



# **IDIBELL Guide to Good Research Practice in the Health Sciences**

## 0. INTRODUCTION

### 0.1 RECORD OF REVISIONS

No. REVISED BY	DATE	DESCRIPTION OF THE MODIFICATION
00	4/12/2015	Guide written.

### 0.2 QUALITY COMMITTEE REGULATION APPROVAL

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### PRESENTATION

Research, like all human activity, has its own particular ethos. The scope of its operation and the values it adheres to must be based on certain principles, while certain methods must be used to assess its practice.

Ethics in general, and biomedicine in particular, have their basis in society: in the cultural, social, political and legal values that prevail at any given moment. Although research is a discipline that is constantly evolving, over the years a number of principles and validation procedures have been established and put into practice on a virtually universal basis.

The major collective agreements (e.g. the Nuremberg Code, Helsinki Declaration, Belmont Report, etc.) have progressively validated a series of recommendations that have provided the basis for legislation and recommendations in the more advanced countries.

Initially, the basic principles of autonomy, beneficence, no harm, and justice underpinned the recommendations made in guides to good practice. Subsequently, the introduction of these principles made it necessary to focus on the habitual practices of researchers themselves. Terms such as ownership, objectivity and honesty have become part of good governance of research and the integrity of the research process.

The autonomy of the research subject is ensured through the giving of informed consent and providing guarantees of confidentiality and the protection of personal data.

In research, as in other fields of human creativity, there is often a dichotomy between the freedom of the researcher to pursue scientific knowledge (i.e. individual values) and the rights and needs of society (i.e. social values). Both cases involve rights and concepts that are legally protected. Ethics committees, in their various areas of specialisation (whether related to care, research or scientific integrity), must promote the honesty and validity of the research process and ensure that institutions, researchers and society in general have an adequate forum in which to resolve their conflicts.

Consequently, research guides have evolved from a set of recommendations and guidelines concerning the subject of scientific research, to broader documents including recommendations, directives and instructions concerning the very structure of scientific practice.

The economic importance of R&D&I in the biotechnology sector has lent great importance to matters such as the ownership and commercial exploitation of scientific discoveries and conflicts of interest with industry. These matters are gradually being incorporated into these research guides.

The aim of this document is to provide IDIBELL's scientific community with an instrument to aid decision-making: not only for the governing bodies, but also for the researchers themselves. At all times, this guide - and its potential application - must be governed by the most stringent and up-to-date ethical principles and values in the field of scientific practice.

This document has been adapted from the original ICS document in order to meet the specific conditions and current circumstances in the research field at IDIBELL, as specified in the original document: "The ICS healthcare network, and the institutes conducting health-related research in particular, must adjust and adapt this guide to meet the specific conditions for health sciences research in each of the institutions in which it is applied".

### 1. GENERAL PRINCIPLES OF RESEARCH

#### 1.1 Exercising methodic doubt

The principle of scientific knowledge is the capacity to be surprised by, or to question, the rationale behind events or situations that have not yet been investigated or resolved. Science pursues an objective knowledge that one can assume to be correct. In order to achieve this knowledge, it is necessary to follow a two-stage analytical process: the exercising of methodic doubt, and proving the explanatory hypothesis. Methodic doubt implies independent judgement, i.e. the non-acceptance, from a scientific perspective, of any idea as absolute or definitive. In order to prove the hypothesis, it is necessary to find evidence or arguments that validate it. Researchers must always adopt this questioning approach, which constitutes the starting-point of scientific activity. After all, if we humans have an inexhaustible capacity for surprise, then the amount of potential knowledge is also inexhaustible, and so any certainty we may think we have can only be provisional.

#### 1.2 General rules governing scientific practice

The aim of observation and experimentation in a clinical, laboratory or natural environment is to generate data that can provide an adequate response to the scientific questions that have been posed. For this reason, research must be conducted in accordance with working protocols that are well-designed and, where necessary, able to be examined and understood by any researcher in the scientific field in question. Experiments and observations must be designed meticulously, with rigour and intelligence, to ensure the best use of the resources available. They must also adhere at all times to the rules and regulations that govern the work carried out at the laboratory in question. This is even more crucial when the objects of the research are people or their data, laboratory animals, or when the health of individuals or the environment could be placed at risk.

- A state of systematic scepticism: openness to doubt, especially regarding one's own results and the results of one's group. The proof of a scientific result is its reproducibility. The more surprising or desired a result, the more important it is to reproduce it independently (within a reasonable cost) within the research group before communicating the result externally.
- It is necessary to maintain a high level of vigilance in the face of any hopes or expectations that may be the result of one's own self-interest or moral prejudices of any kind. It is vital for researchers to be systematically "on the alert" for any erroneous interpretations that may arise due to the limitations of the experimental design, excessive generalisation or superficiality of interpretation.
- It is vital for primary data to be collected in a way that is both systematic and secure, guarantee its storage for ten years, and provide clear, comprehensible documentation that details the methods used to generate said data (e.g. laboratory notebooks, photographs, printed chromatographs, etc.). Secure electronic formats can also be used.

#### 1.3 Application to the Catalan Institute of Health (ICS) and IDIBELL

One of the objectives of the centres that form part of the ICS is to improve scientific knowledge in the field of health sciences through research, the communication of that research through training, and the application of that research through good practice in patient care.

As an organisation, IDIBELL has the following:

Mission: to promote and facilitate translational research that is of proven scientific excellence and

comprises biomedical innovation and technology transfer, generating value for the continued improvement of health and quality of life.

Vision: to become a leading biomedical research institute at the international level by ensuring that its results are translated, in terms of innovation and transfer, into improved healthcare for citizens, and to consider itself a benchmark institution for the attraction of talent, where researchers are the principal asset.

By adhering to this code, IDIBELL aims to fulfill its objectives while maintaining its ethical integrity:

- IDIBELL's researchers undertake to perform their activities in accordance with this guide, and with the widely recognised laws, regulations and other instruments in force (see Annex 1). They also undertake to make these instruments known to all members of their team.
- Researchers must provide the funding agencies with the guarantee that the resources allocated to this centre will be used as efficiently as possible and that the corresponding ethical principles will be observed.
- Researchers must guarantee that their results, including negative results, will be communicated to the scientific community at all times, in order to prevent fruitless repetition.
- Scientific misconduct will be prevented: not only with regard to the research process itself, but also with regard to the subsequent communication or publication of results in the science media.
- The necessary measures will be taken to ensure that the resources allocated to research will always be used optimally, and that the rights of patients and the general public will be protected.

## 2. DISTINGUISHING FEATURES OF RESEARCH IN THE HEALTH SCIENCES

- Clinical practice and healthcare provision are based on a set of scientific knowledge, along with the technical capacities and clinical approaches of healthcare professionals. This knowledge is arrived at through systematic research, and the communication of that research through scientific publications and teaching.
- Research makes it possible to refresh and update this knowledge through an orderly procedure consisting of a chain of processes whose ultimate aim is to improve professional performance and public health. These activities may take place in the areas of basic study, clinical practice or public health.
- Quality research also enables professionals to keep their knowledge up-to-date and adopt a mentality that is open to change. This, in turn, leads to improvements in healthcare.
- To achieve the foregoing, a set of resources - such as time, effort and dedication on the part of researchers - is required.
- A particularly relevant consideration is that, when efforts are allocated to a particular project or directed towards a particular area, alternative options are necessarily discarded. Therefore, it is necessary to highlight the importance of making the correct decision in this respect.
- Communicating results - and thereby enabling the transfer of knowledge and scientific progress - is essential, because once this knowledge enters the public domain, repetition of the procedure can be avoided and all of society benefits.

- In order for this process to be accepted in its entirety by society, which provides the resources to realise said process, it is necessary to observe a set of ethical principles and abide by very strict general conditions. Moreover, the scientific community itself must take responsibility for assessing and accepting the knowledge that is contributed.
- The research environment is competitive, in terms of obtaining the resources to fund research. These resources may come from external funding agencies, non-profit or for-profit organisations and from the healthcare system itself. Nonetheless, the search for sources of funding must not outweigh the most stringent moral considerations, which must apply throughout the entire process.
- Today, research is conducted in increasingly wider contexts. As such, studies involving multiple centres are very common. The healthcare centre in question and its research staff must ensure they undertake extremely thorough checking of any such studies they take part in, where the research design and exploitation of data are outside their control. They must also ensure they do not agree to take part in such studies until these checks have been carried out.
- The Guide to Good Research Practice in the Health Sciences represents a commitment on the part of the researchers and the institution to ensuring that all of these scientific processes will be carried out to the highest possible levels of quality.

### 3. PLANNING AND CARRYING OUT A RESEARCH PROJECT

In order to be successful, a research project must incorporate certain minimum planning-related elements. Without these elements, it cannot be considered a research project and cannot be registered as such with the corresponding research bodies, and it will therefore lack the guarantees and protections referred to in this guide.

Planning the project is an essential part of the research process. It is a necessary condition for securing official registration, and offers guarantees with regard to an assessment of the project's success and providing accountability in terms of the resources invested. For this reason, researchers must always plan their projects with great care before putting them into practice.

Depending on its particular characteristics, a research project may require the approval of the institution's regulatory bodies in the areas of ethics or safety (i.e. the Ethics Committee for Animal Testing, the Ethics Committee for Clinical Research, or the Biosafety Committee). Under no circumstances may a project proceed without the approval of the relevant bodies.

As a general rule, project planning comprises the following:

#### 3.1 Planning a project:

##### Project design stage

- Identify the lead researcher.
- Review the existing information.
- Draw up a hypothesis.
- Define the objectives.
- Specify the focus, the variables and the observational and experimental methodology. Determine the sample size and the statistical methodology.
- Determine the minimum resources needed to make the project viable.
- Identify the available human and material resources.
- Define the system used to collect and store data.

- Plan the different tasks and draw up a schedule.

### **Drawing up a protocol for clinical trials**

- Obligatory nature of the protocol.
- Minimum legal contents.
- Composition of the research team.
- Publication rights and economic agreements.

### **Approving the protocol**

- Collaboration agreements between organisations, groups or services.
- Ethical approval.
- Legal approval.
- Commitment on the part of the research team.
- Existence of a contract.

Once the project plan has been drawn up and approved by the relevant bodies, the project itself can commence implementation.

If it becomes necessary to make significant changes to the project, these must be formally set down in writing, and - if necessary - authorisation must be obtained from all the bodies who gave initial approval to the project.

### **3.2 Responsibilities of the lead researcher**

The lead researcher is the person who is ultimately responsible for carrying out the research project. If the lead researcher is replaced, the replacement must be authorised by the funding agency and the centre's managers before the project can continue. In this instance, the new lead researcher must possess the same or superior capacities as the person they are replacing.

The lead researcher must ensure that the research team follows the authorised protocol at all times. Any trainee researchers must be monitored particularly closely, to guarantee that the protocol is followed correctly and ensure the trainees receive the appropriate training for their role and capacities.

### **3.3 Consumption of resources; auditing**

The lead researcher must collaborate with any inspections and checks that the centre and/or external agencies (where applicable) decide to carry out, and must also help prepare any progress reports that are required, in keeping with the established schedule.

It is necessary to keep a detailed record of payments and corresponding receipts, so that the reports are accurate and can be easily checked by the funding agencies. It is imperative that economic resources be used efficiently. Furthermore, the origin of the funding for any project that may derive from the research being funded must be specified.

### **3.4 Use of equipment**

The team and the lead researcher must ensure the research materials are kept in optimum condition and that the rules governing their use and operation are scrupulously complied with. Any periodic calibrations must be carried out as stipulated: not only to ensure the validity and accuracy of the results, but also to ensure the physical safety of the people using the materials or on whom the materials are used.

The equipment acquired by the lead researcher for the project in question can be used for said

project on a preferential, but not exclusive, basis. Consequently, the rest of the institution's research staff must be granted access to it, and/or therapeutic use of it must be permitted, provided the specific regulations governing the use of therapeutic equipment are complied with. All equipment that enters the institution by virtue of being acquired for a research project automatically becomes an asset of the institution, and forms part of its inventory. The institution will assume responsibility for its maintenance and operating condition.

The use of equipment from outside, and which does not pertain exclusively to the research group, always requires the approval of the person in charge of equipment.

### **3.5 Accuracy and precision of measurements; annotation and recording of data**

Analytical determinations must be carried out, and results recorded, as accurately and precisely as possible. Sufficient quality controls must be established to ensure that measurements are taken correctly.

The data recorded must be dated and the person who recorded them identified. All data must be recorded, including unexpected or negative results. Any unforeseen circumstances that may alter the quality or integrity of the research must also be recorded. The research institute will establish specific rules regarding the appropriate and standardised means of collecting and storing data, and the custody procedure to follow when a researcher leaves the institute. These procedures will be detailed in the welcome documentation given to researchers upon arrival.

The Research Integrity Committee (CIR) and/or the Ombudsperson (see section 10 of this guide) may check the records of primary data in order to ensure its veracity can be audited and its observations verified.

### **3.6 Recording and retaining results**

The lead researcher for each project must ensure the availability, traceability and veracity of the data obtained, and ensure that said data is recorded, stored and held in accordance with the applicable regulations.

Researchers must also bear in mind, and anticipate the implementation of, the concept of Open Data. They must collaborate with and facilitate the collection of such data, as it will form an integral part of future research activities.

Generally speaking, the results of the research must be stored in an unmodified state, i.e. containing all of the original data. They must be stored in a suitable format that will ensure their subsequent traceability for a minimum of five years following the publication of said results.

With regard to clinical studies, the lead researcher must keep the records, patient identification codes and laboratory notebooks containing the results for a period of 10 years, or for the necessary period specified in the rules issued by the funding agencies with regard to auditing.

For clinical trials, the results must be kept for a minimum of 15 years following their completion or interruption.

If the data are stored in electronic files, these must themselves be stored on an appropriate device and a security copy made. Software programs must be made available to allow said data to be accessed and used in the future.

Additional information can be found in Annex 1.

### **3.7 Intellectual property and ownership of results**

If a research project is expected to involve different groups from the same centre or from different centres, it is recommended that the scope and period of collaboration be formalised in writing prior to commencing the project. Any agreements between the parties must specify, at a minimum, the arrangements regarding intellectual property rights and the rights to publication.

With regard to clinical trials, any information that is subject to intellectual property rights and which is provided by the organisation sponsoring the study cannot be communicated via any channel and must be stored securely. Agreements must be drawn up to establish any potential assignment of rights which may be generated as a result of the research.

The intellectual property of the data, primary documentation and biological or chemical materials generated as a result of the research shall be owned by the institution that has employed the researcher in question. However, this ownership may in turn be subject to agreements that subrogate it to third parties (e.g. in the case of ICS, to affiliated institutes or to the sponsor of the study).

The law stipulates that the research data and samples belong to the institution, not to the researcher. The latter must be aware of this. If a member of the research team or the lead researcher severs their relationship with the centre, they will only have the right to use the data they themselves have obtained directly. If the lead researcher leaves the centre, they must seek the centre's approval to use said data outside of the centre, and the centre must supervise said use.

These considerations will be detailed in the welcome documentation given to researchers upon arrival and in the agreement signed by researchers upon joining the centre.

### **3.8 Final report**

At the end of each project, a final report must be prepared that does a minimum of the following: identifies the lead researcher and other researchers and collaborators involved with the project; identifies the laboratory where the project was carried out; specifies any circumstances that may have affected the project; and specifies the start and end dates of the project, the results, and any modifications to the protocol. This report may be the same as the one sent to the funding agency.

## **4. RESEARCH INVOLVING HUMAN SUBJECTS: INFORMED CONSENT AND DATA PROTECTION**

The confidentiality of clinical, biological and genetic data, and of any samples taken from patients, must be ensured at all times. If personal data is to be shared with other institutions or organisations, it must be done in a way that protects the individual's identity, in accordance with the stipulations of the Spanish Data Protection Act (LOPD) (see the Annex on legislation).

### **4.1 Approval by the Ethics Committee for Clinical Research**

The research project cannot begin until the Ethics Committee for Clinical Research has given its definitive approval to the protocol that has been submitted for assessment. The committee works to ensure that the rights of patients, volunteers and other subjects involved in clinical research projects are respected. It must be provided with the corresponding annual reports and final report.

### **4.2 Patient information and informed consent**

If a research project requires the modification of a patient's habitual healthcare provision, the patient must give their prior consent to the project by signing the acceptance document or having their legal representative sign it for them.

The patient must be given the information pertaining to the project before signing the acceptance document. This information must be as comprehensible as possible and respect the patient's cultural values. The patient must be given sufficient time to review the proposal and make an informed, reasoned decision.

The patient must also be given a document specifying the potential risks and benefits of their participation in the study. The document must also identify the person that has given them this information. An official record must be made of the patient's explicit agreement (or the explicit agreement of the patient's legal representative) to take part in the project.

### 4.3 Ethical principles

The biomedical research conducted at the centre must be based on the universally recognised ethical principles of autonomy and beneficence. Particular respect must be given to the principle of autonomy when dealing with patients with diminished capacity who have legal representatives acting on their behalf.

If any adverse effects are produced, the sponsor must be notified immediately. If these effects are potentially serious, the patient must be removed from the study.

### 4.4 Financial compensation

It must be made clear whether any financial compensation will be given to patients in order to cover any additional costs their participation in the study may incur, or if there is any financial compensation that will be given to healthy volunteers.

### 4.5 Biobank

The setting-up, operation and basic organisation of biobanks is governed by the corresponding legislation. Informed consent must be sought in accordance with the type of sample taken and the use that will be made of it. See the Annex regarding legislation.

## 5. RESEARCH INVOLVING ANIMAL SUBJECTS

Projects involving experimentation on animals must be governed by the principle of the three R's: Replace, Reduce and Refine. Under all circumstances, each aspect of the experimentation must be duly justified.

### 5.1 Approval by the Ethics Committee for Animal Testing

The research project cannot begin until the Ethics Committee for Animal Testing has given its definitive approval to the protocol. It must be provided with the corresponding annual reports and final report.

### 5.2 Planning projects involving animal testing

- If it is necessary to use animals in the study, this necessity must be demonstrated on the basis that there are no alternative methods that could *replace* the use of animals.
- The sample size must be determined beforehand, in order to *reduce* the number of animals used as much as possible.
- The project plan must always specify the steps that will be taken to prevent the animals from suffering. It must also specify the method that will be used to euthanise the animals; in accordance with the principle of *refinement*, the most suitable method must be used.

## 6. HEALTH, SAFETY AND THE ENVIRONMENT

Research staff must be aware of the measures related to occupational health, safety and environmental protection that are to be taken into account when conducting research. All research staff and laboratory workers must undergo the specific training in occupational risk prevention provided by IDIBELL's Occupational Risk Prevention Service, and must be aware of the safety protocols that correspond to their area of activity.

Moreover, each centre must ensure that research is conducted with the proper guarantees for the health and safety of the people involved and respect for the environment. Research groups must guarantee that their activities will take place in accordance with the policies on occupational risk prevention and environmental protection: not only the centre's own policies, but also those established by the legislation in force, which contains specific provisions on genetically modified organisms (see Annex 4).

### 6.1 Approval by the Biosafety Committee

Research projects requiring the use of biological agents that pose a hazard to human, animal or plant health, or the use or release of genetically modified organisms (GMOs), require the approval and supervision of IDIBELL's Biosafety Committee or Executive Committee.

### 6.2 Safety measures

Laboratory work requires adherence to a set of regulations and recommendations regarding personal habits (e.g. no smoking or eating in the laboratory, keep the workspace clean and tidy, use personal protective equipment, etc.) and the general use of certain products (e.g. scalpels, pipettes, gloves, etc.).

Likewise, while research is ongoing, many different techniques and physical or chemical materials may be used (e.g. radioactive materials, intercalation agents, etc.). Consequently, it is necessary to know the specific rules and safety measures for each of them.

Anyone who is required to handle radioactive isotopes in the course of their research must have undergone the necessary training and must have the corresponding permit to enter the radiation facility.

### 6.3 Waste disposal

It is also important to know how to handle and dispose of any waste materials that are generated during the research activity and which are governed by specific legislation. Any elements left over from the research activity must be stored and disposed of correctly, taking into account the hazards and risks they pose, in accordance with the regulations governing the protection of people and the environment.

## 7. COMMUNICATION AND DISSEMINATION OF RESULTS: PUBLICATION

Without dissemination of results, the research process is incomplete. Results have to be communicated to the scientific community, regardless of whether or not they are negative or do not meet expectations. This serves to make them the subject of scientific debate, prevents the repetition of a process that has already been completed, and allows new hypotheses to be developed. For these reasons, the lead researcher has a responsibility to publish the results, and is

the only person with the authority to do so.

Researchers must always strive to publish their results in a scientific publication that is peer-reviewed, in order to place the quality and relevance of said publication beyond doubt. Moreover, the research centre and the lead researcher must make efforts to ensure the results are made available in Open Access format, wherever possible.

Failure to publish results, or an excessive delay in their publication, may constitute a misappropriation of resources. It is an ethical imperative to publish the results for a project involving human subjects.

Results that are negative, or different to those that were expected, must still be published. The publications must be relevant and duplicity must be avoided. Nor may results be artificially fragmented in order to publish a greater amount of articles. All of the data obtained must be reported and published with the highest possible levels of accuracy. If any particular cases or variables are omitted, an explanation must be given.

Finally, all of IDIBELL's staff must comply with the requirements regarding signature and acknowledgements, as stipulated by the centre and the funding body. These must also be included in any subsequent works that are derived from the researcher's work at the centre, in order to clearly and unequivocally identify the institute's scientific production.

### **7.1 Authorship**

It is only necessary to name as authors those who have made a significant contribution to the research and who have given written acceptance of their authorship. In this respect, the recommendations of the ICMJE (International Committee of Medical Journal Editors) are to be followed.

"Authors" are deemed to be those who have:

1. Contributed substantially to the conception or design of the project, or to the acquisition, analysis or interpretation of the project's data;
2. Participated in the documentation of the project, or made a significant contribution to the critical review of its intellectual content;
3. Given final approval to the version to be published; and
4. Agreed to be responsible for all aspects relating to the article, in order to ensure that all matters pertaining to the accuracy or integrity of any part of the project are duly substantiated, made ready for submission and resolved. If a particular individual is only responsible for certain specific results, this should be made clear in the publication.

#### **Authors must meet these four requirements.**

The lead author is the person who assumes primary responsibility for communication with the journal during the processes of presentation, peer review and publication of the manuscript. In general, s/he makes sure that all of the journal's administrative requirements, along with all of the details regarding authorship, ethics committee approval, clinical documentation for registration of trials, conflict of interest forms and other declarations, are in order and have been completed correctly.

These functions can also be delegated to one or more co-authors. For biomedical publications, the lead author traditionally signs his/her name last, although this practice may be different in other scientific fields.

### **7.2 Co-authorship**

As well as being responsible for those parts of the project s/he has worked on, the lead author must also be able to identify the co-authors who were responsible for other specific parts of the project. The lead author must also trust the integrity of the contributions of his/her co-authors.

Those who have not played a significant part in the design, execution or revision of either the results or the publication should not be included. It is necessary to identify the centres and institutions the authors work for and those in which the research was conducted, as well as any sources of funding (whether full or partial). IDIBELL authors must follow the guidelines the centre has provided with regard to the format for signatures and accompanying information.

Further information can be found in Annex 2 (Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, revised December 2013).

### **7.3 Authors' contributions**

Wherever possible, and in the corresponding section of the publication, details should be given of the contribution made by each author to the article, in order to credit their individual efforts. Authors should actively request the inclusion of this information, if the option to do so is not specified in the publication guide.

### **7.4 Acknowledgements**

The funding agencies must always be mentioned in the acknowledgements (or equivalent section) for any scientific production that derives from a research project, in order to be able to provide adequate justification for the sources of the funding received.

Any other organisation or person who has assisted with the project, but is not an author, must also be mentioned (with their prior consent) in the acknowledgements.

### **7.5 Media dissemination**

Only after the research results have been communicated or published in a scientific journal or equivalent review platform will it be possible to broadcast these results via non-specialist media channels. However, before this may be done, formal permission must be sought from the institution and (where applicable) the agency that has funded the project. If the project has involved multiple contributors, approval must also be sought from each person and organisation.

## **8. CONFLICTS OF INTEREST**

### **8.1 Concept and origin**

A potential conflict of interest exists when the lead researcher or a member of their team has been influenced by: 1) an economic interest that is not contractually known; or 2) a non-scientific interest, motivated by personal profit, in the design, acquisition or subsequent communication of the results of a research project.

### **8.2 Notification**

Depending on the specific circumstances, the funding agencies, the person(s) responsible for assessing the study and the editors of the scientific journal(s) must be informed of the conflict of interest at the time the study is assessed and before any decisions are made.

### 9. STAFF

IDIBELL has established a series of different staffing categories:

**Research staff:** Any person working within IDIBELL that is directly engaged in research. A distinction is made between the categories of “scientist” and “technician”.

- **Scientist:** a researcher whose work focuses on overall scientific production.
- **Technician:** a researcher whose work focuses on achieving experimental results.

**Support staff:** Any person working within IDIBELL whose work does not impact directly on the obtaining of scientific results.

**Pre-doctoral researcher:** a researcher who holds a university degree, is currently undergoing postgraduate training and carries out his/her educational and research activities within an IDIBELL research group. Pre-doctoral researchers must be enrolled on a doctoral programme in the field of biomedicine and health and must be actively engaged in producing a thesis that is supervised or jointly supervised by a researcher connected to IDIBELL. Equivalent to level R1 of the European framework.

**Post-doctoral researcher:** a researcher who has recently completed a PhD and is categorised as “post-doctoral” for a temporary period as defined by the institution. The work carried out by post-doctoral researchers is still supervised, in order to improve their professional competences and give them the necessary scientific independence to further their professional career. Equivalent to level R2 of the European framework, albeit with junior status.

**Associate researcher:** a researcher working within IDIBELL who has a PhD (or equivalent experience), possesses proven experience, and contributes to the research of his/her group under the supervision of the lead researcher. Equivalent to level R2 of the European framework.

**Affiliated researcher:** a researcher working outside IDIBELL who forms part of and collaborates with an IDIBELL research group, on a continued basis and with the approval of his/her primary organisation. S/he must also have completed the affiliation process for researchers external to IDIBELL.

**Lead researcher or Principal investigator (PI):** a researcher working within IDIBELL who has a PhD (or equivalent experience) and contributes to the organisation’s research activities through an active, funded research project, for which s/he is responsible in both financial and scientific terms. Equivalent to level R3 of the European framework.

**Lead researcher with leadership capacity:** a researcher working within IDIBELL who has a PhD (or equivalent experience) and contributes to the organisation’s research activities through an active, funded research project, for which s/he is responsible in both financial and scientific terms. S/he must also demonstrate a proven capacity for leadership in his/her scientific field. Equivalent to level R4 of the European framework.

#### 9.1 Trainees

Trainees include all researchers in the post-doctoral category, students enrolled on an official PhD programme, and students undertaking an internship at the institution. Generally, trainees must always have a supervisor who monitors their work. They also have certain rights and obligations, as

detailed in the terms and conditions of their post-doctoral contract, IDIBELL's own regulations for pre-doctoral researchers, or the specific internship agreement that governs their work at the centre, as applicable.

## 10. OMBUDSPERSON FOR RESEARCH

### 10.1 Ombudsperson

The Ombudsperson for Research is an independent, suitably qualified individual of outstanding personal integrity.

S/he is appointed by the institute's directors, on the recommendation of the internal scientific committee, to act as a mediator in the event of any conflict related to good scientific practice.

The Ombudsperson for Research must be accessible to all research staff in the event there is any suspicion of a potential contravention of the principles of good scientific practice. The identity of the Ombudsperson for Research must be made known via the appropriate channels.

The Ombudsperson must act with discretion in relation to any information that may indicate potential misconduct. S/he is not obliged to reveal this information to the management bodies of the institute.

The Ombudsperson's role is to act as a mediator between any of the institute's researchers who detect potential misconduct, and any members of staff (whether researcher or technician) who is suspected of scientific misconduct. If a conflict arises, the Ombudsperson may choose to instigate the mediation process by holding a meeting with the person accused of misconduct, or with the directors of the institute. If the Ombudsperson finds the accusation of misconduct to be justified, s/he will ask the directors to set up an **ad hoc committee** of experts who will decide whether or not the misconduct has occurred, based on the primary data.

The Ombudsperson must generally monitor the institute's research activities and identify any problematic areas that may potentially give rise to scientific misconduct.

If it is considered necessary, the centre may also set up a permanent Research Integrity Committee (CIR, see the section below), which removes the need to set up an ad hoc committee. The CIR complements the role of the Ombudsperson and performs his/her functions in centres that do not have such a figure.

The Ombudsperson for Research and/or the CIR must analyse the accusation and listen to both parties separately, making sure the rights of each party are scrupulously respected. They must obtain and maintain custody of the documentation relating to the case, including primary data (e.g. records of results, laboratory notebooks, etc.), and may seek the opinion of other,

independent experts who are not involved in the case. They have the moral obligation to act with the greatest possible diligence in order to reach a well-founded conclusion as quickly as possible.

Under all circumstances, the Ombudsperson, the ad hoc committee, the CIR and the scientific director are obliged to defend and protect the person who has made the accusation, and to prevent them from suffering any negative impacts as a result of making said accusation. This is particularly important when the person making the accusation is part of the same group as the person who is accused.

Once the facts of the matter have been clarified, a report will be issued that investigates the possibility of scientific misconduct in relation to the accusation that has been made. Any deliberations or actions taken with regard to the accuser and the accused will be kept strictly confidential.

If the persons or bodies responsible conclude that misconduct has indeed taken place, the scientific directors will inform the most senior executives at the corresponding centre(s) (typically the healthcare centre and research institute in question), who will decide on the appropriate disciplinary measures to adopt. If no disciplinary measures are to be adopted, but the prestige of the researcher or his/her group has been damaged, efforts will be made to restore the reputation of the researcher or group, in the extent that it is possible to do so.

Appropriate action will also be taken if it is shown that the accusation was made in bad faith.

Misconduct in research can give rise to consequences for third parties, including research agencies, the editors of scientific journals, and legal authorities. In such cases, the head of the centre and the scientific director must ensure that these parties are notified accordingly.

If the misconduct in question may also potentially constitute a crime, the directors of the centre are obliged by law to notify the legal authorities.

### **10.2 Research Integrity Committee (CIR)**

The CIR is a freely constituted body made up of volunteers from among the members of the centre's internal scientific committee and other research staff. It is set up at the behest of the centre's directors and its purpose is to promote internal awareness and adoption of the code of good practice. The CIR also provides arbitration in the event of any conflicts and assists the Ombudsperson wherever necessary.

The CIR operates independently and serves the needs of research staff at the centres that subscribe to this guide to good practice. Its sole objective is to support quality in research and help preserve its integrity.

The functions of the CIR are as follows:

- a) Uphold compliance with the principles outlined in this document.
- b) Act as an arbitrator in cases of uncertainty or conflict that may arise in relation to the integrity of the research, once the Ombudsperson route has been exhausted. In this respect, the CIR's decisions will be binding on all parties that bring their conflicts before the committee.
- c) Inform and raise awareness among the scientific community and institutions of events, needs and guidance related to ethical and good practice-related matters in the field of biomedical research.

d) Remain alert and receptive to any new problems that may arise in relation to the integrity of the research being conducted.

### Scope of application

With regard to the aforementioned functions, the CIR will ensure that it acts at all times with diligence, independence and impartiality, and respects the anonymity and confidentiality of personal data and the security of any information generated therefrom. It also guarantees to act with objectivity and justification in its deliberations, ensure that its resolutions are equitable, and safeguard the possibility of appealing against said resolutions.

### How to contact the Ombudsperson and the CIR

The Ombudsperson and the CIR can easily be contacted via email. In the event of any potential conflicts or doubt, it is recommended that the individuals concerned have an informal meeting with the Ombudsperson. It is particularly advisable to do so prior to making any type of formal contact with the CIR. Under all circumstances, the Ombudsperson and the CIR are obliged to respect anonymity and confidentiality with regard to the processing of personal data and any other information they may receive.

Composition of the CIR:

- Chair: the Scientific Director.
- Vice Chair: the Ombudsperson for Research.
- Ordinary Members: the Internal Scientific Committee

Members of the CIR are appointed for a period of two years, which may be extended only once, for an additional period of two years.

## 11. MISCONDUCT IN RESEARCH

The basic mission of the research centres affiliated to the ICS is to conduct biomedical research of the highest quality while maintaining the utmost respect for the principles of scientific ethics. Consequently, they will reject any research that does not adhere to these principles.

In accordance with the most widely accepted definition of the term, “misconduct” is taken to mean invention, falsification, plagiarism or other practices representing a significant deviation from those practices that are commonly accepted by the scientific community with regard to the planning, conducting and/or presentation of research results. It does not include differences or errors made in good faith in the interpretation or evaluation of data.

In order to prevent scientific misconduct, it is necessary to make researchers aware of the principles of scientific ethics, make sure that frequent, expert supervision and monitoring takes place at all levels of the process, prevent excessive pressure from being placed on the obtaining of results, and promote the exchange of information between research groups. The institute must implement the rules of good practice in the laboratory and research environment as detailed in this guide, with special emphasis on the systems for collecting primary data, to ensure they cannot be altered. These rules not only reduce the risk of involuntary errors, but also, to a large extent, facilitate the investigation of cases of scientific misconduct.

It is the responsibility of the centre’s scientific directors, both directly and through the

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Ombudsperson for Research, to receive and investigate any accusations of scientific misconduct that made be made by a specific, fully identified individual or group.

The directors of the centre, for their part, must guarantee compliance with the recommendations made in this guide, act on any instances of noncompliance and penalise any repeated instances of noncompliance with the rules for good research practice at IDIBELL.

### ANNEX 1. INFORMATION REGARDING THE COLLECTION AND STORAGE OF DATA

#### Plan for the collection and storage of data

All research protocols establish a system for the collection of data, records and the biological or chemical materials produced as a result of the research processes, along with a plan for their storage and retention.

#### Recording data and rectifications

The lead researcher and their collaborators must, without exception, collect all of the data resulting from the experiments and observations that form part of the research project. The data must be permanently recorded in a database, laboratory notebook or any other appropriate format, and under conditions that allow for it to be accessed and reviewed by third parties. These records must also include changes, errors and negative, unexpected or conflicting results, and must identify the person who produced or observed them.

#### Retaining the data and samples collected

Researchers must ensure they have the necessary media and infrastructure to guarantee correct custody and retention of the documentation and biological or chemical materials that are produced as a result of the research project. The data must also be recorded electronically, and the research project must incorporate a specific plan for the making of security copies, including details of their physical location.

#### Custody and access to the data collected

Everyone that forms part of the research team must be able to access the information pertaining to the data obtained and the interpretation thereof. The lead researcher must keep a separate record of the various data-collection tools (laboratory notebooks, databases, etc.) and the custody arrangements for any samples. These samples must be stored in a way that allows access by third parties.

#### Ownership of the data and samples

All primary documentation (i.e. laboratory notebooks, databases, etc.) and biological or chemical material that is obtained during the research is the property of the institute or institutions that employ the person in charge of the project. For researchers with an associated role (i.e. healthcare centre or university), ownership lies with the healthcare centre.

The person in charge of the project is also responsible for recording, storing and custody of the data. In the event that a researcher moves to another institute, and provided it is necessary, the person in charge of the project can provide the successor with a copy of all or part of the records, electronic databases and laboratory notebooks or aliquots of the biological or chemical material obtained. If the move involves the person in charge, this process must be carried out under the supervision of the centre's directors, who will bear responsibility for the process.

#### Sharing data and samples with third parties

The data and materials resulting from the research shall be considered public and may be shared with third parties, except in cases where restrictions have been put in place due to their potential commercial exploitation in the future.

For data and samples to be shared, a request must be submitted beforehand, in which the applicant must specify how they wish to use the data or samples and agree to bear any related costs. The research team must also be made aware of the request, which will be subject to a transfer protocol and ultimate approval by the person in charge of the research.

Sharing may be limited for reasons of availability, competition or confidentiality. Although personal data or materials can be shared, they cannot be identified, unless specific consent has been given by the person(s) who donated them.

#### Retention time for the data and samples

All original and primary information and biological or chemical material stored as part of a clinical research project must be retained for a minimum of ten (10) years, beginning on the date the results were first published and except for cases where the law allows for shorter retention periods or requires longer ones. If the institution allows it, primary material and information can be stored for longer periods, and may only be disposed of with the approval of the person in charge of the research. For clinical trials, the retention period is 15 years. For experimental projects, the retention period may be reduced to five years following the publication of the data.

### **ANNEX 2. INFORMATION REGARDING AUTHORSHIP OF SCIENTIFIC STUDIES, PUBLICATIONS AND PATENTS**

The condition of author is not dependent on membership of a particular profession, holding a particular hierarchical position, or having a particular type of employment relationship. Rather, it is based on the nature of one's contribution to the research.

Who can be considered an author?

In order to be considered the author of a publication or patent, it is necessary to:

- a) Have made a substantial contribution to the creative process, i.e. the project's conception, design and implementation, or to the analysis and interpretation of the data;
- b) Have contributed to the preparation of the resultant communications, reports or publications; and c) Have the capacity to give a detailed presentation of one's own personal contribution to the research and to discuss the main aspects of the research as a whole.

Authors must give their written approval to the final draft of the original manuscripts that will subsequently be registered or published.

#### Data provision, conclusions and experimental subjects

Simply taking part in the gathering of resources or collection of data (e.g. the provision of routine data or experimental subjects) does not necessarily justify the condition of authorship, although it does necessitate recognition in the acknowledgements.

In projects where the use of samples, analyses or conclusions supplied by third parties is anticipated, researchers should first establish a plan for communication and authorship that takes into account each person's potential intellectual contribution to the project and any other matters related to authorship and copyright.

#### Partially responsible authors

If a publication includes an author who cannot assume responsibility for the entirety of its content, his/her specific contribution must be identified separately, except where such matters are already governed by the journal's own rules.

#### Honorary authors and ghost writers

Any person connected to a research group who, on the basis of their hierarchical position or employment relationship, demands to be included as an author on an ex officio basis, shall be deemed to have violated the principles of research and academic freedom and committed an injustice, if not an outright abuse of authority. Conversely, the omission of anyone who has made a proven contribution to the project in accordance with the criteria detailed in section 8 shall be considered an act of unlawful appropriation of work and intellectual property on the part of the other authors.

#### Indicating authorship in reports

The publishing of reports, monographs or technical documents of a similar nature intended for consumption by third parties must always include a list of the authors of the research project or study, the centre or centres that supported the research and any grants that were received, in the same way that these would be required in a scientific publication or patent document.

#### Order of authorship

As a general rule, the naming order for the authors of scientific publications is as follows:

- a) The first author named is the person who has made the greatest contribution to the research and prepared the first draft of the article.
- b) The last author named is the senior researcher who directed and/or has ultimate responsibility for the research protocol
- c) The rest of the authors can be ordered by the importance of their contributions, or in certain cases in alphabetical order. The author who is in charge of correspondence is the one who bears chief responsibility for the publication process and future interactions that may result from publication of the project.

#### Shared primary authorship

Scientific publications have the right to justify the naming order of the authors of an article. In fact, some journals impose it as a prerequisite for publication. If, in relation to a given project, two or more authors have made equally important contributions and shared the task of preparing the manuscript, they shall both be considered primary authors. This circumstance will be made explicit in the publication of their work. The same criteria can be applied to senior and intermediate authors.

**ANNEX 3. INTERNAL REFERENCES AND INFORMATION**

RESEARCH STAFF REGULATIONS BIOSAFETY

COMMITTEE REGULATIONS ETHICS

COMMITTEE FOR ANIMAL TESTING (CEEA)

REGULATIONS

ETHICS COMMITTEE FOR CLINICAL RESEARCH (CEIC) REGULATIONS

IDIBELL USER MANUAL

DEFINITION OF CATEGORIES AND LEVELS FOR RESEARCH STAFF

## **ANNEX 4. LEGISLATION, REGULATIONS AND DOCUMENTS**

### **A: Research involving human subjects**

Royal Decree 561/1993 on 16 April establishing the requirements for performing clinical trials with medication. (Official State Gazette (BOE) 114 of 13 May 1993.)

Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Oviedo, 4 April 1997. Consulted on 5 July 2002.

Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine. Approved by the Council of Europe's Committee of Ministers on 19 November 1996. Opened for signing by Member States in Oviedo on 4 April 1997 and ratified by the Spanish Parliament on 5 October 1999 (BOE 251 of 20 October 1999). <http://www.boe.es/boe/dias/1999/10/20/pdfs/A36825-36830.pdf>

Decree 406/2006 of 24 October regulating the requirements and accreditation procedures for ethics committees in clinical research. Official Gazette of the Government of Catalonia (DOGC) no. 4748, p. 44904. Ministry of Health, Government of Catalonia.

<http://www.gencat.cat/diari/4748/06293139.htm>

Royal Decree 223/2007 of 6 February regulating clinical trials involving medicines. BOE 33 of 7 February 2004, p. 5429.

<http://www.boe.es/boe/dias/2004/02/07/pdfs/A05429-05443.pdf>

World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. Helsinki, Finland, June 1964. Revised at the 52nd General Assembly. Scotland, October 2000. Consulted on 1 July 2002.

Universal Declaration on the Human Genome and Human Rights: From Principles to Practice. UNESCO, 3 February 2000. Consulted on 5 July 2002.

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

Circular 15/2001 of the Spanish Agency for Medicines. Application of Royal Decree 561/1993 of 16 April on the use of clinical trials involving medicines.

Directive 2001/20/EC of the European Parliament and Council of 4 April 2001, on the approximation of the laws, regulations and administrative procedures of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJEU of 1 May 2001).

European Standard for the Clinical Investigation of Medical Devices for Human Subjects. EN 540: 1993. June 1993.

Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 18 April 1979. Consulted on 1 July 2002.

Royal Decree 426/1980 of 22 February implementing Law 30/1979 of 27 October on the removal and transplantation of organs. BOE 13 of 13 March 1980, p. 5705. <http://www.boe.es/boe/dias/1980/03/13/pdfs/A05705-05707.pdf>

Nuremberg Code, Standing Committee of European Doctors (CPME). Nuremberg, 1967. 16 May 2002.

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

Law 29/2006 of 26 July on Guarantees and Rational Use of Medicines and Healthcare Products. BOE 178 of 27 July 2006, p. 28122.

### **BIOBANKS**

Royal Decree 1716/2011 of 18 November establishing the basic requirements for the authorisation and operation of biobanks for the purposes of biomedical research and processing of biological samples of human origin, and regulating the operation and organisation of the National Register of Biobanks for Biomedical Research.

Decree 234/2013 of 15 October regulating the authorisation, creation and operation of biobanks for the purposes of biomedical research in Catalonia and the Catalan Biobank Network.

### **B: Research involving animal subjects**

Law 32/2007 of 7 November on the welfare of animals with regard to use, transportation, experimentation and euthanasia.

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

Royal Decree 53/2013 of 1 February establishing the basic regulations for the protection of animals used for experimentation and other scientific purposes, including teaching.

Decree 214/1997 of 30 July regulating the use of animals for experimentation and other scientific purposes (DOGC 2450 of 7 August 1997).

### **C: Employee protection**

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

Royal Decree 665/1997 of 12 May on protecting employees from risks related to exposure to carcinogenic agents at work.

Royal Decree 664/1997 of 12 May on protecting employees from risks related to exposure to biological agents at work, and on the Technical Guide for the assessment and prevention of risks related to exposure to biological agents.

Law 31/1995 of 8 November on occupational risk prevention.

### **D: Environmental protection**

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

Law 9/2006 of 28 April on assessing the effects of certain environmental programmes and plans. BOE 102 of 29 April 2006, p. 16820.

Law 22/2011 of 28 July on Law 10/1998 of 21 April on waste.

<http://www.boe.es/boe/dias/2006/04/29/pdfs/A16820-16830.pdf>

### **E: Protection of personal data**

Organic Law 15/99 of 13 December on the protection of personal data. BOE 298 of 14 December 1999.

Royal Legislative Decree 1/1996 of 12 April approving the Consolidated Text of the Intellectual Property Act, regulating, clarifying and harmonising the current legal provisions in this area.

### **F: Other legal texts**

Law 14/2007 of 3 July on biomedical research. BOE 159 of 3 July 2007, p.28826.

<http://www.boe.es/boe/dias/2007/07/04/pdfs/A28826-28848.pdf>

Uniform Requirements for Manuscripts Submitted to Biomedical Journals. International Committee of Medical Journal Editors. NEJ. Med 1997; 336: 310-315.

Law 5/2001 of 2 May on foundations (DOGC 3388, 15-5-2001, p. 6899). Modified by Law 21/2005 of 29 December on financial measures (DOGC 4541, 31-12-2005, p. 44058).

Law 4/2008 of 24 April on volume three of the Civil Code of Catalonia regarding legal persons.

Law 7/2012 of 15 June modifying the third volume of the Civil Code of Catalonia regarding legal persons.

Ministry of Health and Social Security. Statement of citizens' rights and obligations with regard to health and healthcare. Barcelona: Government of Catalonia, 2002.

Policies of general applicability. Subpart A - Responsibility of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science. Consulted on 7 June 2002.

Royal Decree 339/2004 of 27 February on the accreditation of healthcare research institutes (IIS). BOE 63 of 13 March 2004, p. 11409.

Royal Decree 1277/2003 of 10 October establishing the general regulations on the authorisation of healthcare centres, services and establishments.

Decree 407/2006 of 24 October on the creation of the Catalan Council for Continued Education in the Healthcare Professions and Technical Councils for Continued Education. DOGC 4748, p. 44904. Ministry of Health, Government of Catalonia.

Law 30/2007 of 30 October on public sector contracts. BOE 261 of 31 October 2007, p. 44336. <http://www.boe.es/boe/dias/2007/10/31/pdfs/A44336-44436.pdf>

Law 4/2008 of 24 April on volume three of the Civil Code of Catalonia regarding legal persons. DOGC 5123 of 2 May 2008, p. 34378-34424. Correction of errata in DOGC 5170 of 10 July 2008, p. 53507. [http://www.gencat.cat/diari\\_c/5123s.htm](http://www.gencat.cat/diari_c/5123s.htm).

### G: Other reference documents

Berlin Declaration on Open Access to Knowledge: <http://openaccess.mpg.de/Berlin-Declaration>

Law 14/2011 of 1 June on Science, Technology and Innovation; article 37 on dissemination in open access format.

European Research Advisory Board. Scientific publication: policy on open access (online). 2006. EURAB 06.049.

[http://ec.europa.eu/research/eurab/pdf/eurab\\_scipub\\_report\\_recomm\\_dec06\\_en.pdf](http://ec.europa.eu/research/eurab/pdf/eurab_scipub_report_recomm_dec06_en.pdf)

European Scientific Council guidelines for open access (17 December 2007).

[http://erc.europa.eu/sites/default/files/document/file/erc\\_scc\\_guidelines\\_open\\_access.pdf](http://erc.europa.eu/sites/default/files/document/file/erc_scc_guidelines_open_access.pdf)

European Heads of Research Councils (EUROHORCs) Recommendations on Open Access:

EUROHORCs' Recommendations on Open Access:

[http://www.eurohorcs.org/SiteCollectionDocuments/EUROHORCs\\_Recommendations\\_OpenAccess\\_200805.pdf](http://www.eurohorcs.org/SiteCollectionDocuments/EUROHORCs_Recommendations_OpenAccess_200805.pdf)

OpenAire Open Access Infrastructure for Research in Europe, a body created by the European Union in order to develop Open Access. <http://www.openaire.eu/>

## **ANNEX 5. DOCUMENTATION CONSULTED IN THE REVISION OF THIS GUIDE**

- Pere Virgili Institute of Healthcare Research (IISPV) Code of Good Scientific Practice (2012 version)
- Barcelona University (UB) Code of Good Research Practice (2010)
- Barcelona Biomedical Research Park (PRBB) Code of Good Practice (2009)
- August Pi i Sunyer Biomedical Research Institute (IDIBAPS) Code of Good Research Practice (2012)
- Spanish National Research Council (CSIC) Code of Good Scientific Practice
- Carlos III Institute of Health (ISCIII) Accreditation Guide