



CODE OF GOOD SCIENTIFIC PRACTICE

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Fundació Privada Sant Joan de Déu per a la Recerca i la Docència

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1. Introduction

The maintaining of ethical principles, honesty in work, and compliance with a code of good scientific practice are essential elements in all investigative work aimed at expanding scientific knowledge that is both credible and respected by society. To this end, the Fundació Privada Sant Joan de Déu per a la Recerca i la Docència has put in place a Code of Good Practice in Research to be adopted by researchers and the centers of Sant Joan de Déu.

There is at present a high level of consensus regarding common principles of good scientific practice. The present document is based upon these and the principles of the Hospital Order of Saint John of God, so as to create a code of good practice adapted to our environment, with full recognition of the fact that the biomedical and social research carried out in our centers is closely tied to our providing of healthcare. Research activity and the fruit that it bears are at the service of society; it is therefore incumbent upon us to be very careful in our treatment of those who participate in this activity.

The vulnerability of the patient, who is the object of healthcare and/or research, has to be reconciled with the individual's dignity as a human being, which he or she is entitled to as a subject requiring understanding, a role in decision-making, and a collaborator in research projects. The Sant Joan de Déu centers attend to those who are especially vulnerable, making it all the more important that we take great care in observing these principles and in maintaining an ethical code.

This document is intended for distribution to all the professionals of the institutions that adhere to this code of good scientific practice.

The body responsible for resolving any conflicts that may arise in the application of this code is the Good Scientific Conduct Committee (CBCC in Catalan), whose members will be named by the governing board of the Fundació privada Sant Joan de Déu per a la Recerca i la Docència. Given that our society and its centers are subject to constant change, it will be this body as well that will have the power to modify this code should the need arise. Such changes as they decide upon will be subject to approval by the governing board.

The centers that have voluntarily adhered to this Good Scientific Practice Code are the following:

- Fundació privada Sant Joan de Déu per a la Recerca i la Docència
- Hospital Sant Joan de Déu, in Esplugues de Llobregat
- Parc Sanitari Sant Joan de Déu
- Escola Universitària d'Infermeria Sant Joan de Déu

2. Research protocol

2.1 All research must have a research protocol with clear objectives, and methods oriented to answering the question posed in the objectives with methodological rigor.

2.2 The research protocol includes: definition of the hypothesis of the study, antecedents to the proposal, specific objectives, the methodology to be followed, the work plan, the calendar foreseen, the resources needed and available, the participating team, and, when the study involves human or animal subjects, the ethical aspects and the provisions made for safety.

2.3 No research protocol may be maintained either partially or totally in secret. Protocols may be restricted in their distribution for reasons of competitiveness or confidentiality, but in no case may this interfere with compliance or with the principles of good practice.

2.4 Any research that joins with a research project that is already underway may involve the need to determine whether the defined objectives of the original project need to be modified. In this case a supplementary project might need to be drawn up. This is of particular importance if there are potentially risky procedures involved that might affect people or animals, as well as the need for biological samples or the use of pharmacological substances. In all of these events the new project that is drawn up will have to be re-evaluated by the corresponding committees, as specified in sections 3.1, 3.2 and 3.3.

2.5 In the event that there is more than one technique for a particular research procedure, the one that is selected must be specified in the protocol and described in a clear and comprehensible manner.

2.6 It is advisable that any research protocol be examined by an independent third party. In some cases this examination is obligatory and is a standard procedure.

3. Required norms of the research protocol

3.1 All research protocols must be submitted to the research committee of the institution where they are going to be carried out. In the event that the institution does not have a research committee, the protocol will be submitted to the research committee indicated in the address of the Fundació Sant Joan de Déu.

3.2 All research protocols that involve studies with human subjects require the go-ahead of the Clinical Investigation Ethics Committee (CEIC in Catalan).¹

3.3 All research protocols that involve studies with animal subjects require the go-ahead of the Animal Experimentation Ethics Committee (CEEA in Catalan).²

3.4 All research protocols that involving the obtaining, treatment, or preservation of human embryonic material require the authorization of the Ministry of Health prior to the go-ahead of the appropriate CEIC.⁴

3.5 All research protocols that involve the obtaining and/or preservation of biological samples must guarantee the confidentiality of donors, regardless of the degree of identification associated with the storage of the samples. Clear information must be provided in writing to interested parties concerning the manner of storage and the end use of the samples. When non-anonymous samples are stored for use in genetic testing, written consent must be provided again each time a new analysis is to be undertaken that is different from what is specified in the first protocol.

¹ Decree 223/2004, February 6

² Decree 214/1997 July 30

³ Commission of Guarantee of Donation and Use of Human Cells and Tissues, affiliated with the Instituto de Salud Carlos III and considered in the bill governing biomedical research currently being acted upon in the parliament.

⁴ In Catalunya the only reference CEIC for this kind of study is affiliated with the CMRB, in accordance with the Decree 406/2006 October 24, regulating the requirements and procedures for accreditation of clinical investigation ethics committees (DOGC 26/10/2006).

3.6 All research protocols that involve the use of institutional information technology files or the creation of databases with information concerning patients or their family members must guarantee the anonymity of these people and are subject to the prevailing regulations regarded recorded databases.⁵

3.7 The principal investigator and the collaborators of research projects involving human subjects will closely follow the research protocol, especially regarding the obtaining of informed consent from subjects, as well as the confidentiality of data, samples, and results.

4. Responsibilities of those who make up the research team

4.1 The principal investigator of the research protocol is responsible for seeing that the research protocol is consistent with all the applicable norms.

4.2 The researchers must bear in mind that their research should be relevant to society and should avoid unnecessarily duplicating prior research carried out by other investigators.

4.3 The researchers have to move their research forward applying the maximum level of scientific rigor.

4.4 The researchers must avoid plagiarism of any kind and must follow the principles of intellectual property, and co-property of the data in projects carried out in collaboration with other investigators. The validation of the results of research with new studies does not constitute plagiarism, as long as the study that is being replicated is explicitly referenced.

4.5 The researchers must maintain a critical perspective on their work and the work of others, and must accept the constructive criticism of other researchers.

4.6 The researchers must be honest and fair in recognizing the work of collaborators, competitors, and predecessors.

4.7 It is the responsibility of the principal investigator to guarantee the accuracy of all of the information included in the project report.

4.8 When research requires using third-party facilities or equipment, authorization of those responsible for the facilities or equipment is required. In the event that the facilities or equipment belong to the same institution, prior authorization of the person in charge of the institution, facilities, or equipment is required. A detailed report must be made on the nature of the project, the use to which it will be put, and the ethical considerations involved in the project. The cost estimate of the project should take into account the possible costs entailed in the use of the facilities.

4.9 The principal investigator of a research project is responsible for periodically ascertaining that the research protocol is being followed, especially regarding the recording and storage of data. The principal investigator and collaborators are responsible for the quality of the collected information and the custody of the data.

⁵ Organic Law 5/1992 October 29; Decree 29/1995, January 10. Law 17/1987 and Law 12/1989

4.10 In the preparation of the individual's curriculum vitae, the author is responsible for the contents. To indicate acceptance of this responsibility the C.V. should be signed.

4.11 Authorization must be requested from the research committee for collaboration in projects based outside the institution to be carried out within it. In those cases involving studies with human subjects the go-ahead of the Clinical Investigation Ethics Committee (CEIC) is required.

4.12 The principal investigator and the collaborating personnel in research projects, whether or not they are in charge of the clinical treatment of subjects involved in the project, have the obligation not to interfere in any action taken by those responsible for treating the subjects in question.

5. Supervision of research personnel

5.1 All personnel who make up the research teams, regardless of their category (technicians, predoctoral fellows, students in practicum, and others) will be supervised by a tutor who is responsible for their training during their time on the project and for assuring that they have the best possible scientific learning experience in their area of research.

5.2 The responsibilities of the tutor are as follows:

a) The tutor will meet regularly with the people in training, in order to insure that their growth and maturity, and scientific progress, are appropriate.

b) The tutor is responsible for regular individualized interaction with the people in training under his or her charge. The tutor provides incentive for the participation of personnel in training as well as the researchers working on the project. Regular meetings are to be held with the aim of insuring that everyone is informed of the different tasks being carried out as part of the project, and also so that the people in training may learn new techniques from the researchers with more experience.

c) The tutor's functions in his or her capacity of trainer include:

Providing support during the design of a research project.

Delving into the methodological problems related to the correct development of the research project design.

Providing support to people in training at difficult moments, lending help and stability so that they can make the effort needed to bring the project to successful completion.

Support in the analysis and publication of research results.

Exploring in depth the ethical dimensions, with special emphasis on those aspects that have a more direct bearing of the particular research carried out by the person in training.

Looking out for the working conditions of the training personnel, as well as their appropriate preparation in matters of workplace risk prevention.

d) The total number of people in training under the charge of a tutor should be appropriate and commensurate with his or her duties and commitments.

e) The personnel in training have rights and obligations distinct from the rest of the personnel having contractual ties with the center as employees. The centers have a document that lays out these rights and obligations. The tutor must remain especially

diligent with the scientific personnel in training, making certain that they are not involved in tasks that are inconsistent with their training.

6. Collaborative projects

6.1 In collaborative projects among different groups at the same institution or at different institutions a document should be drawn up to formalize the terms of the collaboration.

6.2 The collaboration agreement, distinct from the research protocol, should include a description of the research plan for each group, the budget for each group, the follow-up criteria for the project, the distribution of rights and obligations to each group, a plan for the communication of results, procedures for the storage and distribution of data and samples, the distribution of possible commercial rights or patents emerging from the research, and any other subject that might be seen as a source of potential conflict.

6.3 The centers will incentivize collaboration among groups at the same center, among different groups of the Order, and among groups from different institutions, in that a multidisciplinary approach increases the quality of research and enriches both the investigators and the different centers that are involved in the research.

7. Recording and storage of data

7.1 Data, both written and electronic, will be collected in accordance with a previously established protocol. The protocol must include, among other details, the data to be collected and the person to do the collecting. In cases where there is biological or chemical material to be collected, the protocol must also include a registry of collected material. In all cases the storage and preservation of biological and chemical material must be recorded in detail.

7.2 The principal investigator must foresee the necessary support for the proper storage and preservation of both the documentation and the biological and chemical material. A permanent record of the follow-up in log books and notebooks on data collection will be maintained.

7.3 In the case of data collected in electronic form a procedure for storage and security guarantees to restrict access to authorized persons will be put in place.

7.4 If the processes of data collection and data recording do not occur simultaneously, the date of each will be recorded. In like manner subsequent modifications of the first registry will also have their dates noted, as well as the identity of the individual making the modification. Proper registry of books will be used for the follow-up on chemical and biological material banks.

7.5 It is absolutely essential that the principle of protection of the privacy of individuals be maintained, both in the storage of collected data and throughout the process of research, and in the distribution of the results. In all cases the applicable legislation will be observed.

7.6 Those materials used for the obtaining of data (informed consent sheets, reports, images, analytical forms, questionnaires, etc.) must be stored with an identification system that allows for their recognition and association as well as guaranteeing their confidentiality.

7.7 It is important for the principal investigator, or someone delegated by him or her, to define and implement security measures regarding the form and place of data storage, as well as mechanisms for the protection of the data in the event of incidents that may affect their integrity. There needs to a protocol establishing a specific plan for the storage and recovery of backup copies of registries in electronic format. The data must be stored in a clear and orderly fashion so as to allow periodic monitoring and, if needed, a retrospective audit.

7.8 In the case of storage of images, the originals should be kept, whenever possible, even when digitized copies of them are made.

7.9 The principal investigator will insure access to the data registries and chemical and/or biological material banks related to the research at all times and for all members of the research team. He or she will also place this information at the disposition of the other researchers in the center if they should request access to and use of the data, unless there are restrictions placed upon them in consideration of future commercial use. The request for access will be accompanied by a research protocol to be reviewed by the scientific committee and the Clinical Investigation Ethics Committee, the approval of both of which will be required before access to samples may be granted. Those requesting this use will be responsible for the production and processing costs.

7.10 All primary, original information, as well as biological and chemical material collected, must be stored for a minimum of ten years' time from the first publication of the results, except when a longer period of time is established. The disposal of biological material will require the go-ahead of the principal investigator.

7.11 All of the documentation and biological and chemical material collected in the course of research are the property of the institution, where they will remain in storage in accordance with the criteria of the principal investigator of the project. In the case of studies with external promoters, ownership of the documentation and collected material will be defined by the contract that is signed.

7.12 If a member of an investigative team changes institutional affiliation and requires information concerning the research carried out during his or her research period, the principal investigator may provide a partial or complete copy of the documentation or part of the material collected, based on the researcher's participation in the research activity and the reason for the request made for such material. In the event that the member of the research team changing institutional affiliation is the principal investigator, the copies will be made under the supervision of the Management of the Fundació and the scientific management of the center.

7.13 Special care should be taken regarding information concerning the purpose, drawbacks, and possible risks and benefits of the research, as well as the obtaining of specific written consent of those participating, and the confidentiality of data, samples, and results obtained. Furthermore, as clinical research is a process in which obtaining data is complex, and not necessarily repeatable, the research team should pay special attention to the quality of data collection and the procedures for storage and care of the data.

7.14 All primary, original information, as well as biological and chemical material stored as results of any research project, must be preserved for a minimum of ten years from the date of the first publication of the results, except in those cases in which the law permits shorter periods or requires longer periods. If the center allows, the information and primary material shall be stored for prolonged periods and their disposal will require the approval of the person in charge of the research.

8. Protection of equipment and use of dangerous materials

8.1 The scientific management of the center (or the medical management if there is no scientific management *per se*) and the management of the Fundació will undertake to study the appropriate location for any equipment that is acquired, in conjunction with the person responsible for equipment and the personnel in the center in charge of this area. Before requesting any equipment the future location planned for it needs to be considered. The authorization of the person in charge of research at the center is therefore required.

8.2 The researcher responsible for the equipment will also insure its correct use and functioning, as well as making certain that it is available to other research groups at the center and in the Order. The guiding principle here is collaboration.

8.3 The scientific director of the center (or the medical director if there is no scientific director *per se*) will insure as far as possible that the scientific equipment acquired by the centers is used in an optimally efficient manner. It should be used by as many research groups as possible. If the demand at the center for this equipment is less than the internal supply, the equipment should then be made available to other research groups outside the center, while also reckoning the cost that this might entail for the center.

8.4 Each piece of equipment shall be covered by a protocol governing its use, maintenance, protection, and repair, as well as by a protocol concerning the measures to be taken in the event of equipment malfunction or failure.

8.5 The center that owns the equipment will be responsible for its maintenance, as well as for the training of the personnel that handle it.

8.6 The protocols for the handling of equipment are to be included in the workplace risk prevention plan of the center that owns it.

8.7 Incidents involving the equipment used for data collecting should be recorded in writing with ample documentation.

8.8 The professionals that handle hazardous materials should be properly trained and supervised to avoid risks to themselves, third parties, and the environment.

9. Circulation of research results

9.1 The results of research should be presented to the scientific community for critical evaluation and for verification by professionals who are expert in the material at hand.

9.2 Whenever possible these results shall be published in prestigious specialized journals, both national and international.

9.3 Excessive delay in publication, or non-publication of the results of an investigation, as well as exaggerated claims made, may be considered misuse of resources. Furthermore, attempts should be made to publish negative results and those that differ from initial expectations.

9.4 Reporting of research results will also be made at scientific congresses as well as by any other means of communication that is directed not only at the scientific community, but also at society at large—the ultimate beneficiary of such research activity.

9.5 The authors of a study must recognize and publicize any errors that may have been made in the research they carried out.

9.6 The transfer of technology developed in research projects is necessary and helps to enrich society. It must always follow the applicable laws governing intellectual and industrial property.

9.7 Fragmentary publication of unitary research is not acceptable. Fragmentation is only justified by reasons of extension.

9.8 Duplicate or redundant publication is considered to be unacceptable. Secondary publication is only justified under the terms established by the Norms of the Vancouver Group.⁶

10. Publication policy

10.1 The person with ultimate responsibility over the research project shall be the one to authorize publication of the results, both in terms of the content and the place or means of publication.

10.2 The definitive publication of the results of the research shall make reference to the institutions or centers with which the authors are affiliated, the institutions that have made the research possible, the scientific method followed, the legal aspects that apply, the ethical committee that approved the study, and the financial aid received to carry it out.

10.3 Publication of the results aimed at society in general should follow publication in scientific journals. Prior or premature publication may be exceptionally justified for reasons of public health. In such cases mechanisms shall be put in place to guarantee that the results may be reviewed by independent scientific investigators either before or concurrent with publication. This publication must be approved by the Committee for Good Scientific Practice.

10.4 If the carrying out of the research involves the use of other scientific studies these must be explicitly mentioned.

10.5 The acknowledgements section must strictly observe the principal that those persons or institutions given recognition also give their permission to be recognized in this manner.

⁶ See the criteria regarding “Acceptable secondary publication,” Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, Updated February 2006. International Committee of Medical Journals Editors, [http:// www.icmeje.org/](http://www.icmeje.org/)

10.6 All publication must make specific mention of all financial aid received by the project and the researchers from both public and private sources.

10.7 Priority should be given to the quality of publication rather than the quantity. Repetitive and redundant publication that adds no new results to the research should be avoided. Secondary publication of results is only acceptable under the terms of the Norms of the Vancouver Group.

10.8 If the results obtained from research may lead to inventions or applications potentially subject to protection because of their commercial value, the person in charge of the research project has the obligation to inform the management of the center and to manage the publication of the results in scientific journals with this possibility in mind.

11. Publication authorship

11.1 Publication should include those investigators who contributed significantly to the research (conception and design and/or analysis and interpretation) and who are familiar with the completed content of the published text. The authors must have participated sufficiently with the investigation so as to be publically responsible for it.

11.2 Authorship is determined by contribution to the research work, and not by professional position held at the center. Anyone requesting recognition as an author by dint of his or her position in the hierarchy is violating the principles of fair play. The omission of a participant in the list of authors implies an unwarranted appropriation of authorship.

11.3 All authors must accept, in writing, the final version of the manuscript to be submitted for publication.

11.4 The following order shall be observed when ascribing authorship:

- The principal author shall be the person making the greatest effort in the research and the one making the first draft of the future article. If an article represents equal efforts and equally important contributions to the research, more than one principal author may be identified as such.
- The participant with the next greatest level of responsibility will follow.
- The remaining authors will be listed either in order of importance or in alphabetical order (to be decided).
- If an author has not contributed to all aspects of the study, he or she may be credited for the specific contribution made.

11.5 The production of final reports, working reports, and technical reports, or any other documents intended for third parties, must include, in the same manner as a scientific article or patent application, a list of the authors of the research or investigation, the center or centers where it is carried out, and the financing received for it.

11.6 In preparing his or her curriculum vitae, the author is responsible for the accuracy of its content. To this end, every copy of the CV that is provided must be signed. In the case of a collective article, it need only be signed by the person responsible for the application.

12. Peer review

12.1 The term 'peer review' covers the examination by and criticism of expert peers of a manuscript submitted for publication, an annual report, an experimental clinical protocol, or a final report.

12.2 Reviews must be objective and carried out in good faith. An offer to review should be rejected when there may be conflicts of interest on the part of the investigator.

12.3 Reports and other documents subject to review are always to be handled as confidential and privileged material, and must never be used in an inappropriate manner (using the information obtained from the review for the benefit of an individual, or revealing the contents to third parties without explicit consent to do so). A review must never be delayed in order to obtain advantage of any kind.

13. Research projects sponsored by the healthcare and pharmaceutical industries or other profit-making organizations

13.1 One of the aims of investment in research is to see that the results are transferred to industry, so as to increase the competitiveness and wealth of a region or country. Industry promotes the transfer of technology and can provide resources to centers that carry out research.

13.2 Centers must provide incentives for collaboration with industry, but they must also establish agreements that regulate the intellectual property that results from research.

13.3 All agreements on financing intellectual property, as well as all compensation, either direct or indirect, that may result from research, must be included in a single written agreement to be signed by the institutions with which the researchers participating in the study are affiliated. Financial agreements must be accessible by the bodies, committees, and individuals with responsibility in the matters concerned.

13.4 The publication of the results of sponsored research is an ethical obligation. In the case of projects financed by external entities, agreements may be made with the sponsors allowing them to examine the results of the research before its publication, including the regulation of the sharing of intellectual property rights. To this end, the sponsoring company may enjoy, exclusively, the rights to the results obtained from the research for a maximum of 90 days' time.

13.5 Research sponsored by healthcare industry companies or other profit-making companies must follow the same procedures and guidelines as all other research projects.

13.6 In the event that a promoter requests the participation of researchers from the institution solely for the collecting of data under a protocol (as, for example, in a clinical trial), and the contract between the institution and the promoter includes an agreement concerning communication and publication of the results, then these must be made public regardless of the results of the research.

14. Research projects sponsored by donations from individuals or other organizations

14.1 Research projects carried out with donations from individuals or organizations will follow the same procedures as all other research projects.

14.2 The publication of the results of the research will include explicit acknowledgement of any financial aid received.

14.3 It is not permitted to accept donations or enter into collaboration agreements with entities whose activities represent a hazard to public health.

15. Good Scientific Conduct Committee

The Good Scientific Conduct Committee (CBCC) is a body whose composition will be designated by the management of the Fundació on the basis of nominations made by the research committees of the centers, the Clinical Investigation Ethics Committee, and the executive board. It shall be composed of five members, one of whom will act as chairperson and another as secretary.

Its aims are to:

1. oversee compliance with this code.
2. act as an arbitrating body in the event of conflict.
3. be open to needs and problems that may arise related to good scientific conduct, and update the code when deemed necessary.
4. keep the scientific community informed and increase awareness in the centers concerning events, needs, and approaches related to ethical and deontological questions in biomedical research.

5. stay attentive and open to new questions and problems that may arise concerning the integrity of research.
6. remain impartial in its decision-making.
7. meet at least once a year, or more frequently if needed, at the convenience of the members.
8. hold *ad hoc* meetings when a matter of urgency requires.

Investigative personnel of the center and the centers may approach the CBCC through a formal letter addressed to the chairperson thereof.

Acknowledgements

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