Code of Good Practice in Research

MA-GNR-02

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IDIVAL

CODE OF GOOD PRACTICE IN RESEARCH (CGPR)

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Note: This CGPR is an Adaptation to the Code of Good Scientific Practice and Research Integrity Committee of the Carlos III Health Institute.

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1. INTRODUCTION

Today, scientific development is a significant activity driving economic and industrial improvement in developed countries, alongside the emergence of a "scientific career", a profession whose characteristics distinguish it from other activities. The need for scientists to accredit their research capacity with scientific publications or patents, together with the search for fame or profit, can lead to various types of scientific fraud relating to the misrepresentation of published data, the ownership of discoveries, authorship of publications, training of scientists or relationships with private companies.

Various ethical issues affect this activity directly. For this reason, intergovernmental institutions responsible for ethics in science, such as the Council of Europe, UNESCO, the World Medical Association, and the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, have developed major collective agreements for biomedical research and drafted standards or recommendations that address the ethical dilemmas arising with scientific developments. The Declaration of Helsinki is the basic document all biomedical researchers must take on board.

Other academic ethical aspects in scientific practice have been addressed in standards accepted by the scientific community, such as peer review and the Vancouver rules on the authorship of publications. Ownership of discoveries is regulated in the legislation of each country.

To ensure compliance with existing ethical and legal standards, research institutions must set up independent *ad hoc* committees. Thus, DIAL has established the IDEAL Internal Council (to advise on research conducted at the institution), the Clinical Research Ethics Committee (focused on aspects of research with humans), and the University of Cantabria Research Ethics Committee. These committees ensure the quality and rigour of scientific practice at the institutions; therefore agencies responsible for funding research, as well as assessing the scientific quality of the research proposed, require suitability reports by the relevant committees before deciding to fund a research project.

The last link in the guarantees that ensure ethically acceptable research is the personal commitment of researchers not to engage in unfair practices, falsify results or misrepresent the authorship of research. In recent years, research institutions have developed what are known as "Codes of Good Scientific Practice", which include guidelines on various ethical aspects that must be followed by the institution's management and researchers.

Article 12 f) of Law 14/2007, of 3 July, on Biomedical Research, indicates that one of the duties of Research Ethics Committees of centres conducting biomedical research is to develop codes of good practice in line with the principles established by the Spanish Bioethics Committee, as well as to manage disputes and proceedings arising from non-compliance.

To complete a structure meeting the need to guarantee ethically correct research, this document establishes a CGPR designed as a collective instrument for self-regulation to favour scientific practice.

IDIVAL is committed to the current CGPR as an adaptation of the Code of Scientific Practice and Research Integrity Committee developed by the Carlos III Health Institute, the entity which defines the model of Healthcare Research Institutes in Spain, which sets out some of the essential overall aspects of the organisational structure of these institutes in general, and IDIVAL in particular.

2. PURPOSE

To establish an ethical behaviour code for IDIVAL personnel, both inhouse and associated, setting guidelines to avoid conflicts in order to not engage in unfair practices or falsify results, and to guarantee that the authorship of publications and ownership of discoveries in respected.

3. AREAS INVOLVED and SCOPE

The content of this document affects the development and management of projects, research agreements, and contracts for researchers, interns or research support staff.

Its scope covers all healthcare in Cantabria, and specifically IDIVAL inhouse and associated personnel.

4. RESPONSIBILITIES IN SCIENTIFIC PRACTICE

4.1. Responsibilities of the Institute

IDIVAL Management must ensure its personnel that its infrastructure complies with requirements and that it has the relevant authorisations to conduct any scientific practice subject to specific regulations. In addition to processes that regulate scientific research in humans, human samples or data, experimental animals or material of human embryonic origin, IDIVAL will meets the requirements for the use, display and storage of radioactive material, genetically modified organisms and any other potentially hazardous biological agent.

4.2. Research in humans

Any research protocol that directly involves the participation of individuals or is based on any biological information or samples obtained from individuals must comply with the provisions of Law 14/2007 of 3 July, on biomedical research, particularly regarding having the informed consent of participating subjects (both healthy and ill), and submitting to the approval of the University of Cantabria Bioethics Committee when activities require experimenting with animals or using biological agents or genetically modified organisms. Particular care must be taken in relation to information on the purpose, inconveniences and possible risks and benefits

of the research; obtaining express, specific and written consent from participants; and the confidentiality of data, samples and results obtained.

4.3. Research for genetic purposes

Any research protocol that involves collecting, processing and/or conserving biological samples for genetic analysis will comply with the provisions of the Biomedical Research Act; specifically, the patient must be informed of the data arising from the project. Whenever biological samples are to be used for purposes other than those foreseen at the time of donation, consent must be obtained again.

4.4. Research with embryo material

Any research protocol that involves collecting, processing and/or conserving human embryo material or functionally similar cells must request a report from the Guarantees Committee for the donation and use of human cells and tissue according to the Biomedical Research Act.

4.5. Personal data protection and confidentiality guarantees

Any research protocol that involves using institutional computer files or preparing databases with information on individuals must guarantee the anonymity of participants and must comply with current regulations, especially Organic Law 15/1999, of 13 December, on data protection and its implementing regulations, as well as the applicable provisions of the Biomedical Research Act.

Regarding the right to confidentiality, Article 5 of Law 14/2007, of 3 July, on Biomedical Research will apply; it states that any individual who accesses personal data in the exercise of their duties relating to a medical-healthcare action and/or biomedical research, regardless of their scope, will be subject to the duty of secrecy. This duty will persist after completion of the research or action.

4.6. Insurance for interventions in humans

If the project involves any intervention in humans (monitoring, stress or image tests, express sampling), pursuant to Article 18 of the Biomedical Research Act on compensation for damage and insurance, insurance for the relevant damage must be provided.

4.7. Research with human biological samples

Pursuant to the Biomedical Research Act, all samples (from patients, relatives, or controls) used for research must have express consent for the research or line of research. Consent requested for diagnostic testing does not allow the use of samples for research. Express informed consent must be obtained for research (both consents may be requested at the same time on a single document).

4.8. Storage of biological samples for research purposes

If samples are to be stored for subsequent research, express informed consent must be requested for storage, as well as consent for the project or line of research. Samples collected after the Biomedical Research Act may only be used according to temporary provision two of this act.

4.9. Research with experimental animals

Any research procedure that involves experimenting with animals must comply with RD 1201/2005, of 10 October, on the protection of animals used for experiments and other scientific purposes.

4.10. Research with genetically modified organisms

Any research procedure that involves experimenting with genetically modified organisms must comply with RD 178/2004, of 30 January, approving the general regulation for the development and implementation of Law 9/2003, of 25 April, establishing the legal system for the confined use, voluntary release and marketing of genetically modified organisms.

5. RELATIONSHIPS BETWEEN WORKING GROUP MEMBERS

5.1. Supervision of research trainees

Trainees completing doctoral studies are governed by Royal Decree 63/2006, of 27 January, approving the research trainee statute. The following aspects will also be taken into account for this type of trainees at the Institute:

5.2. Tutor assignment

Anyone associated with any of the centres by means of a contract or scholarship to acquire training will be assigned a tutor.

5.3. Tutor's responsibilities

The tutor is the person responsible for setting objectives and overseeing the educational process of the trainee. They advise and guide trainees to meet their training expectations according to the initial goals and within the average set timeline. They must provide the trainee with the best possible conditions for their future scientific career.

5.4. Limits in the number of individuals assigned to a single tutor

The total number of trainees assigned to a single tutor must be appropriate and compatible with the scope of their obligations and commitments.

5.5. Rights and obligations of research trainees

Research trainees have different rights and obligations to other individuals contracted by the centre. The tutor must be particularly diligent with scientific trainees so that they are not involved in tasks unrelated to their training.

5.6. Tutor's obligations

The specific obligations of the tutor are:

a) to maintain regular, personal contact with trainees assigned to them to supervise the assigned tasks and ensure compliance,

b) encourage regular group meetings to discuss progress in the assigned tasks and contribute to the scientific and methodological advancement of trainees,

c) check the working conditions of trainees are suitable and that they have been suitably trained in occupational risk prevention,

d) keep trainees up-to-date with legal regulations affecting scientific practice.

5.7. Monitoring research trainees.

If trainees or a tutor wishes to request a change in their training programme conditions (change of subject, tutor or centre), they must contact the committee and submit a written document detailing the causes for the request.

The Internal Council may be consulted in the event of disputes between trainees and other Institute personnel.

5.8. Other personnel participating in research projects

IDIVAL hires various categories of personnel and specialists to implement research projects and/or agreements; these include: administrative personnel, laboratory technicians, graduates, PhDs (post-doctoral contracts) who are no longer considered in training.

Legal relationships can also be established which involve the presence of personnel from external institutions working at IDIVAL facilities and on IDIVAL projects, for example, CIBER, academic or private institutions, etc. This code of good practice is also applicable in all these cases.

6. PREPARATION OF RESEARCH PROTOCOLS

6.1. Regulations that must be taken into account for drafting a project

All research projects must have been formulated in a written protocol prior to starting. The protocol text generally matches the report needed to obtain funding, and the following regulations must be taken into account when drafting the document:

When the research involves using humans, human samples or human data, researchers must comply with current legislation, particularly Law 14/2007, of 3 July, on Biomedical Research, and Organic Law 15/1999, of 13 December, on data protection. If research animals are to be used it must comply with Royal Decree 1201/2005, of 10 October, on the protection of animals used for animal experimentation and other scientific purposes. If genetically modified organisms are to be used it must comply with Royal Decree 178/2004, of 30 January, approving the general regulation for the development and implementation of Law 9/2003, of 25 April, establishing the legal system for the confined use, voluntary release and marketing of genetically modified organisms.

Based on these regulations, IDIVAL has the following Committees to review research protocols:

- If the protocol directly involves people or human material or data, the text must have been independently reviewed by the Clinical Research Ethics Committee of Cantabria.

- If the protocol directly involves animals, the text must have been independently reviewed by the University of Cantabria Bioethics Committee.

- For submission to public calls, projects are also supervised by the IDIVAL Internal Scientific Council.

6.2. Extension or modification of a research protocol

Developing an additional or unforeseen research question will require the relevant complementary protocol to be written before implementation. If the new question so requires, the protocol must follow the established authorisation and external supervision procedures. This is essential when research directly involves individuals, experimental animals or human embryo material, and when there are changes in the primary research objectives.

6.3. Rejection of secret research

Under no circumstances must secrecy of a research protocol or part thereof be accepted. Nevertheless, for reasons of competitiveness and confidentiality, it may be appropriate to temporarily restrict the distribution of certain protocols or parts thereof.

6.4. Exceptionally urgent research

When public security or health require a research project to begin immediately, especially when involving individuals or experimental animals, the commencement of activities must also be backed by a protocol of action, although it may be simplified. Simplified or urgent protocols, whenever possible, must also be reviewed by the relevant Committees and processed according to the procedure required for regular protocols.

6.5. Use of external facilities or equipment

Any research protocol that involves the use of inhouse or external healthcare facilities or equipment, or any research facility or equipment that is not exclusively for inhouse use, will require prior approval from the head of the institution, centre, facility or equipment to be used. The use of external centre facilities or special shared facilities must have a favourable report from the IDIVAL Internal Council. The use of IDIVAL facilities by external personnel, even if they are associated with collaboration projects, must also have the relevant authorisations.

6.6. Collaboration projects

When a research project foresees the participation of different groups from the same centre or different centres of the organisation, compliance with requirements in the above sections must be guaranteed.

7. CONSERVATION OF RECORDS, DATA AND SAMPLES

7.1. Data collection and conservation plan

All research protocols must set forth a system for collecting data, records and biological or chemical material resulting from the research, as well as a plan for their safeguarding and conservation. If the protocol includes the use of humans, human samples or human identification data, the data protection plan must be designed pursuant to Organic Law 15/1999, of 13 December, on data protection. There must also be a plan to collect informed consent, when appropriate, and guarantee the confidentiality of results obtained with human samples, in accordance with Article 5 of the Biomedical Research Act.

If files are created with databases containing personal data, they must be registered with the data protection agency through IDIVAL management.

7.2. Record of data and rectifications

All data resulting from research experiments or observations must be recorded without exception. This information must be permanently recorded in databases, log books or any other relevant format, and in conditions to be reviewed by third parties. Records will also include changes, errors, and negative, unexpected or conflicting results, as well as the person completing or observing them. The equipment and procedures used will also be recorded.

7.3. Conservation of data collected

The necessary resources and infrastructure must be planned for the correct safeguarding and conservation of the resulting documentation and biological or chemical material. In the case of data recorded on electronic media, include a specific backup and physical location plan for them.

7.4. Safeguarding and access to data collected

Any member of the research team must be able to access information on the data obtained and their interpretation. The project leader will have a single record of the different instruments to collect data (notebooks, databases, etc.) and safeguard samples; this record must be available to third parties. The transfer of third party personal data will be governed by the provisions of the Data Protection Act and the Biomedical Research Act.

7.5. Ownership of data

All primary documentation (data collection notebooks, databases, etc.) and the biological or chemical material obtained during a research project is owned by the centre with which the project leader is associated. They will be recorded, stored and safeguarded according to the criteria and responsibility of the project leader. In the event of a change of institution, and whenever necessary, the project leader may provide a photocopy of part or all of the log books, copy of existing electronic information, photocopy of data collection notebooks or aliquots of the biological or chemical material available to new centre. When the change affects the project leader, this process will be conducted under the responsibility and supervision of centre management.

7.6. Data and samples shared with third parties

The data and materials resulting from research must be public and in conditions to be shared with third parties, except in the cases where restrictions have been established due to possible future marketing. Transfers require prior knowledge of the desired use of the applicant, knowledge of the request by the research team, a transfer protocol approved by the research leader, and the applicant must be willing to bear any production or shipping costs. Transfers may be limited due to availability, competitiveness or confidentiality. Material or data obtained from individuals must be used according to the Data Protection Act. Thus, the information will be used in a way that prevents the identification of the source subjects, otherwise specific consent for the transfer will be required from the donors. In any case, the transfer must comply with the Biomedical Act and have a favourable report from the Clinical Research Ethics Committee.

7.7. Data retention period

All primary and original information stored as a result of any research project must be kept for at least five years from the first publication of results, except cases in which the law permits shorter periods or requires longer periods. If the centre permits, information may be stored for longer periods and their destination will require approval from the project leader.

7.8. Conservation of human samples

According to Article 61 of the Biomedical Research Act, if a sample is conserved, the source subject will be informed in writing of the conservation conditions, objectives, future uses, transfer to third parties and conditions for removing them or requesting their destruction. However, biological samples used in biomedical research will only be conserved if they are necessary for the purposes for which they were collected, unless the source subject has granted explicit consent for other subsequent uses. The above provisions are applicable provided the identification data of the samples have not been anonymised.

8. PUBLICATION STANDARDS

8.1. Unpublished results

The non-publication or excessive delay of research results may be considered a serious breach due to misappropriation of resources. The publication of clinical study results in which individuals have participated is an ethical imperative.

8.2. Publications including personal data

If research results cannot be published without identifying the individuals participating or contributing biological samples, the results may only be published with the prior, express consent of the source subjects.

8.3. Negative results

In clinical studies and certain epidemiological studies, negative results or results different to the expectations foreseen in the research project must equally be published.

8.4. Fragmented publication

Fragmented publication of a unitary research project is not acceptable. Fragmentation can only be justified by the size of the project.

8.5. Repeated publication

Duplicated or redundant publication is an unacceptable practice. Secondary publication is only justified in the terms established in the Vancouver Group Rules (see criteria on “Acceptable secondary publication” in Uniform Requirements for Manuscripts Submitted to Biomedical

Journals: Writing and Editing for Biomedical Publication, Updated December 2016 International Committee of Medical Journal Editors, http://www.icmje.org/)

8.6. Bibliographical references to third parties

In publications and patent or utility model files, reference to all work directly related to the research project must be included, and unjustified or honorary references avoided. References to third party work must sufficiently recognise their merit.

8.7. Acknowledgements

The "Acknowledgements" section of a publication must be strict. The individuals or institutions mentioned are entitled to decline their mention. Some journals require written authorisation from the individuals included in the acknowledgements. The same practice is applicable to mentions referred to as "personal communication".

8.8. Institutional credits and grants

Communications to conferences and other type of presentations prior to the final publication of results must explicitly state:

- The institutions or centres to which the authors belonged or belong, and where the research was conducted;

- The independent ethical committees that supervised the research protocol, as well as the specific permits obtained, where applicable;

- Details of the subsidies, grants or economic sponsorships received.

8.9. Presentation in the media

Results presented in the media must always include an informational explanation or a part of the presentation adapted to non-specialised audiences. In this type of public presentations, the name of the authors must always be associated with their institutions and, whenever possible, the subsidies and grants received will be mentioned. Communicating and disseminating research results to the press prior to their peer review, i.e., before they are accepted for publication or presented at certain types of conferences, is unacceptable.

8.10. Urgent presentation

The prior or premature dissemination or publication of results may only be justified exceptionally due to reasons of public health. In these cases, the authors must ensure that the results will be reviewed in parallel and urgently by a scientific publisher. Furthermore, the publishers of journals where the definitive results are to be published must be informed regarding the scope of the prior communication.

8.11. Use of publications for assessment purposes

In personal or group assessments that analyse scientific publications for the purposes of promotion or any type of reward, the assessment will always be based on the quality and potential relevance of the scientific output, and not merely on number.

9. AUTHORSHIP OF SCIENTIFIC PAPERS, PUBLICATIONS AND THESES

9.1. Peer Review

9.1.1. Concept of peer review. This includes any personal assignment received as an expert or similar to conduct a specific assessment, examination or critique, either in relation to a manuscript sent for publications, a report for which an individual or group grant is requested, a clinical or experimental protocol subject to examination by an ethical committee, or a report resulting from an onsite visit to a laboratory or centre.

9.1.2. Conflicts of interest. Reviews must be objective, in other words, based on scientific criteria and not on personal opinions or ideas. A review must be rejected if there are conflicts of interest (e.g., when there is direct association or competition with the authors) or the person invited is not considered sufficiently prepared for the review.

9.1.3. Use and destination of documentation for assessment. Reports and written documents subject to review are confidential and privileged information. Therefore, this documentation: a) may not be used to benefit the reviewer until the information has been published, b) may not be shared with any other colleague if not for specific reasons and without explicit permission from the publisher or research agency, and c) may not be stored or copied unless permitted by the individuals responsible for the publishing process or by the agency. Material is usually destroyed or returned after the process.

9.2. Conditions for authorship

Conditions for authorship do not depend on belonging to a profession or specific hierarchical position nor to the labour relationship, but to the type of contribution to the research.

To hold full authorship of a publication or patent requires: a) having substantially contributed to the creative process, i.e., to its conception and design, or to the analysis and interpretation of the data, b) having contributed to preparing the resulting communications, reports or publications, and c) being able to present details of the personal contribution to the research and debate the main aspects of the research project as a whole. Authors must accept in writing the final draft of original manuscripts processed for recording or publication.

9.3. Individuals who provide data, cases or samples

Merely participating in obtaining resources or collecting data, for example, supplying routine data or providing experimental subjects or samples, does not necessarily justify the status of

author, even when this must be recognised in the acknowledgements. Research projects that will use samples, analysis or opinions from third parties should previously establish a communication and authorship plan, taking into account the potential intellectual contribution to the project and any other factor relating to authorship rights.

9.4. Partial authors

When a publication has an author who cannot assume responsibility for the full content, their specific contribution will be identified separately, except when this issue is already regulated by publishing rules.

9.5. Honorary or ghost authors

An individual associated with the research group who, due to their hierarchical position or labour relationship, requests mention as an ex officio author, is infringing academic freedom and committing an act of injustice, if not abuse of authority. Inversely, omitting the name of any individual who has made proven contributions according to the criteria expressed above is an act of misappropriation of intellectual property by the other authors.

9.6. Inclusion of authorship in reports

The publication of reports, working or technical reports or any other written document aimed at third parties must always include a list of research authors, the centre or centres they depend on and subsidies received, in the same terms as if it were a scientific publication or patent.

9.7. Order of authorship

As a general rule, the order of signing of authors in scientific publications will be as follows: a) the first author is the person who has made the most significant effort in the research and has prepared the first draft of the article, b) the senior researcher who directs and/or is ultimately responsible for the research protocol will be last, and c) other authors may appear by order of importance and, depending on the case, alphabetical order. The author who takes charge of correspondence is primarily responsible for the publishing process as well as future interactions arising from the publication of the work.

9.8. Shared primary authorship

Scientific publications offer the right to justify the order in which authors sign the paper. Some journals request this as a condition for publication. When two or more authors have dedicated the same effort to a paper and shared the main work of preparing the manuscript they will all be considered first author. This will be explicit in the publication. The same criteria can also be applied in the case of intermediate and senior authorship.

9.9. Curriculum vitae

In drafting personal curriculum vitae, the author is responsible for the accuracy of the content. They must always sign the document provided. Group curricula need only be signed by the person responsible for the application.

9.10. Doctoral theses

The development, reading and publication of a doctoral thesis written at IDIVAL is subject to the criteria developed in this Code of Good Research Practice. Research protocols must comply with current legislation, and specifically:

- Be subject to a report by the relevant Committees before starting any scientific work.

- The Thesis manuscript must expressly indicate details of the Thesis Director, IDIVAL Group in which it was developed, and the Committees authorising the protocols and presentation.

- Data and records prepared while drafting the thesis must comply with the provisions of the relevant section of this Code on record format and ownership of data.

- Publications arising from the doctoral thesis will comply with the drafting and authorship requirements detailed in the relevant sections of this document.

10. PROTECTION OF PROPERTY

10.1. Protection of results with possible commercial interest

If the results obtained by a research project may lead to inventions or applications that may be subject to protection for their commercial interest, the project leader must notify centre management. From this moment a patent may be processed through the Research Results Transfer Office according to Law 24/2015, of 24 July, on Patents.

10.2. Industrial property rights

When research personnel participating in a project promoted by industry essentially contribute to design and implementation, agreements will be established with the promoter entity to share the relevant industrial and intellectual property rights. In any case, the provisions of Law 24/2015, of 24 July, on Patents must be upheld.

10.3. Intellectual property rights

When the research group offers a technical services or research personnel take part exclusively in collecting data for a protocol developed by third parties, the conditions for communicating and publishing the results obtained will be established in agreement with the promoter entity, always taking into account the precepts established in the rules on “authorship of scientific work” in this document.

11. RELATIONSHIPS WITH COMPANIES

11.1. Relations with entities external to IDIVAL

Any collaboration relationship with another entity must be formalised by an agreement between the parties.

11.2. Transparency and primacy of interests

Public interest must always take precedence in the exchange or transfer of knowledge and technology with private entities, thus agreements must be reached with full transparency. Furthermore, IDIVAL will set the necessary limits to protect the intellectual freedom of research personnel, avoid disproportionate confidentiality commitments or unjustified restrictions in the publication of the results obtained.

11.3. Protocol of technical and financial considerations

All resolutions adopted between the sponsoring entity and IDIVAL on which the research leader or leaders depend will be included in the relevant agreement or contract. The agreement must include all aspects of the technical and financial considerations directly or indirectly related to the research. These pacts will be accessible to the bodies, committees and individuals responsible for the agreed issue.

12. UPDATE OF THE CODE OF GOOD SCIENTIFIC PRACTICE

The IDIVAL Internal Council will ensure that the content of the Code of Good Scientific Practice is regularly analysed and discussed in graduate studies or activities conducted by scientific trainees associated with IDIVAL.

13. REFERENCE REGULATIONS

13.1 Research in humans

- Royal Decree 1716/2011, of 18 November, establishing the basic authorisation and operation requirements for biobanks with biomedical research purposes and on the treatment of human biological samples, and regulating the operation and organisation of the National Biobank Register for biomedical research
- Order ECC/1404/2013, of 28 June, amending the appendix to Royal Decree 1716/2011, of 18 November, establishing the basic authorisation and operation requirements for biobanks with biomedical research purposes and on the treatment of human biological samples, and regulating the operation and organisation of the National Biobank Register for biomedical research
- Law 14/2007, of 3 June, on Biomedical Research

— Law 14/2006, of 26 May, on assisted human reproduction techniques

— Royal Decree 1301/2006, of 10 November, establishing the quality and safety rules for the donation, obtaining, assessment, processing, preservation, storage and distribution of human cells and tissue, and approving the coordination and operation rules for their use in humans

— Royal Decree 65/2006, of 30 January, establishing the requirements for importing and exporting biological samples

— Royal Decree 223/2004, of 6 February, regulating clinical trials with medications

— Royal Decree 120/2003, of 31 January, regulating the requirements for conducting controlled experiences, for reproductive purposes, of fertilisation with previously frozen oocytes or ovary tissue, related to assisted human reproduction techniques

— Law 41/2002, of 14 November, regulating the independence of the patient, and rights and obligations regarding information and clinical documentation

— Law 30/1979, of 27 October, on extracting and transplanting organs

— Royal Decree 1090/2015, of 4 December, regulating clinical trials with medications, Research Ethics Committees with medications, and the Spanish Clinical Trial Register.

13.2. Use of animals in research

— Law 6/2013, of 11 June, amending Law 32/2007, of 7 November, for the care of animals, their use, transport, experimentation and sacrifice

— Royal Decree 53/2013, of 1 February, establishing the basic rules applicable for the protection of animals used in experiments and for other scientific purposes, including teaching

— Directive 2010/63/EU of the European Parliament and of the Council, of 22 September 2010, on the protection of animals used for scientific purposes

— Law 32/2007, of 7 November, for the care of animals, their use, transport, experimentation and sacrifice

— Royal Decree 65/2006, of 30 January, establishing the requirements for importing and exporting biological samples

— Royal Decree 1201/2005, of 10 October, on the protection of animals used for experiments and other scientific purposes

— Law 8/2003, of 24 April, on animal health

13.3 Protection of workers

- Law 54/2003, of 12 December, reforming the regulatory framework on occupational risk prevention
- Law 10/1998, of 21 April, on waste
- Royal Decree 665/1997, of 12 May, on the protection of workers against risks related to exposure to carcinogens at work
- Royal Decree 664/1997, of 12 May, on the protection of workers against risks related to exposure to biological agents at work
- Technical guide for the assessment and prevention of risks related to the exposure to biological agents
- Law 31/1995, of 8 December, on occupational risk prevention

13.4. Personal data protection

- Royal Decree 1720/2007, of 21 December, approving the implementing regulations of Organic Law 15/1999, of 13 December
- Organic Law 15/1999, of 13 December, on personal data protection

13.5 Other legal texts

- 1978 Spanish Constitution
- Law 14/2011, of 1 June, on Science, Technology and Innovation
- Law 30/1992, of 26 November, on the Legal Regime of Public Administrations and the Common Administrative Procedure
- Organic Law 3/2007, of 22 March, for the effective equality of men and women
- Royal Decree 1/1996, of 12 April, approving the consolidated text of the Intellectual Property Act

14. REFERENCES

- Convention for the protection of Human Rights and Dignity of human beings with regard to the application of biology and medicine: Convention of Human Rights and Biomedicine. Council of Europe, Oviedo, 4 April 1997. Open link
- Universal Declaration on Bioethics and Human Rights, UNESCO, Paris 19 October 2005.

— Ethical principles for medical research in humans, World Medical Association Declaration of Helsinki, June 1964 and subsequent.

— Belmont Report. Ethical principles and guidelines for the protection of human subjects of research. Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1976.

— Committee of Medical Journal Editors. Uniform Requirement for Manuscript Submitted to Biomedical Journal. N Engl J Med 1997; 336:309-315.

— 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

— First World Conference on Research Integrity: Fostering responsible research. (Lisbon, Portugal, 16-19 September 2007). http://icsu.org/5-abouticsu/PDF/WC_final>_report

— Code of Good Scientific Practice and Research Integrity Committee. Carlos III Health Institute. http://www.isciii.es/ISCIII/es/contenidos/fd-el-instituto/fd-organizacion/fd-comites/CodigoPracticasCientificas.pdf