Guide to GoodPractice in Health Sciences Research of the ICS

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Guide to Good Practice in Health Sciences Research

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Presentation

Research, like all human activities, has a particular ethos. Its field of action must have some principles that inspire it, together with a set of values and some methods of evaluation of its practice.

Ethics, in general, and biomedical ethics, specifically, have their foundations in society, in the cultural, social, political and legal values of each moment. It is a discipline in constant evolution but, over the years, principles and procedures of practically universal validity have been consolidated.

The large collective agreements (Nuremberg Code, Helsinki Declaration, Belmont Report, etc.) have been validating a series of principles that have been permeating the legislation and recommendations of the most advanced countries.

In a first phase, the basic principles of autonomy, benefit, non-maleficence and justice have presided over the recommendations of the good practice guides. On the other hand, the introduction of these principles has made it necessary in a second phase to pay attention to the habitual practices of the research staff. Terms such as belonging, objectivity, honesty, etc., are already present in the good governance of the investigation or in the integrity of the investigative process.

The aim is to ensure the autonomy of the person subject to the investigation through informed consent and guarantees of confidentiality and protection of personal data.

In research, as in other creative human activities, the dilemma between the researcher's freedom to obtain scientific knowledge (individual values) and the rights and needs of society (social values) frequently arises. In both cases, they are legally protected rights and assets. Ethics committees, in their different specializations (care, research, scientific integrity), must promote the honesty and validity of the research process and must ensure that institutions, research staff and society find the appropriate forum to resolve their conflicts.

Therefore, it has evolved from a code of recommendations and guidelines for the subjects of scientific research to broader codes that include recommendations, guidelines and instructions related to the structure of scientific practice.

The economic importance of research, development and innovation (R+D+i) activities in the biotechnology sector has led to great relevance being given to the aspects of authorship of scientific discoveries, their commercial exploitation and conflicts of interests with the industry. These aspects are progressively incorporated into the core of these guides.

The drafting of a corporate guide to good practice in health sciences research in 2003 demonstrated the ICS's commitment to quality research and has been a very useful instrument for the daily work of the research institutes linked to the Catalan Institute of Health and for its accreditation. This Guide was an initiative of the ICS Scientific Department, led by Dr. JJ Navas Palacios and coordinated by Dr. Carles Miquel Collell with the contribution of Dr. Josep Maria Borràs, Miguel Gómez Clares, Antonio Dávalos Errando, Xavier Matias Guiu,

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On the other hand, the Scientific Council of the Catalan Institute of Health is made up of the scientific directors of the research institutes linked to the entity, the care director and a representative of the Agency for Health Quality and Evaluation of Catalonia. It meets periodically and advises the ICS Management Department in coordinating and directing the research policy.

The Scientific Council of the ICS considered it opportune to review and expand the content of the Good Practice Guide in health sciences research, in force since 2004. The preparation of the Guide that is now presented was carried out from a joint reflection , after multiple meetings, and is the result of a broad consensus.

The mission of this document is to make available to the ICS scientific community a decision-making tool for both government bodies and research staff. At all times, the Guide and its potential application must be governed by the values and ethical principles of the most demanding and up-to-date scientific practice.

It corresponds to the ICS health network and, especially, to the linked health research institutes, to adapt and adapt this Guide to the particular conditions of research in health sciences of each of the institutions in which it is applied .

1. General principles of research

Methodical doubt exercise

The principle of scientific knowledge is the ability to surprise or question why of facts or situations that up to that moment have not been investigated or resolved. The science pursues objective knowledge that can be assumed as true based on the knowledge of that historical moment. To do this, he follows a reflective process that has two phases: methodical doubt and the justification of the explanatory hypothesis. The methodical doubt implies the independence of judgment and the acceptance, from a scientific point of view, of any idea as absolute or final. For the justification of the hypothesis it will be necessary to find proofs or arguments that validate it. this attitude inquisitiveness, which is at the starting point of the scientific task, must always accompany the researchers, because if the human capacity for surprise is inexhaustible, the possible knowledge and, therefore, the certainty that it is available at all times must be provisional.

General rules governing scientific practice

1. Observation and experimentation in clinical practice, laboratory or natural environment are intended to obtain data that facilitate the appropriate answers to the scientific questions that are formulated. For this reason, research must be carried out following well-designed work protocols and that, where appropriate, can be examined and understood by any researcher of the given scientific field. Experiments and observations must be carefully designed, with rigor and intelligence, with the purpose of achieving the best use of resources available, always taking into account existing work standards in the laboratory or in the research center at all times. This is required even more when the object of the research are human beings, or their data, and laboratory animals or when the safety of people or the environment may be at stake.

2. The state of systematic skepticism must be maintained: openness to doubt, even in the results of the researcher himself and those of his own group. The proof of a scientific result is its reproducibility. The more amazing or desired a result is, the more important it is. reproduce it independently (with reasonable costs), within the research group, before communicating it externally.

3. It is necessary to maintain a high degree of vigilance to deal with any motivated "illusion" for their own interest or for moral prejudices of any origin. You need to keep the sense critical to promote a systematic state of alert to detect misinterpretations as a consequence of the limitations of the experimental design, of the excessive generalization and of superficiality in interpretation.

4. It is essential to carry out a systematic and secure collection of primary data and guarantee the storage for ten years of documentation, which must be clear and understandable, on the methods used to generate this data (for example, laboratory books, photographs, printing of the chromatograms). Alternatively, secure electronic formats can be used.

Application at the Catalan Health Institute

The centers of the Catalan Health Institute (ICS) have as one of their objectives to improve knowledge scientist in health sciences through research, its transmission through training and its application with good care practice.

- The ICS research staff agrees to rely on this Guide, in addition to doing so on the laws, standards and other existing documents (see Annex I), widely recognized, and that the Guide is known to all his team.

- These personnel must provide funding agencies with a guarantee that the resources allocated to their center will be used in the most efficient way possible and also complying with ethical principles.

- Before the scientific community, it must be guaranteed that the results will be communicated at all times, including the negative ones, to avoid useless repetitions.

- Scientific malpractice must be prevented, both in carrying out the research process and in its subsequent communication or publication in the scientific media.

- The necessary means must be used to assure society that the resources allocated to the research will always receive the best use and that the rights of sick people will be protected.

2. Differential aspects of research in health sciences

- Healthcare practice and health care are based on a body of scientific knowledge, in addition to to do so in the technical skills and attitudes of the professionals. To these knowledge it comes through systematic research and its transmission is carried out through scientific publications and teaching.

- Research makes it possible to renew and update this knowledge through an orderly procedure that It consists of a chain of processes destined to an ultimate goal, which is to improve professional practice. and the health of the population. It can be developed in the basic, clinical or public health fields.

- The search for quality also allows professionals to keep their knowledge up to date. and that they have an open attitude to change, which has an impact on an improvement in assistance.

- To achieve this, a sum of resources is required, such as effort, time and dedication of the research staff.

- A particularly relevant aspect is that when efforts are allocated to a project and towards a determined direction, other options are ruled out, so it is worth noting the importance of deciding in the proper sense.

- The communication of results, which allows the transmission of knowledge and scientific progress, is essential so that once this knowledge is in the public domain, repetitions of the procedure are avoided and benefit the whole society.

- For this whole process to be accepted by society, which provides the resources for its realization, compliance with a set of ethical postulates is required and very specific general conditions are required. strict. The scientific community itself must be, in this sense, the one who values and accepts knowledge contributed.

- The research environment is competitive in terms of obtaining the resources to finance it. These resources may come from external funding agencies, non-profit organizations, for-profit companies or from the health system itself. This search for funding sources should not make us forget the high moral demand that must exist throughout the process.

- Research is currently being carried out in increasingly broad areas and, in this sense, studies multicenter are very common. The healthcare center and its research staff must be committed, on the one hand, to carefully review their participation in this type of study (in which the design and use of the data are beyond their control) and, on the other, not to participate until such time as the the review process.

- The Guide to good practice in research in health sciences of the Catalan Institute of Health constitutes a commitment by the institution and the research staff to carry out all this scientific process with the highest possible level of quality.

3. Planning a research project

A research project, in order to have a chance of success, needs a minimum of planning elements. Without these elements, a project cannot be considered, it cannot be registered as such in the research organizations and, therefore, the guarantee and protection elements to which it refers are missing.
this document.

3.1 Project design phase

1. Designation of the principal investigator

2. Review of pre-existing information. Establishing a hypothesis

3. Elaboration of the objectives 4. Selection of the approach, variables and observational and experimental methodology

5. Determination of sample size

6. Definition of a data analysis plan and statistical methodology 7. Determination of the minimum resources necessary for the viability of the project

8. Definition of the data collection and custody system

9. Task planning

3.2 Preparation of the protocol in the case of clinical trials

1. Compulsory nature of its preparation

2. Minimum contents

3. Research team 4. Publication rights and economic agreements

3.3 Approval of the protocol

1. Collaboration agreements between services

2. Scientific approval

3. Ethical approval 4. Legal approval 5. Commitment of the research team

6. Existence of a contract

4. Research in humans. Informed consent

4.1 Prior informed consent document

Whenever the execution of a research project modifies the usual practice in the assistance of one or a patient, this person must give consent, before starting it, through their signature or the person who legally represents them.

4.2 Ethical principles

The center's biomedical research must be based on the universally recognized ethical postulates of autonomy and benefit principle. Autonomy must especially respect handicapped people, for whom their tutors are responsible.

4.3 Sufficient information prior to informed consent The

Information about the project that must be provided to the patient must be prior to the signing of the document accepting to participate. This information must be provided in terms that are as understandable as possible and respecting the cultural values of the patients, who must have the necessary time to be able to consult the proposal and make an informed decision.

4.4 Written information

Patients will be provided with a document specifying the potential benefits and risks of their participation in the study and the name of the person who informed them. will be done state their explicit acceptance of participating in the project, or that of their tutors.

4.5 Financial compensation

It must be stated if there are certain economic compensations that the sick people, in relation to the extraordinary expenses that their participation may cause in the study, as well as those perceived by healthy volunteers.

4.6 Approval from the clinical research ethics committee or from the body that assume your functions

The investigation cannot begin until said committee has given its final approval to the protocol subject to its evaluation. This committee ensures that the rights of patients, volunteers and people, in general, involved in a clinical research project are respected. The mandatory reports will be sent to this committee, on an annual basis and at the end of the study.

4.7 Notification and action in case of possible adverse effects

If adverse effects occur, the sponsor should be notified immediately. If these are potentially serious, the patient must be withdrawn from the study.

4.8 Biobank

The constitution and operation of biobanks, and their basic organizational requirements, are established in the specific regulations in force. It is necessary to have the corresponding informed consent according to the type of sample and the intended use (see the legislation annex).

5. Search in animals

It must be governed by the principle of the three Rs: "replace, reduce and refine" and, in any case, each aspect must be justified.

5.1 Rationale for the animal model

In the event that it is necessary to use animals as experimental subjects, the aforementioned need will be argued due to the non-existence of equivalent alternative methods that can replace them.

5.2 Determination of the number of animals

The study sample size will be determined and reduced as much as possible.

5.3 Reduction of suffering

Procedures to avoid animal suffering must be specified, as well as the method of sacrifice, which should be the most appropriate, applying the principle of refinement.

5.4 Approval of the ethical committee for animal experimentation

Research cannot be started until the ethical committee for animal experimentation has given its final approval of the protocol. At the end of the study, the mandatory annual and annual reports must be sent to the committee. final.

6. Safety, health and environment

The research staff must be familiar with safety, occupational health and environmental protection measures. environment that must be taken into account in carrying out research activities.

It is necessary for each center to ensure that the development of the research is carried out guaranteeing the safety and health of the personnel involved and respect for the environment. research groups must ensure that their activities are carried out within the framework of risk prevention policies labor and environmental protection, both those of the center and those established by the regulations current legislation, which includes specific sections for genetically modified organisms (see the annex 4).

7. Realization of the projects

7.1 Responsibility of the principal investigator

The principal investigator is the person ultimately responsible for carrying out the project. In the event that it is replaced, the substitution must necessarily be authorized before continuing the research project by the funding agency and the management of the center. In these circumstances, the person proposed as the new Principal Investigator must have at least the same capacity as the replaced person.

7.2 Study supervision

The principal investigator must ensure that his or her research team follows the authorized protocol at all times, with special control by pre-doctoral research staff (trainee researchers) and trainee personnel, to ensure that they comply with the protocol and receive the appropriate teaching appropriate to their training and condition.

7.3 Modifications

In case it is necessary to introduce significant changes in the project, these must be formalized in writing and, if they are relevant, they will require the authorization of all those organizations that approved the realization.

7.4 Audits

The principal investigator must collaborate in the inspection visits and in the verifications that both the center and the relevant external agency, where appropriate, decide to carry out, as well as in the preparation of the progress reports that are necessary according to the foreseen periodicity. .

7.5 Expenditure Record

A detailed record of payments and receipts must be maintained so that reports are accurate and can be easily reviewed by funding agencies. It is imperative to make a efficient use of economic resources.

7.6 Use of equipment

It is mandatory that the research team keep the research material in the best possible conditions and that scrupulously comply with the operating rules. The pertinent periodic calibrations, both to ensure the validity and precision of the results and the physical safety of the people using it or those to whom the material is applied.

The equipment acquired by the researcher to carry out a project is of preferential but not exclusive use of this person, so it must facilitate access to the rest of the research staff of the institution and allow it to be used for care if it complies with the regulations specific to healthcare facilities. All the equipment incorporated into the institution through of the research projects becomes part of its patrimony and is included in its inventory. The institution must be responsible for its maintenance and proper functioning.

7.7 Accuracy and precision of measurements, recording and recording of data

Analytical determinations and recording of results must be as exact and precise as possible. Sufficient quality controls must be established to ensure that the measurements are carried out correctly.

Recorded data must be dated and signed by the person collecting it, and all data must be noted, including unexpected or negative results, as well as unforeseen circumstances that may alter the quality and integrity of the research. The research institution must establish specific rules on the appropriate and standard data collection supports and the custody procedure, when a researcher leaves the institution. These procedures must be included in the reception plan of the research staff.

The Investigation Integrity Committee (IRC) and the Investigation Ombudsperson (see Sections 11 and 12 of this Guide) should regularly review primary data records to ensure accuracy and priority auditability of the observations.

7.8 Waste disposal

Surplus elements resulting from the investigation must be stored and disposed of according to their danger and risk, following the existing regulations for the conservation of the environment and the protection of people.

7.9 Ownership of the results and intellectual property

The law establishes that the research data and samples belong to the institution and not to the researchers, of which they must be aware. In the event that a researcher (member or not of a team) ceases his relationship with the center, he will only have the right to dispose of the data that he has obtained directly. In the case of the principal investigator, he or she must have the approval and supervision of the center to use these data outside the institution.

The intellectual property of the data that is the result of a research project is owned by of the institution that hires the person, but may be subject to agreements that subrogate them to third parties (for example, from the ICS to related institutes or the promoter).

These aspects will be included in the reception plan for research staff and the commitment that Sign this staff when they join the project.

7.10 Preservation of results

In clinical studies, the principal investigator must keep the records and notebooks of results, as well as the patient identification codes for a period of ten years or the necessary time indicated by the regulations of the funding agencies for the performance of the tests. audits. In clinical trials, these documents must be kept for a minimum of fifteen years from the end or interruption of the trial. In all other cases, a minimum of 5 years from the date of the last publication in the scientific literature that refers to the results.

The center is responsible for the custody and security of the data.

This aspect must be included in the reception plan for the research staff.

Attached to this document, as Annex 1, is additional information in this regard.

7.11 Electronic record In the event of maintaining an electronic file of the data, these must be kept on a suitable medium that allows a backup copy to be made. The computer programs will be available to enable its consultation and future use.

Additional information is attached to this Guide as Annex 1.

7.12 Protection of personal data The confidentiality of clinical, biological and genetic data, as well as samples belonging to patients, will be ensured at all times. The sending of personal data to other institutions or organizations will be carried out in such a way that their identity cannot be revealed, in accordance with the regulations established in Organic Law 15/99, of December 13, on the protection of personal data (see the legislation annex).

7.13 Third Party Intellectual Property

In the case of a clinical trial, the reserved information that is the subject of intellectual property that is provided by an entity promoting the study cannot be disseminated by any means and must be reliably guarded. The agreements that stipulate the possible rights that may be generated as a result of the investigation.

7.14 Final report

At the end of each project, a final report must be prepared, which, at a minimum, must include: the identification of the principal investigator and of the other researchers and collaborators involved in the study, the identification of the laboratory in which the carried out the work, the circumstances that may have affected it, the start and end dates of the investigation, its results and the modifications of the protocol. This report may be the same one that is sent to the funding agency.

8. Communication and dissemination of results. Publication

8.1 Obligation to disseminate results

Without the dissemination of the results, the research process is incomplete. The results must be communicated to the scientific community, regardless of their sign or even if they do not coincide with those expected or are negative data. This makes them subjects of the scientific debate, avoids the repetition of a process already carried out and allows the elaboration of new hypotheses. For this reason, the principal investigator has the duty to make them public and is the only person who can authorize their publication.

8.2 Authorship

Only those people who have made a significant contribution to the research and who agree to do so in writing should be listed as authors. In this sense, the recommendations of the International Committee of Medical Journal Editors, International Committee of Medical Journal Publishers (ICMJE).

Authors are those people who have:

1. contributed substantially to the conception or design of the work, or to the acquisition, analysis, or interpretation of job data;
2. participated in the writing of the work or the critical review of its intellectual content in an significant;
3. given final approval of the version to be published;
4. agreed to be responsible for all aspects of the item to ensure that issues concerning the accuracy or completeness of any part of the work are duly substantiated, ready to deliver and resolved. If it is only responsible for specific results, it must be stated in the publication.

The authors and authors must meet the four listed requirements.

The author or main author is the person who assumes primary responsibility for communication with the journal during the submission, peer review, and publication process of the manuscript and, in general, who ensures that all administrative editorial requirements, such as all details of authorship, approval of the manuscript, Ethics Committee, documentation trials registration, collection of conflict of interest forms and declarations have been completed correctly, although these functions may be partly delegated to one or more several co-authors. Traditionally, in biomedical publications, this author or author principal is the last signatory person, but this depends on the scientific field.

In addition to being responsible for the parts of the work that they have done, the author or author must be able to to identify co-authors responsible for other specific parts of the work. In addition, authors must have confidence in the integrity of their co-authors' contributions.

People who have not been substantially involved in the design, implementation or review of results, or in the publication should not be included. Centers and institutions must be identified

to which the authors belong and those entities in which the research has been carried out, as well as the sources total or partial financing.

The following additional information is attached to this Guide as Annex 2: Recommendations for the realization, preparation of reports, edition and publication of academic works in medical journals*, reviewed December 2013.

8.3 Acknowledgments

Its purpose is to recognize the help of organizations and individuals in the project and in carrying out the research. To be able to mention them, they must have previously given their consent.

8.4 Projects subsidized by entities and industry

The Agreements between both parties must be in writing, and must establish intellectual property rights and publication rights.

8.5 Ethics of publications

Publications cannot be redundant and duplication must be avoided. Cannot be artificially fragmented to increase their number. All the data obtained will be provided accurately. If any case or variable is removed, this change must be justified.

8.6 Dissemination in the media

Only after the communication or publication of the research results in a scientific journal, or by an equivalent review system, they can be made known to non-expert media. Before, it is necessary to have the formal consent of the institution and of the agency that has financed the project, if applicable. If it is a project coordinated, the approval of all participating persons and entities is required, if applicable. should be avoided sensationalist formats that may generate false expectations.

9. Conflict of interest

9.1 Concept and origin

There is a possible conflict of interest when the principal investigator or any component of his team has been influenced by: 1) an economic interest, not known through a contract, or 2) an interest of personal gain, other than the scientist, in the design, realization or subsequent communication of results of a research project.

9.2. Notification

Depending on the case, the conflict of interest must be communicated to the financing agencies, to the project evaluation staff or to the editors of scientific journals, at the time of study evaluation and subsequent decision-making .

10. personal

10.1 Research staff

Research personnel are organized into various categories according to their degree of experience and responsibility in the field.

Project:

• Principal investigator or investigator • Staff

collaborating researcher • Research staff

predoctoral (or researcher in training) • Postdoctoral research staff •

Senior technical staff (PhD or not)

• Technical laboratory staff

• Laboratory and clinical assistants

• Management and administration support staff

10.2 Staff in training

In the field of research, there is a long tradition of training through participation in projects. The people who find themselves in this situation are called pre-doctoral researchers or trainee researchers (formerly known as scholarship staff). Due to the dependency situation of these personnel, it is important that they specifically regulate their situation in the respective research center.

Definition: the personnel in training of a research center can have a middle or higher degree that, according to with the previous description, develops his research and training work and is registered as a predoctoral researcher or researcher-in-training at the center.

NOTE: See Annex 3 for information related to the assignment of a mentor.

Rights

Predoctoral research staff or research trainees have the right to receive the amount of their scholarship, participate in accordance with their degree and training in a well-defined and viable research project within a period of time stipulated, be supervised periodically by the director, receive general training in their field of study and actively intervene in the research teaching program. Your participation in a project research should be reflected in the authorship of the publications resulting from the project, in accordance with the rules that on this are internationally recognized and appear in section 8.2. of this Guide.

Obligations

The predoctoral research staff or researcher in training have the obligation to make the maximum effort to carry out your project, respect the internal operating rules of the center in which you carry out your work, do the best use of research equipment and supplies and to not disclose your research data until the person who directs your project deems it appropriate. This limitation is not absolute, since the realization of a project of research

includes the disclosure of its results and, therefore, these cannot remain unpublished indefinitely, even if this were the will of the principal investigator.

These rights and obligations must be included in the reception plan of the research staff.

Dedication

In general, the dedication required of pre-doctoral research staff or research trainees in their research project is complete and, therefore, is incompatible with other activities, with the exception of teaching and assistance activities necessary for the development of the project and guards, if This is how his research program contemplates it.

Protection

Pre-doctoral research staff or trainee researchers may resort to the research coordinator, scientific director or academic authority, if they have well-founded reasons for non-compliance with the conditions set forth in the previous sections. If your institution has a research mediator (Ombudsperson), this person will be responsible for the protection of the researcher who declares a grievance with their superiors.

11. The figure of the research mediator. Ad hoc commissions and the Committee for Research Integrity (CIR)

11.1 Investigation Mediator

The investigative mediator, figure equivalent to the Ombudsperson, is an independent person, duly qualified and of great personal integrity.

It must be a person appointed by the management of each research institute at the proposal of the internal scientific committee, from among the scientific staff of the institution. Exceptionally, it may belong to another research institute with a similar structure and purpose, to act as a mediator in the event of a conflict regarding good scientific practices.

The research mediator must be available to all research staff in cases where there is a suspicion of a possible violation of the principles of good scientific practice. The name of the mediating person must be disclosed in an appropriate manner.

This person must maintain discretion regarding information that indicates possible misconduct and is not required to disclose this information to the management bodies of the Institute of research.

The job of the research mediator is to act as an intermediary between the institute researcher who detects possible scientific misconduct and the person (researcher or technician) who is suspected of this misconduct. In conflict situations, the mediator can choose between initiating the procedure through a meeting with the person suspected of the reported misconduct or with the management of the institute. If you find the suspicion of misconduct justified, you must ask management to create an ad hoc commission with experts who, based on primary data, can rule on whether there has been misconduct.

The mediator should keep an eye on the overall progress of the investigation and identify problem areas that may give rise to scientific misconduct.

Each center can have, if it deems it necessary, a permanent research integrity and ethics committee (CIR) (see the following section), which obviates the need to designate an ad hoc commission in each case, and which complements the actions of the research mediator or carry out their functions in those centers that do not have this figure. This person and the CIR must analyze the complaint and listen to both parties separately, scrupulously respecting their rights, they must obtain and keep the documentation related to the case, including the primary data (records and notebooks of results), and they can request the opinion of other independent experts outside the case. They have a moral obligation to act with the greatest possible diligence to reach a well-founded conclusion in the shortest possible time.

In any case, the investigation mediator, the ad hoc commission, the CIR and the director or scientific director are obliged to defend and protect the complainant and avoid the negative consequences that their accusation/complaint may cause. This is particularly important if the reporting person belongs to the same group as the reported person.

Once the reported facts have been clarified, a report will be issued regarding the existence of scientific misconduct in these facts. The deliberations, as well as the negotiations with the person complainant and with the accused must be strictly confidential.

In the event that the conclusion of the existence of malpractice is reached, the scientific management must put it into question. knowledge of the heads of the corresponding center or centers (generally, the care center and the research institute) who are the ones who will decide on the appropriate sanction. If the existence of bad practice and would be detrimental to the prestige of the researcher or group denounced, those responsible must ensure that, to the extent possible, the reputation of the denounced person is restored in the most appropriate manner .

Appropriate actions must also be taken in the event that it is shown that there has been bad faith in the complaint. evident.

Misconduct in research may result in consequences for third parties: research agencies, editors of scientific journals or judicial authority. In this case, the person responsible for the center and the director or scientific director must ensure that they receive the corresponding notification.

If in the type of malpractice there are signs of the possible commission of a crime, the head of the center is obliged to to enforce the law and report it to the judicial authority.

11.2 Committee for Research Integrity

The CIR is a free and voluntary body constituted by the members of the internal scientific committee and other personnel researcher of the center, at the initiative of the management, and is intended to promote knowledge and internal adoption of the code of good practice. Likewise, the CIR arbitrates the consultations and conflicts that may arise and assists, when it is necessary, to the research mediator.

The CIR acts independently and is at the service of the research staff of the centers adhering to compliance of this good practice document, with the sole objective of supporting the quality of research and contributing to preserve its integrity.

11.3 Functions

The functions of the CIR are:

1. Ensure compliance with the precepts included in this document.
2. Act as an arbitration institution in the face of uncertainties or conflicts that may arise in relation to the integrity of the investigation, once the actions of the mediator have been exhausted; in this sense, the decisions of the Committee are binding for any person who submits the conflicts.
3. Inform and sensitize the scientific community of the institutions about the events, needs and guidelines relating to ethical and deontological aspects of biomedical research.
4. Be attentive and responsive to new issues related to research integrity.

11.4 Scope of action

The CIR's scope of action is the research institute of which it is a part. In relation to the aforementioned functions, the CIR must guarantee at all times diligence, independence and impartiality in its efforts and actions, as well as anonymity and confidentiality in the processing of personal data, and the solvency of the information generated.

11.5 How to contact the mediator and the CIR

Communications with the mediator and the CIR must be sent to an easily accessible email. In case of doubts or potential conflicts, it is advisable to previously hold informal consultations with the mediator. This is especially recommended before proceeding to any type of formal communication in the CIR. In any case, the mediator and the rest of the CIR members are obliged to respect anonymity and confidentiality in the processing of personal data and any other information received.

11.6 Composition of the CIR

- President: director or scientific director.
- Vice President: research mediator.
- Vocals: representative of each of the types of research: pathophysiological or basic, clinical and epidemiological and health services.
- The duration of the position is two years, renewable once, for two more years.
- The proposal for members will be made by the management and the research mediator.

12. Research misconduct

The fundamental mission of the research centers linked to the ICS is to carry out research biomedical medicine of the highest quality, maintaining rigorous respect for the principles of scientific ethics. Therefore, they refuse to carry out any research that does not observe these principles.

According to the most accepted definition, misconduct is understood as the invention, falsification, plagiarism of data or other actions that deviate in a significant way from the practices that are commonly accepted by the scientific community for the proposal, performance or presentation of research results. Not included errors or bona fide differences in interpretations or judgments of the data.

In order to prevent the appearance of situations of scientific misconduct, knowledge of the principles should be promoted. of scientific ethics, ensuring frequent expert supervision and monitoring at all levels, Avoid excessive pressure to obtain results and promote the exchange of information between stakeholder groups. research. The institution must implement the standards of good laboratory and research practice, included in this document, with special emphasis on the primary data collection systems so that they do not can alter. These standards not only reduce the risk of inadvertent errors, but also greatly facilitate

the search for cases of scientific misconduct.

It is the task of the scientific management of the research center, directly and through the mediator of investigation, receive and investigate allegations of scientific misconduct made by a person or group fully identified.

In the event that the center does not have that mediator or CIR or that the seriousness of the complaint exceeds its capacity to act, the scientific management must create an ad hoc commission made up of independent and impartial with respect to the investigation group and the person denounced and the complainant, who are experts in the specific scientific field, who have extensive research experience or are well versed in the aspects of scientific research and who have an impeccable personal record.

Annexes

Appendix 1

Information related to the collection and custody of data

Data collection and retention plan

All research protocols must provide a system for collecting data, recording and biological material or resulting from the execution of the investigation, as well as a plan for its custody and conservation.

Registration of data and rectifications

The researcher or researcher and their collaborating staff must collect, without exception, all the data resulting from the experiments and observations of the investigation. This information must remain permanently registered in databases, registry books or in any other pertinent format, and in conditions that allow its review by third parties. Records should also include changes, errors, negative, unexpected or discordant results, as well as the person who performs or observes them.

Conservation of data and collected samples

It is necessary to foresee the necessary means and infrastructures to guarantee a correct custody and conservation of the diverse documentation and biological or chemical material resulting from the research. Likewise, if there is a record of the data in electronic support, a plan must be included backup copies and their physical location.

Custody and access to the data collected

All the people who are part of the research team must be able to access the information of the data obtained and its interpretation. The person responsible for the project must have a single record of the different data collection elements (notebooks, databases, etc.) and sample custody, access to which must be made available to

third persons.

Ownership of data and samples

All primary documentation (data collection notebooks, databases, etc.) and biological material or chemical obtained in the course of research is the property of the institution or institutions to which The person responsible for the project is employed. In the case of persons holding a linked place (in a care center or university), the property corresponds to the care center.

The person responsible for the project must be responsible for the registration, storage and custody of the data. In the event of a change of institution and, whenever necessary, this person can provide the successor a copy of part or all of the record books, the information

existing electronics and data collection notebooks or aliquots of the available biological or chemical material. When the change affects the person responsible for the project, this process must be carried out under the responsibility and supervision of the center's scientific management.

Sharing of data and samples with third parties

The data and materials resulting from an investigation will have the status of public and will be able to be shared by third parties, with the exception of cases in which restrictions derived from their possible future commercialization have been established.

The assignment will require a prior request from the claimant, where the use he wants to make must be indicated, as well as a statement in which he assumes the possible expenses that may arise. The research team must be informed of the request, which will be subject to the transfer protocol and the final approval of the person responsible for the research.

The assignment may be limited for reasons of availability, competitiveness or confidentiality. Material or personal data must be shared without being able to identify you. Otherwise, it will be necessary for the donors to sign a specific transfer consent.

Data and sample retention time

All primary and original information, as well as biological or chemical material stored as a result of any clinical research project, must be kept for at least ten years, from the first publication of the results, except for those cases in which the law allows shorter periods or requires longer ones. If the institution allows it, the information and primary material can be stored for longer periods and its destination will always require the approval of the person responsible for the investigation. In the case of clinical trials, the conservation period will be fifteen years. Experimental projects may reduce the custody period to five years after the publication of the data.

Appendix 2

Information related to the authorship of scientific papers, publications and patents

The condition of author or author does not depend on belonging to a certain profession or hierarchical position, nor on the character of the employment relationship, but to the type of contribution to the research.

To have the full status of author or author of a publication or patent, it is necessary:

1. Having contributed substantially to his creative process, that is, both to its conception and design as in the execution, or in the analysis and interpretation of the data;
2. Having contributed to the preparation of the resulting communications, reports or publications;
3. Be able to present in detail the personal contribution to the investigation and to discuss the main aspects of the whole investigation.

The authors must accept in writing the final wording of the original manuscripts that are processed for registration or publication.

Provision of data, opinions or subjects of experimentation

The mere participation in the obtaining of resources or in the collection of data, such as the provision of data assistance or the provision of experimental subjects, does not necessarily justify authorship, although it must be recognized in the thanks section.

In those projects in which it is planned to use samples, analyzes or opinions made by third parties It is advisable to establish a communication and authorship plan in advance, in which the potential intellectual contribution to the project and any other dimension regarding copyright.

Authors partially responsible

When in a publication there is an author or author who cannot assume responsibility for all the content, they must separately identify their specific contribution, except for cases in which this issue is already regulated by editorial guidelines.

Honorary authors and unrecognized authors (ghost writing)

The person linked to the research group who, due to their hierarchical position or employment relationship, requests to be listed as author or ex officio author violates academic and research freedom and commits an act of injustice, if it cannot be considered a authority abuse. Conversely, the omission of the name of any person who has made proven contributions, according to the criteria expressed in section 8, it constitutes an act of misappropriation of work and property intellectual carried out by the rest of the authors.

Indication of authorship in reports

The edition of reports, work or technical reports or any other writing addressed to third parties should always include the list of the authors of the investigation or inquiry,

center (or centers) on which they depend and the subsidies received, in the same terms as if it were a publication scientific or patent

order of authorship

As a general rule, the order in which authors sign in scientific publications should be as follows:

1. The first person listed as the author is the one who has made the greatest effort in the research, has carried out the experiment or fieldwork and has prepared the first draft of the article, and is often the researcher who is doing or have already finished their thesis.
2. The second person author is usually the senior researcher who came up with the idea and who has supervised and directed the investigation directly.
3. The last author is the senior person who directs and/or has the last responsibility in the research protocol. usually be responsible for the development and supervision of the research program on which the project is based.
4. The rest of the authors may appear in order of importance and, where appropriate, in alphabetical order. The author person who takes charge of the correspondence is the one who has the main responsibility in the whole process editorial, as well as in future interactions that derive from the publication of the work.

Shared primary authorship

In scientific publications there is the right to justify the order in which the authors sign. Some journals already request it as a condition for their publication. When in a work, two or more authors have dedicated the same effort and shared the main work of preparing the manuscript, will have the same consideration of first authors. This circumstance will be explicit in the publication of the original. The same criteria can also be applied in the case of authors intermediates and seniors.

Annex 3

Competence and supervision of research staff in training

All research staff must have the necessary competence to carry out the activities entrusted to them. Students and staff undergoing training must be adequately supervised to ensure the quality of the results they generate.

Any person linked to the research center, through a contract or scholarship, with the purpose of acquiring some type of training will be assigned a mentor (who will carry out their direction or supervision), who must accept this order in writing.

The mentor or mentor must be responsible for the training process taking into account the objectives set and the estimated time to get them. Likewise, it will provide research staff in training with the best conditions possible for its future scientific projection.

The person in the training process is responsible for complying with the conditions established in the contract or scholarship, as well as as to follow the indications of the mentor or mentor in accordance with the planned training process.

The mentor or mentor must:

1. Interact personally and regularly with the trainee staff in their charge in order to Supervise the tasks entrusted to him and guarantee their fulfillment;
2. Promote the holding of meetings to discuss the progress of the assigned investigation and contribute to scientific and methodological updating of training personnel;
3. ensure that the investigation is carried out in safe conditions;
4. Provide all the necessary information in relation to the existing legal norms that affect research activity (see sections 9, 10 and 11);
5. Agree on the participation of the personnel in training under their charge in the research activity.

Annex 4

Legislation, standards and documents

A: Human Research

Nuremberg Declaration, Standing Committee of European Doctors (Comité Permanente des Médecins Européens, Standing Committee of European Doctors, CPME). Nuremberg, 1967.

Belmont Report. Ethical principles and guidelines for the protection of human research subjects. The National Commission for the Protection of Human Subjects of Research Biomedical and Behavioral Science, April 18, 1979.

Royal Decree 426/1980, of February 22, which develops Law 30/1979, of October 27, on organ extraction and transplantation. BOE, March 13, 1980, no. 13, p. 5705 (http: www.boe.es/boe/dias/1980/03/13/pdfs/ A0570505707.pdf).

Law 25/1990, of December 20, on medicines (BOE 306, of December 22, 1990).

Royal Decree 561/1993, of April 16, which establishes the requirements for carrying out clinical trials with drugs (BOE 114, of May 13, 1993).

European standard. Clinical investigation of medical devices for human subjects. IN 540: 1993. June 1993.

Convention of the Council of Europe for the protection of human rights and the dignity of the human being regarding the applications of biology and medicine. Convention on human rights and biomedicine. Oviedo, April 4, 1997.

Convention for the protection of human rights and the dignity of the human being in relation to the applications of biology and medicine. Approved by the Committee of Ministers of the Council of Europe on November 19, 1996. Opened for signature by the states in Oviedo on April 4, 1997 and ratified by the Spanish Parliament on October 5, 1999 (BOE, 20 October 1999, no. 251). (http:www.boe.es/boe/dias/1999/10/20/pdfs/ A3682536830.pdf).

Universal Declaration on the Human Genome and Human Rights: From Principles to Practice. UNESCO, February 3, 2000.

Circular 15/2001. Spanish Medicines Agency. Application of Royal Decree 561/1993, of April 16, on conducting clinical trials with drugs.

Directive 2001/20/CE of the European Parliament and of the Council, of April 4, 2001, relative to the approximation of the legal, regulatory and administrative provisions of the Member States on the application of good clinical practices in the conduct of clinical trials of medicines for human use (OJEC of May 1, 2001).

Law 29/2006, of July 26, on guarantees and rational use of medicines and health products. BOE, July 27, 2006, no. 178, p. 28,122.

Decree 406/2006, of October 24, which regulates the requirements and accreditation procedure of the clinical research ethics committees. DOGC no. 4748, p. 44,904. Department of Health of the Generalitat of Catalonia (www.gencat.cat/diari/4748/06293139.htm).

Royal Decree 223/2007, of February 6, which regulates clinical trials with drugs. BOE, 7 February 2004, no. 33, p. 5,429 (www.boe.es/boe/dias/2004/02/07/pdfs/A0542905443.pdf).

Law 14/2011, of June 1, on science, technology and (http:www.boe.es/boe/dias/2011/06/02/ the innovation pdfs/BOEA20119617.pdf).

Declaration of Helsinki of the World Medical Association. Ethical principles for medical research in humans. Helsinki, Finland, June 1964. Revised at the General Assembly. October 2013.

BIOBANKS

Royal Decree 1716/2011, of November 18, which establishes the basic requirements for authorization and operation of biobanks for purposes of biomedical research and treatment of biological samples of human origin, and regulates the operation and organization of the National Registry of Biobanks for Biomedical Research.

Decree 234/2013, of October 15, which regulates the authorization for the constitution and operation biobanks for biomedical research purposes in Catalonia and the Catalan Network of Biobanks.

B: Animal Research

Decree 214/1997, of July 30, which regulates the use of animals for experimentation and other purposes scientists (DOGC 2450, of August 7, 1977).

Royal Decree 65/2006, of January 30, which establishes requirements for the import and export of biological samples.

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

Royal Decree 53/2013, of February 1, which establishes the basic rules applicable for the protection of animals used in experimentation and other scientific purposes, including teaching.

C: Protection of workers

Law 31/1995, of November 8, on Occupational Risk Prevention.

Royal Decree 664/1997, of May 12, on the protection of workers against risks related to Exposure to biological agents during work o Technical guide for the evaluation and prevention of risks related to exposure to biological agents.

Law 10/1998, of April 21, on waste.

Royal Decree 349/2003, of March 21, which modifies Royal Decree 665/1997, of May 12, on the protection of workers against the risks related to exposure to carcinogenic agents during work, and for which its scope of application is extended to mutagens.

Law 54/2003, of December 12, reforming the regulatory framework for risk prevention labor.

D: Environmental protection

Law 9/2003, of April 25, on the confined use, voluntary release and commercialization of modified organisms genetically.

Law 9/2006, of April 28, on the evaluation of the effects of certain environmental plans and programs ambient. BOE, 29 of April of 2006, num. 102, p. 16,820 (http://www.boe.es/boe/dias/2006/04/29/pdfs/A1682016830.pdf).

E: Protection of personal data

Royal Legislative Decree 1/1996, of April 12, which approves the revised text of the Intellectual Property Law, which regularizes, clarifies and harmonizes the current legal provisions on the matter (BOE No. 97, of April 22).

Organic Law 15/1999, of December 13, on the protection of personal data. (BOE 298, of December 14, 1999).

F: Other legal texts

Uniform requirements for manuscripts submitted to biomedical journals. International Committee of Magazine Editors medical. NEJ. Med 1997; 336: 310315.

Law 5/2001, of May 2, on foundations (DOGC no. 3388, 1552001, p. 6899). Modified by Law 21/2005, of 29 December, of financial measures. DOGC no. 4541, 31122005, p. 44,058.

Policies of general application. Subpart A: Responsibility of PHS Recipients and Applicant Institutions deal with and report possible misconduct in science.

Royal Decree 1277/2003, of October 10, which establishes the general bases for the authorization of centers, health services and establishments.

Royal Decree 339/2004, of February 27, on the accreditation of health research institutes (IIS). BOE, March 13, 2004, no. 63, p. 11,409.

Decree 407/2006, of October 24, creating the Catalan Council for Continuing Education for the Health Professions and of the technical councils of continuous training. DOGC no. 4748, p. 44,904. Department of Health of the Generalitat of Catalonia.

Law 14/2007, of July 3, on biomedical research. BOE, July 3, 2007, no. 159, p. 28,826 (http://www.boe.es/boe/days/2007/07/04/pdfs/A2882628848.pdf).

Law 30/2007, of October 30, on public sector contracts BOE, October 31, 2007, no. 261, p. 44,336 (http://www.boe.es/boe/dias/2007/10/31/pdfs/A4433644436.pdf).

Law 4/2008, of April 24, of the third book of the Civil Code of Catalonia, relative to legal entities. DOGC no. 5123, of 252008, p. 34.37834.424. Correction of errors in the DOGC no. 5170, of 07-10-2008, p. 53,507 (http://www.gencat.cat/diari_c/5123s.htm).

Law 7/2012, of June 15, modifying the third book of the Civil Code of Catalonia, relating to legal entities.

Annex 5

Documentation consulted for the review of this Guide

- PRBB Code of Good Practices (2009)
- ISCIII accreditation guide (2009)
- Code of good practices in research of the UB (2010)
- CSIC Code of Good Scientific Practices (2011)
- IISPV Code of Good Scientific Practices (2012 revision)
- Code of good practices in IDIBAPS research (2012)