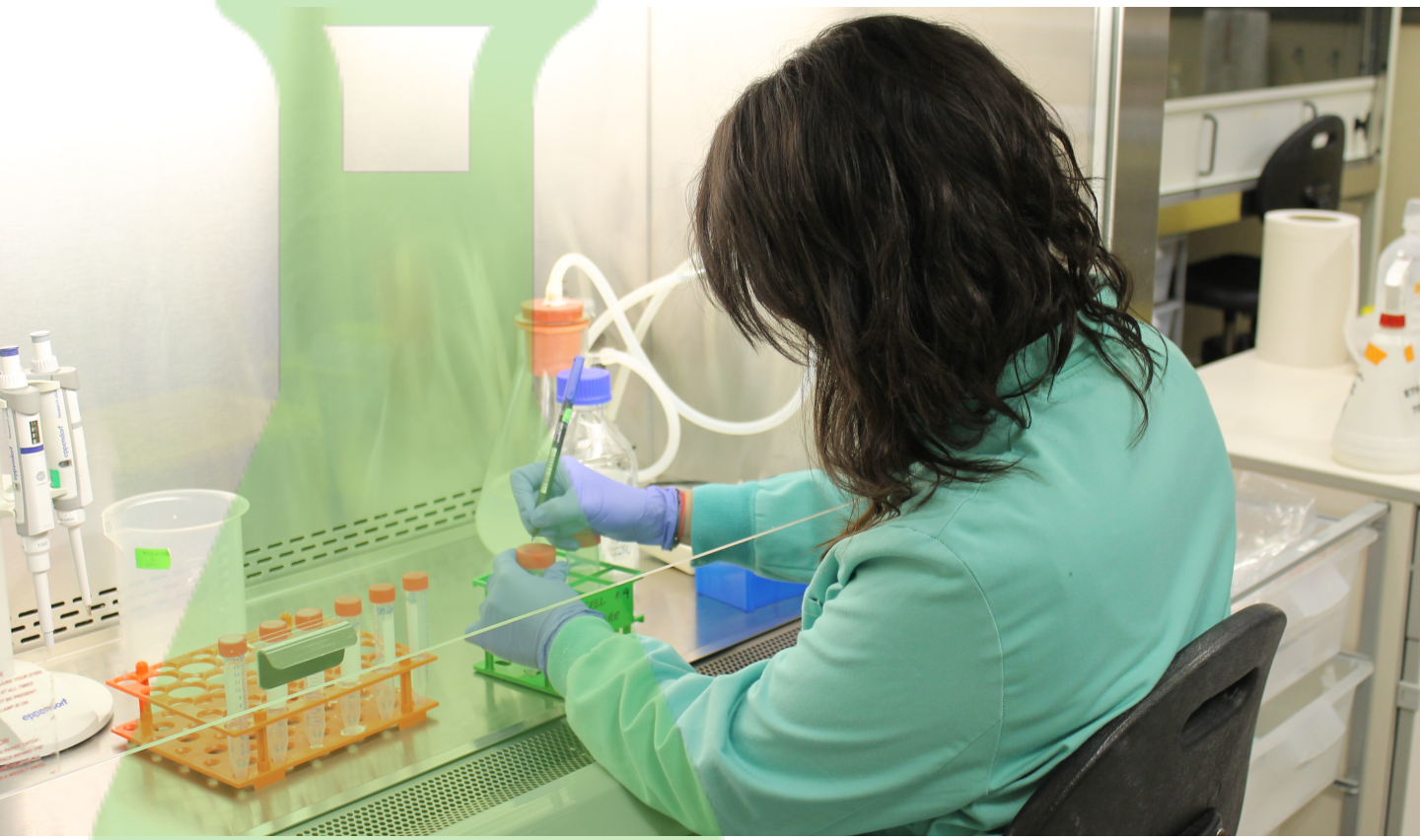
CODE OF GOOD SCIENTIFIC PRACTICE



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and the Josep Carreras Leukaemia Research Institute

The IJC's *Code of Good Scientific Practice* has been drawn up with the aim of improving the quality of the IJC's research and defining an ethical and legal framework for its research.

This *Code* encapsulates our centre's commitment, and that of its research staff, to aim for the highest possible level of excellence throughout the entire scientific process.

Evarist Feliu
President of the Delegate Committee of the Josep Carreras Leukaemia Research Institute

0. Contents

1. Responsibility

1.1 The Centre's responsibility

The management of the Josep Carreras Leukaemia Research Institute (IJC) must ensure that the research facilities fulfil all requirements and have the necessary authorisations for the centre's staff to be able to carry out their scientific tasks.

1.2 The researcher's responsibility

All the Institute's researchers (including staff in training) have the moral and ethical obligation to employ their best efforts to carry out their project, respecting internal regulations and making the best use of the research facilities and material at their disposal.

2. Good practice

The aim of good laboratory practice is to promote quality in the results obtained, avoid the duplication of studies, and save time and resources. The application of these principles contributes to the continued improvement in the protection of human health and that of the environment. These principles can be found in Royal Decree 1369/2000 (see section 12.1 of this manual).

2.1 Relationship between group members and members of other groups

At the Josep Carreras Leukaemia Research Institute we are aware of the importance of a good working atmosphere and comradeship. Our workers should feel at ease in their daily work and this should be a stimulus and cause for motivation. Colleagues in the laboratory, whether they be in the same research group or not, must help each other as far as possible, encourage cooperation and avoid rivalry.
Scornful and/or confrontational attitudes are not tolerated in our centre.

2.2 Laboratory work

The Institute's researchers have the obligation to take all necessary precautions to ensure their personal safety, that of other workers, and the environment. Researchers must use equipment for personal protection (white coats, gloves, goggles), and any additional kind of protection if the protocol so requires.

Eating and smoking in the laboratories is not permitted.

All research activities must be documented in the corresponding Laboratory Logbook which the Lab Manager makes available to each worker. The log entry must be made in pen (or another instrument that can not be erased) and headed by the date and time. No page may be removed and any rectification corrected with a line through the previous text in such a way that it can still be read. Images or results added to the Logbook are to be attached and signed in the margins.

2.3 Residue management

IJC workers must know how to manipulate and eliminate the residues generated in research activities, always ensuring their own safety, that of others, and that of the environment, and using the corresponding labelled containers, when appropriate, in accordance with the regulations concerning dangers and risks. (More information about the manipulation and elimination of residues generated in research activities covered by specific legislation can be found in section 12.2.)

2.4 Research instruments

All scientific instruments acquired by researchers associated with the Josep Carreras Leukaemia Research Institute, are the property of the Institute. If a lead researcher leaves the IJC, the equipment will remain at the Institute, unless an agreement is reached and a waiver document is signed by the two parties involved.

2.5 Research instruments

All the facilities must be appropriate for the carrying out of the planned research activities, both with regard to the personal safety of the people working there, and with regard to the results obtained.

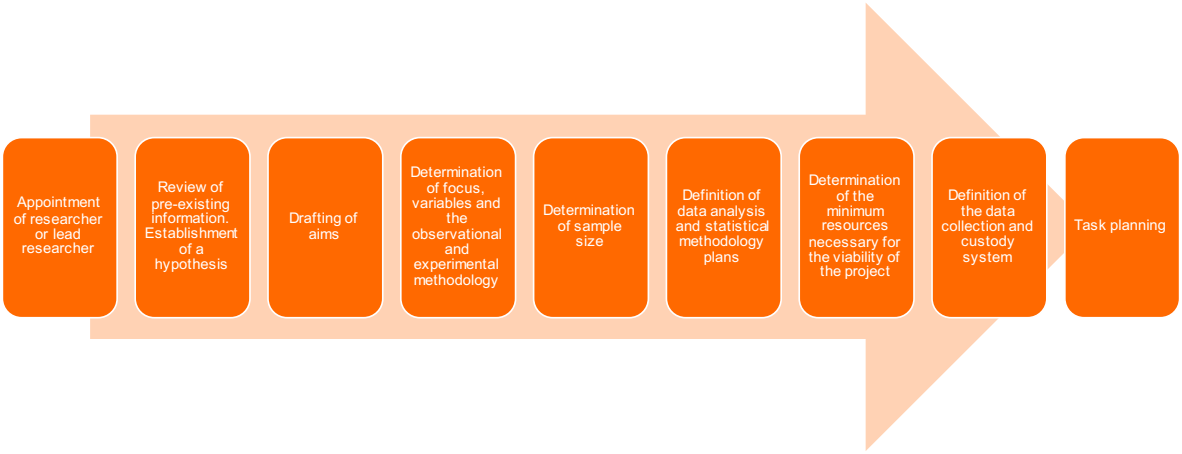
When equipment is used for research activities, researchers must ensure that it is the right equipment for the activities which are to be performed, and that the staff who are to use it have received the necessary instructions to ensure it is used correctly.

All equipment used for research activities is subject to preventive maintenance to avoid any malfunction from altering the results obtained. Similarly, researchers must, at all times, ensure the reliability of the measures provided by the equipment.

3. Research project planning

All research projects require a minimum amount of planning. Without such planning it can not be considered a project, and can not be registered as such with research organisations and, consequently, the criteria necessary to ensure success are lacking.

The design phases for any research project are[1]:



[1] Drafted on the basis of the ICS 2015 guide to good practice in health science research.

4. Supervision of trainee research staff

Everyone at our Institute associated with a research project with the aim of acquiring any kind of training is assigned a tutor.

4.1. Responsibilities of the tutor

Supervisors are to guide those being trained, define their aims and be responsible for their educational process. They must guide and advise them so that they can achieve their aims in the time planned, avoiding their involvement in tasks which do not form part of their training process.

4.2. Number of trainees under the same mentor

The number of trainees under a tutor must be appropriate and compatible with their obligations and commitments.

4.3. Obligations and commitments of the tutor

Tutors must interact personally and regularly with trainees studying under them, supervising their tasks and ensuring their completion. They must also hold regular collegiate meetings to discuss progress made in the assigned tasks and to contribute to keeping trainees' scientific methodology up to date.

Supervisors must vouch for the working conditions of trainees studying under them and for their appropriate training with regard to the prevention of risks in the workplace, as well as with regard to legal regulations in force concerning scientific practice.

4.4. Obligations of trainee researchers

Trainees must take full advantage of the training opportunities provided by the Institute and its supervisors. They must undertake, like all others associated with the IJC, to observe the provisions of the good scientific practice manual and report any situations in which they consider their rights to have been infringed.

5. Research protocols

Before any research can commence it must be previously formulated in writing in a research protocol or project. The lead researcher is responsible for drafting this document and coordinating the team for its implementation.

5.1. Design and drafting of the research protocol

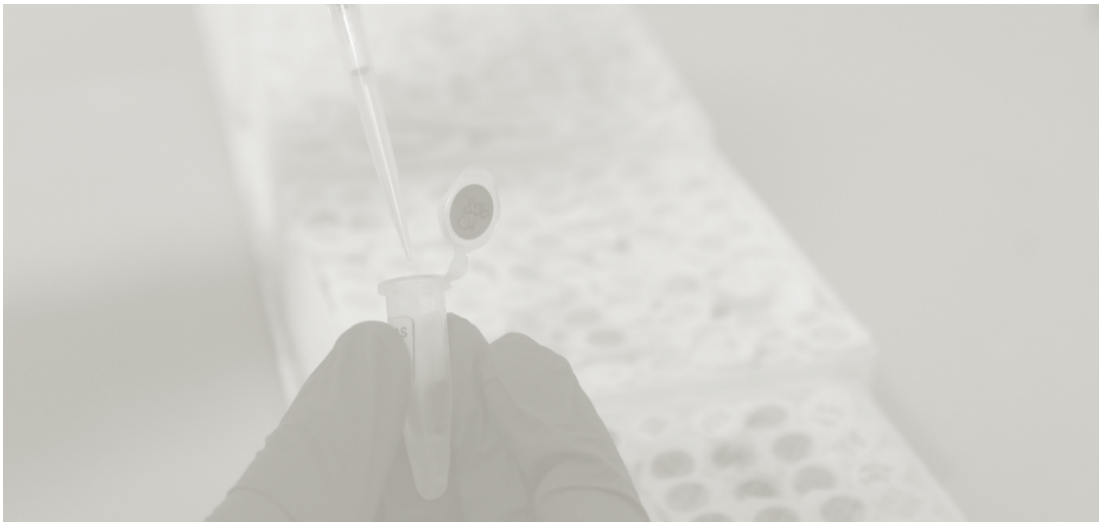
All research protocols must formulate a hypothesis and define aims. The aims must be clear, concise, measurable and achievable so that the proposed hypothesis may be validated or refuted, either partially or totally.

In order to achieve the stated aims, the kind of experiments to be carried out must be previously determined, as well as the number or measure of the sample (so as to have a statistically significant result) and the statistical methodology to be employed in their analysis.

The research protocol must also include a description of the necessary resources to carry out the project, and the time needed to carry it out.

5.2. Research can not be secret

The Josep Carreras Leukaemia Research Institute does not accept the secrecy or omission of research, or of any part of it.



6. Research in humans

If the research to be carried out involves the use of people, human samples, or human data, researchers must observe current legislation (see points 12.3, 12.4 and 12.5).

Protocols that involve the participation of human subjects must specifically address the requirements regarding ethical principles contained in the Helsinki Declaration (latest version: Fortaleza 2013) in order to guarantee the protection of rights, safety and the well-being of the subjects. (See 12.6).
All the protocols involving the participation of human subjects must be reviewed and accepted by the Clinical Research Ethical Committee (CEIC – more information in section 12.9). This committee vouches to respect the rights of patients, volunteers, and people in general who are involved in clinical research projects. Preceptive reports must be sent to this committee on an annual basis and upon conclusion of the study.

6.1. Clinical trials

Clinical trials are experiments conducted in humans with the aim of discovering whether a new drug, therapy, appliance or surgical procedure is safe and efficacious in the treatment of a determined illness.
Clinical trials with drugs must observe, not only the previously mentioned current legislation regarding research in humans, but must also comply with specific legislation (see section 12.10) and be assessed by the CEIC and the Spanish Drug and Health Products Agency (AEMPS).

Any person participating in a study, or donor of a biological sample, for the purposes of biomedical research must be previously informed of the risks and possible benefits and have decided to participate of their own free will. This procedure, known as Informed Consent, must be explained in writing to the possible participant in understandable language and the researcher or doctor must answer any possible doubts the participant might have.

6.2. Biobanks

When biological samples of human origin for the purposes of biomedical research are incorporated into a biobank, these latter are subject to specific regulations, given biobanks' particular vocation as a public service. All human sample collections for the purpose of research must be registered with the National Biomedical Research Biobank Registry in accordance with Royal Decree Law 1716/2011 and annex Order ECC/1404/2013 (see 12.7 and 12.8).

7. Research with experimental animals

When planned research involves the use of experimental animals, such research must comply with Royal Decree Law 50/2013 (see 12.11).

All researchers must base their research with animals on the "Three 'Rs' Rule", understood as:

3R's

Replacement (use of another biological system whenever possible in order to avoid the use of animals)
Reduction (use of the minimum number of absolutely necessary animals)
Refinement (use of suitable procedures to cause animals the least suffering).

In the event that animals must be used as experimental subjects, this need must be justified on the basis of the inexistence of alternative equivalent methods that might be substituted. The procedures for avoiding the suffering of the animals must also be specified, as well as the method of sacrifice, which must be the most appropriate, in accordance with the principle of refinement.

Research staff working with experimental animals must have received prior training and be accredited as research staff authorised to work with experimental animals, in accordance with current legislation. All research with experimental animals must be conducted in an accredited animal unit.

Research may not commence until the animal experimentation ethical committee has given its definitive approval. Upon the conclusion of the study, the preceptive, annual and final reports must be sent to the ethical committee.

8. Research with genetically modified organisms

If the research to be carried out includes the use of genetically modified organisms, it must comply with Royal Decree Law 178/2004, of 30 January, approving the general Regulations for the development and implementation of Law 9/2003, of 25 April, establishing the juridical regime for the confined use, voluntary liberation and commercialisation of genetically modified organisms. (See 12.12.)

9. Registration and conservation of data and biological samples

All research protocols must include a system for collecting data, registers and biological or chemical materials resulting from the research, as well as a plan for their custody and conservation. All research projects that include the obtaining of biological samples are subject to the stipulations of current legislation as specified previously (points 5, 6 and 7).

9.1. Data register

All the data and observations arising from the research must be permanently registered in databases and laboratory logbooks (see point 2.2). The registers must also include the changes, errors and negative, unexpected or discordant results, as well as the name of the person who produced or observed them. Everyone forming part of the research team must have access to the data obtained and their interpretation. The necessary means and infrastructure to ensure the correct custody and conservation of the various forms of documentation must be anticipated. In the case of data recorded on electronic media a specific plan must be included for backup copies with details of their physical location.

All data must be kept for a minimum period of five years from the date of publication (except in cases where a longer period has been agreed) in a way that ensures their integrity and security to avoid any non-authorised modification.

9.2. Property of the data and samples

All the primary data and the biological samples generated during the course of a research project, the person responsible for which is linked to our centre, belong to the Josep Carreras Leukaemia Research Institute. The registration, storage and custody of these data and samples is the responsibility of the person responsible for the project.

In the event of the lead researcher changing institution, all the original registers and collections of biological material shall remain at the IJC, duly identified and placed in the charge of the person made responsible for them. In such a case, the new person responsible for the project may provide the previous person with a photocopy of part or the whole of the logbooks, a copy of the existing electronically stored information, a photocopy of the data registration logs or a part of the biological or chemical material available. In the case of human biological samples (blood, serum, DNA, tissue, etc.) a material transfer agreement must be signed.

9.3. Period for the storage of data and samples

The lead researcher is responsible for the maintenance of the project's data and samples. All the primary information, as well as the samples obtained during the research, must be kept and correctly stored for a minimum period of five years from the date of first publication of the results, except in cases where the law allows for shorter periods or stipulates longer ones (for clinical trials with drugs the minimum period is fifteen years).

9.4. Personal data

None of the data arising from a research project with participating people may contain any kind of information that could lead to their identification. All the derived data must therefore be identified with an individual code for the patient that does not enable their identification. The lead researcher will be the only person to have access to the personal codes associated with participants' personal data.

In the event of it being necessary, in a publication, to identify the participants in a project, the results may only be published if the subjects involved have given their prior approval. Staff responsible for access to personal data are bound by professional secrecy even after their relationship with the Institute has ended.

9.5. Falsification and fabrication of data

Falsification is understood to mean the complete or partial modification of data, the concealment of results, or inexactitude with the intention to deceive. Fabrication of results is the invention of results or data, or procedures which have not been carried out. The IJC does not allow any of these activities and they are considered serious misconduct.

10. Publication, protection and dissemination of research and results

The communication of research results makes the transmission of knowledge and scientific progress possible. Researchers are therefore obliged to publicly present the results of their research, and it is for the scientific community itself to accept and evaluate this new knowledge.

10.1. Peer-reviewed publications

The communication or publication of research results must be presented publicly in peer-reviewed publications or scientific congresses or meetings. This is an ineludible part of any research project.

10.2. Non-published results

The non-publishing of research results, or an unreasonable delay in their publication, may constitute misconduct on account of the misuse of resources. The publication of the results of studies in which people have participated is an ethical imperative.

10.3. Negative results

Negative results, or results which differ from prior expectations, should be published, especially if they are the results of clinical and/or epidemiological studies.

10.4. Incomplete, repeated or plagiarised publication

The fragmentary publication of a study is not acceptable, except as an extension.
The repeated publication of a manuscript, or part of a manuscript, that has already been published is totally unacceptable. If, for reasons of research, properly speaking, it is necessary to include part of a previous publication, this must be clearly stated in the new manuscript and its publishers informed of the fact, as specified in the Vancouver Group Recommendations (see reference 4).

Plagiarism, or the use of ideas, data or results from other sources without consent or acknowledgement is considered scientific malpractice and is totally unacceptable.

10.5. Bibliographic references

All works directly related to the research must be included or cited, both in publications and patent applications and utility models. Reference to such works must be justifiable and deserving of recognition, honorific references must be avoided.

10.6. Acknowledgements

The acknowledgements section of a publication must be strict. People, research groups, services and institutions might decline to be mentioned. The same applies to mentions referred to as "personal communication".

10.7. Ineludible information

Any publication or communication must specifically include the following information:

- The institutions or centres to which the authors of the research belong or belonged, and where they performed their research.
- Their University affiliation.
- The ethical committees that supervised and approved the research protocols.
- Mention of the subsidies, sponsorship or financial assistance received, directly or indirectly, to perform the research.
- A conflict of interest declaration. Conflicts of interests may be financial or personal and should be avoided insofar as possible. Whatever the case, all the authors must sign the declaration.

10.8. Media presentation

The results of research projects may not be presented to the public via the mass media without having previously been accepted by being published in peer-reviewed scientific journals or at specialised congresses.

The dissemination of results in the media must, at least in part, be adapted for a non-specialised audience. In such cases, the names of the authors of the research must be associated with their institutions and, whenever possible, the sources of funding for the project should be mentioned.

The premature dissemination of results in the media is only justifiable for reasons of public health and the authors must ensure that the results are, at the same time, urgently reviewed in parallel by a scientific journal.

Any public dissemination must be based on research results, the opinions expressed must be prudent, and false expectations should not be raised, as recommended by the Barcelona College of Doctors Ethical Code (see reference 5). An incorrect communication can have serious consequences for the researchers and their institution.

11. Authorship of the research

All scientific publications must include the names of its authors, who must endorse in writing the final version of the original manuscript presented for registration or publication.

11.1. Conditions for authorship

To be considered as an author it is necessary:

- To have contributed in a significant way to the creative process, the conception of the project, design of experiments and/or the analysis and interpretation of the results obtained.
- To have contributed to the preparation of the resulting publication or patent.
- To be able to present one's personal contribution to the work in detail and discuss the main aspects of the research as a whole.
- If an author can not assume responsibility for the entire contents of the work, their specific contribution is to be indicated separately.

11.2. Obtaining resources and collecting data

Contributions in the form of obtaining resources (for example, samples or subjects for experimentation), or in the collection of data, do not, by themselves, directly imply the condition as an author of the study, although such contributions should be included in the acknowledgements section.

11.3. Honorary and omitted authors

Any person who, on account of their hierarchical position or social relationship, requests to be included amongst the authors of a work without fulfilling any of the conditions set out in section 10.1 violates academic liberty and commits an act of injustice, which might constitute an abuse of authority.

On the other hand, the omission of the name of any person who has demonstrably contributed to the work constitutes an act of misappropriation of intellectual property by the other authors of the publication.

11.4. Order of mention of authors

As a general rule the order of mention is as follows:

- The first signatory is the person who has contributed the greatest effort to the research and who is the person who prepared the first draft of the manuscript.
- The research director and person responsible for the research and final manuscript signs next.

- The other authors appear in order of importance, contribution or, in some cases, in alphabetical order.

The author responsible for correspondence is the one with responsibility for the entire publishing process and for future contacts and interactions deriving from the publication.

When two or more authors have devoted the same efforts to the project and to the drafting of the initial manuscript, they may share the primary authorship for the project and are to be considered as primary authors. This consideration may also extend to the next signatory.

12. Protection of property

If the results obtained from a research project could lead to inventions or applications that might be of commercial interest, the person responsible for the project is obliged to inform the Institute's management of the fact, so that it may proceed with their protection.

In the case of projects in which the promoter does not form part of the IJC, mutually agreed accords must be drawn up in which all the intellectual and/or technological contributions of the Institute's researchers are noted as well as the conditions for communication and publication of the results obtained.

13. Safety, health and the environment

Researchers must be aware of the safety, health and environmental protection measures to be borne in mind in the exercise of research activities.

Research groups must ensure that their activities are carried out within the terms of the IJC's policies for the prevention of risks in the workplace and for the protection of the environment.

Elements left over from research must be stored and eliminated according to the level of risk and danger they represent in accordance with current regulations for the preservation of the environment and protection of people.

All staff have the right to access information, and to effective protection, with regard to health and safety in the workplace, and have the duty to know the centre's safety regulations and to use the resources, means, installations and services the IJC makes available to them in an appropriate manner.

14. Bad practice in research

Research institutes have, as a fundamental mission, to carry out research of excellence while maintaining a rigorous respect for scientific principles and ethics. We therefore reject any research that does not observe these principles.

According to the most widely accepted definition of the term, bad practice consists of invention, falsification, plagiarism of data and other actions which deviate in a significant way from the practices which are commonly held as acceptable by the scientific community for the proposal, realisation and presentation of research results. Errors or differences made in good faith are not included in the interpretation or judgement of the data.

To prevent the appearance of bad scientific practice, knowledge of the principles of scientific ethics must be promoted, along with expert supervision and follow-up at all levels. Excessive pressure to produce results must be avoided and the exchange of information between research groups encouraged. The Institute must implement the regulations for good practice in the laboratory and in research contained in this document, with a special emphasis of the systems for collecting primary data so that they can not be altered. These regulations not only reduce the risk of involuntary errors but greatly facilitate the identification of cases of bad scientific practice.

It is the task of the research centre's scientific management to directly, and through mediating research staff, accept and investigate any reports of bad scientific practice that may be received from any fully identified person or group.[2]

[2] Drafted on the basis of the ICS 2015 guide to good practice in health science research.

Annex 1
Instructions with regard to the authorship of publications

Introduction

The IJC is an Institute for research into leukaemia and other malignant blood diseases, promoted by the Josep Carreras International Leukaemia Foundation and the Generalitat de Catalunya (Government of Catalonia) ministries of Health, and Business and Knowledge. The Foundation is presided by Mr. Josep Carreras.

The IJC forms part of the of the Generalitat de Catalunya network of Research Centres (CERCA), something that enables it to receive funding from the Generalitat de Catalunya Government Ministries of Health, and Business and Knowledge, in addition to the competitive funding its researchers obtain (from the Carlos III Health Institute, amongst others) and from research projects for private promoters

Although a health institute's research can not be reduced to a single indicator as a significant parameter, research centres use the impact factor as comparative data for their activity.

The activities undertaken by the IJC's researchers within the setting of two centres of knowledge creation and innovation, under the purview of the University of Barcelona and the Autonomous University of Barcelona, namely, the Hospital Clínic-UB Campus and the Catalan Institute of Oncology/Germans Trias i Pujol Campus, leads us to believe that over the coming years there will be a significant increase in research.

Similarly, the diversity of the institutions that form part of the IJC (HCB, ICS, ICO, IDIBAPS, FCRB FIICSGTP, IMPPC, UB, UAB and BSTC), ensures the multiple affiliation of its researchers.

Consequently, in order for people to see their research efforts reflected correctly by the national and international research indicators, certain clear guidelines are required so that the real impact of the IJC may be seen, something expected and required by the Institute's partners.

General guidelines

As a general rule all scientific works in which IJC researchers participate, whatever their contractual arrangements may be, **must always be signed off with the acronym, 'IJC'.**

For the purposes of consistency the **acronym should always be upper case.**

Of course, researchers who also work for other institutions must also mention these too. In this way all the researchers' affiliations are acknowledged together.

The acronym 'IJC' may be accompanied by the full name of the Institute in the language of the publication:

- **Catalan**: Institut de Recerca contra la leucèmia Josep Carreras
- **Spanish**: Instituto de Investigación contra la Leucemia Josep Carreras
- **English**: Josep Carreras Leukaemia Research Institute

Sphere of application

The guidelines that appear in this document are applicable to all scientific works carried out by IJC researchers. 'Scientific works' are understood to mean:

- An original article published in an indexed journal
- A review article published in an indexed journal
- A letter published in an indexed journal
- An editorial published in an indexed journal
- A communication presented at a congress
- A chapter of a book
- Articles of dissemination published in any media
- Opinion articles published in any media
- Other communications of a scientific character.

Structure of the signature

The following order is suggested for the signatures of IJC researchers:

- The name of the researcher. (Given name and one surname. In the case of common surnames, such as López, Fernández, Sánchez, etc., the second surname should also be mentioned, if applicable).
- The name of the Institute [Josep Carreras Leukaemia Research Institute] (IJC)*.
- The name of the clinical institution: ("Servei d'Hematologia Clínica" - HCP or "Servei d'Hematologia - ICO).
- The name of the ISCIII accredited centre: Institut Germans Trias i Pujol (IGTP).
- The name of the corresponding University Campus.
- The name of the other research institutes participating in, or funding, the work.
- The name of the agency funding the research (ICREA, Ramón y Cajal,..), or the name of the thematic network (CIBER, RETIC).
- Others,
  - Name of the town or city: **Barcelona** and/or **Badalona**
  - Country: Spain.

For reasons of space or convenience in some media (opinion articles, for example) the signature can be simplified. The acronym 'IJC', however, must always be maintained.

These guidelines do not affect the postal address of the building where researchers carry out their tasks. The postal address remains the same.

* The full name of the Institute, in square brackets, is optional and may be written in Catalan, Spanish or English in accordance with the indications set out above.

Examples:

IJC Campus Clinic

Pablo Menéndez
Stem cells, mesenchymal cancer and development Group, [Josep Carreras Leukaemia Research Institute], IJC, Clinic-UB Campus, University of Barcelona Faculty of Medicine, 08036 Barcelona, Spain

Ruth Muñoz
Leukemia Stem cell Group, mesenchymal cancer and development, [Josep Carreras Leukaemia Research Institute], IJC, Clinic-UB Campus, University of Barcelona Faculty of Medicine, 08036 Barcelona, Spain

Joan Bladé
Unitat de Gammapatíes Monoclonals, [Institut de Recerca contra la Leucèmia Josep Carreras], IJC, Servei d'Hematologia Clínica, [Hospital Clínic de Barcelona], HCB [Universitat de Barcelona] UB, 08036 Barcelona, Spain

Francisco Cervantes
Unitat de Neoplàsies Mieloproliferatives Cròniques ([Institut de Recerca contra la Leucèmia Josep Carreras], IJC, Servei d'Hematologia Clínica, [Hospital Clínic de Barcelona], HCB, [Universitat de Barcelona] UB, 08036 Barcelona, Spain

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IJC Campus ICO-Germans Trias i Pujol (ICO-GTIP)

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Marcus Buschbeck, Mayka Sanchez, Tanya Vavouri, Fumi Yamamoto
Name of the Group [Josep Carreras Leukaemia Research Institute], IJC ICO-Germans Trias i Pujol Campus, [Programme for Predictive and Personalized Medicine of Cancer at the Institute Germans Trias i Pujol (IGPT)], PMPPC [Autonomous University of Barcelona], UAB, 08916 Badalona, Spain

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Isabel Granada
Cytogenetics Unit, [Josep Carreras Leukaemia Research Institute], IJC ICO-Germans Trias i Pujol Campus, Hematology Service, Catalan Institute of Oncology, Hospital Germans Trias i Pujol, Germans Trias i Pujol Institute (IGTP), 08916 Badalona, Spain

IJC Campus Sant Pau

Name of the Group, [Institut de Recerca contra la Leucèmia Josep Carreras], IJC Campus Sant Pau, Servei d'Hematologia, Hospital Sant de la Santa Creu i Sant Pau, Institut Germans Trias i Pujol (IGTP), 08026 Barcelona, Spain

Annex 2
Scientific practice regulations and legislation

2.1 Royal Decree 1369/2000, of 19 July, modifying Royal Decree 822/1993, of 28 May, establishing the principles of good laboratory practice and their application in the implementation of non-clinical studies on substances and chemical products.
http://www.boe.es/boe/dias/2000/07/20/pdfs/A25832-25838.pdf

2.2 Technical guidelines INSHT, Ministry of Employment and Immigration. http://www.insht.es.

2.3 Law 14/2007, of 3 July, on biomedical research.
https://www.boe.es/boe/dias/2007/07/04/pdfs/A28826-28848.pdf

2.4. Organic Law 15/1999, of 13 December, on the protection of data of a personal nature.
https://www.boe.es/boe/dias/1999/12/14/pdfs/A43088-43099.pdf

2.5 Law 41/2002, of 14 November, on the basic regulation of patient autonomy, and rights and responsibilities with regard to clinical documentation and information.
http://www.boe.es/boe/dias/2002/11/15/pdfs/A40126-40132.pdf

2.6 World Medical Association – Helsinki Declaration: ethical principles for medical research involving human subjects. https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

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