.

Presentation in the media and emergency review

The presentation of results through the media should be approached from an informative language or include a part of the presentation adapted to non-specialized audiences. In this type of public presentation, the name of the authors should always be associated with that of the institution.

The communication and dissemination of research results to the media prior to their appearance in a scientific publication or patent, or even prior to peer review, would only be justified for public health reasons. In this case, the possibility of having the results reviewed as a matter of urgency in a scientific publication will be assessed, or the scope of this exceptional communication will be agreed with the editors of the publications in which they have planned their definitive publication.

4.2 Authorship, review and evaluation of scientific production

Authorship and participation in inventions

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

In the acknowledgements section, recognition may be given to those persons who participated in obtaining the resources or providing routine data. It is considered unacceptable to base authorship solely on employment or hierarchical position.

In multicentre studies involving many participants, collective authorship and the designation of an editorial committee will be accepted. In the case of establishing a nominal list of authors, the order should be established according to objective criteria.

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

In the case of inventions protectable by means of intellectual and industrial property rights, it shall be an indispensable requirement to have contributed intellectually to the obtaining of the same to be recognized as the inventor thereof.

Conditions for authorship

The conditions for authorship depend on the contribution to the research, and not on belonging to a particular profession or hierarchical position, nor on the nature of the employment relationship. To have full authorship of a publication or patent, it is necessary to have contributed substantially to the creative process (conception, design, analysis or interpretation of the data), to have participated in the preparation of the resulting communications, reports or publications, and to be able to present in detail the personal contribution to the research and to discuss the main aspects of the research as a whole.

Mere participation in obtaining resources or in data collection does not necessarily justify the condition of author, although it should be acknowledged in the acknowledgment's sections.

The content, place and time of dissemination should be mutually agreed upon by different groups and entities that have participated in the project.

Order of authorship

The order of appearance of authors in any publication derived from a research project should be a joint decision of the PI and all collaborators. However, the following rules are recommended:

- The first signatory is the person recognized by the rest of the group as having the greatest participation in the conception and development of the research and is the person who has written the first draft of the article prior to its publication.
- The last signatory must be the senior researcher who directs and/or has ultimate responsibility for the project.
- The rest of the authors can be ordered according to the importance of their contribution or in alphabetical order.
- The corresponding author has the main responsibility for the entire editorial process and future interactions resulting from the publication of the work.

Shared principal authorship

In scientific publications there is a right to justify the order of signatures in a footnote.

When two or more authors share the same effort in the development of the research, under the recognition of the rest of the group, both authors can be considered as first authors, and this should be explicitly reflected in the publication of the original. The same criteria can also be applied in the case of intermediate and senior authorship.

Peer review

The institute ensures an independent peer review of all research projects to be developed. This concept refers to any personal assignment received as a reviewer to carry out a specific evaluation, review or critique, whether in relation to a manuscript submitted for publication, a report for which an individual or collective grant is requested, a clinical or experimental protocol under review by an ethics committee or a report resulting from an on-site visit to a laboratory or centre.

During the process, reviewers will treat the information with the utmost confidentiality and will not share or use it for their own benefit. The reviews will be objective and based on scientific criteria that can be evidenced. Any invitation to participate in an expert review will be declined in the event of any existing conflict of interest.

4.3 Transparency

Curriculum vitae

In the preparation of the personal *curriculum vitae*, the author is responsible for the accuracy of its content. In this regard, you must always sign the curriculum document provided. In the case of a collective curriculum, it is sufficient that it is signed by the person responsible for the application.

As far as possible, the research personnel should edit the Standard Curriculum Vitae model provided by FECYT for the calls for grants for projects with Health Research Funds-Carlos III Institute of Health or use the CV models provided by the calling entities.

Conflicts of interest

All research staff (principal investigator or collaborator) must inform the Internal Scientific Committee in writing of any aspects that involve or may involve a conflict of interest in relation to a specific research project. A conflict of interest is a situation in which a person's actions may be influenced by a secondary interest of any kind (economic, professional, academic, political or personal). A conflict-of-interest situation does not inherently present any ethically questionable behaviour, if they are made public and do not compromise the objectivity and integrity of the design, development, interpretation, publication and evaluation of the research.

In the exchange or transfer of knowledge and technology with private entities, the public interest must always be paramount, so that agreements must be made with full transparency. In the case of research financed by for-profit entities, all agreements reached must be included in a contract or agreement expressly stating the economic, intellectual property and industrial agreements.

Such agreements should be accessible to institutions and persons with responsibility in the field, should protect intellectual freedom, avoid disproportionate confidentiality commitments or unjustified restrictions on the publication of the results obtained.

In the case of existing interest or links with the entities or companies financing specific research, INCLIVA should be informed in order not to compromise the ethical integrity of the research project in question.

5. Training

The research staff must supervise that training of young researchers and scholarship holders, encouraging their participation in training courses and scientific meetings related to the field of their research.

Scientific Seminars

The research staff will participate in the design of the Research Training Plan of INCLIVA and has the obligation to attend the seminars and scientific activities organized by INCLIVA, as well as to participate in the internal meetings organized by the research group which he/she belongs.

Tutor

Every person linked to a research group by means of a contract or grant will be assigned a tutor or responsible researcher, who will be in charge of supervising the training process.

The tutor will inform INCLIVA about the research staff in training under his/her charge. Likewise, he/she will have to set the objectives, advise and guide this staff so that the training and chronological expectations are fulfilled according to the initial purposes. For this reason, he/she commits himself/herself to:

- Supervise the tasks entrusted ensuring their fulfilment through personal and regular interaction with the trainees.
- Hold periodic meetings to discuss the progress of assigned tasks and contribute to the scientific and methodological updating of staff in training.
- Ensure the working conditions of the staff under training, as well as their adequate preparation in occupational risk prevention.
- Special care shall be taken to ensure that scientific staff in training do not become involved in tasks unrelated to their training.
- Ensure that every predoctoral researcher under his/her charge publishes at least one scientific article as first author during his/her doctoral training period.

Doctoral Thesis, Final Degree Thesis (TFG) and Final Master's Thesis (TFM)

The execution, reading and publication of a doctoral thesis elaborated in INCLIVA is subject to the criteria contained in this CBPI. The research protocols must comply with the current legislation already mentioned in previous sections (2.1 and 2.2) and must be submitted to the corresponding committees before submitting the scientific work.

The thesis or TFM manuscript should state expressly and in detail the name of the thesis supervisor, the centre attached to INCLIVA where it has been carried out and the committees that authorized the protocols and the presentation.

6. Treatment of waste, data and material resulting from research

Waste treatment and disposal

The norms established in the respective specific plans of the different assigned centres must be complied with regarding the storage, treatment, collection and disposal of waste generated because of the research carried out, with the objective of guaranteeing the conservation of the environment and the protection of people.

Storage and custody of documentation

INCLIVA guarantees the protection of the personal privacy and the confidential treatment of the personal data resulting from the research activity, according to the current regulations. The same guarantees are applicable to the biological samples that represent a source of personal information with special consideration to the following:

- The PI must guarantee the correct custody and conservation of the data and biological or chemical material resulting from the research, during the legally established period for each type of project. In case personal data are collected, it is the PI's responsibility to ensure compliance with current regulations, based on the established procedures.
- Any research protocol should consider standard procedures for data and biological or chemical material collection, recording, custody and preservation, to ensure consistent and accurate data. Any intermediate or final data must correspond to the original documents.
- A specific protocol for storing and accessing computerized data must be established to ensure its security, as well as its traceability (control of changes and who makes them), so that a retrospective audit can be carried out if necessary.
- Copies of the most relevant software used will be kept being able to retrieve the original data in the future if necessary.
- The convenience of incorporating the biological samples derived from the research to the INCLIVA Biobank or that they are collected from the beginning in biobank regime must be assessed. For this provision, the approval of those responsible for the Biobank must be obtained prior to the collection of the samples.
- If the biological samples collected are intended to be stored for future research outside the organizational scope of a biobank, the PI, in compliance with Spanish RD1716/2011, must constitute a collection of biological samples and register it in the National Biobank Registry. The information and informed consent document must contain all the relevant aspects mentioned in Spanish RD 1716/2011 for these cases.