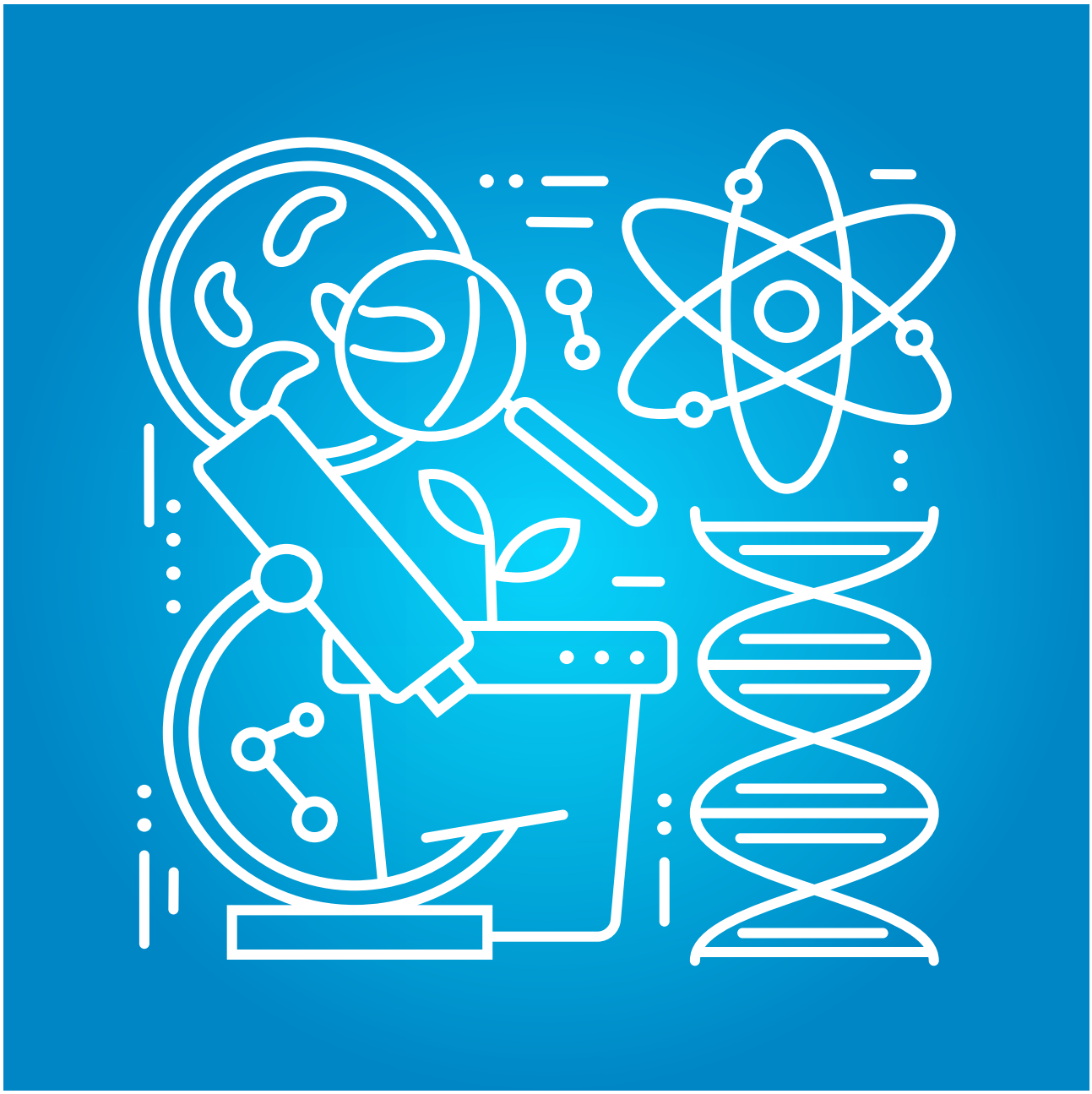
SJD
Sant Joan de Déu
Institut de Recerca

CODE OF BEST SCIENTIFIC PRACTICES



2021 version (approved on 28 June 2021 by the IRSJD Governing Council)

This document has been prepared by the Working Group on Best Scientific Practices (E. Mazarico, S. Ochoa, N. Riba, O. Nadal, E. Puig, P. Brotons, R. Artuch and J. Ribot) based on the Code of Best Practices of the FSJD, drawn up in 2006 and reviewed in 2009.

SJD
Sant Joan de Déu
Institut de Recerca

Santa Rosa, 39-57
08950 Esplugues de Llobregat · Barcelona
T. 936 00 97 51
info@fsjd.org
www.irsjd.org

Introduction

This document sets out the key principles intended to govern our organisation and guide our day-to-day work in science. We aim to conduct biomedical research characterised for its excellence, honesty, integrity and professionalism, with a common goal of enhancing the health, quality of life and living conditions of patients and their families.

The goal is to lay out a framework incorporating all those general best practice principles that are relevant to all those people involved in research – those who direct, coordinate, take part in, foster and manage research – taking into consideration the applicable legislation and regulations. This code should allow us to promote and ensure we deliver research of scientific and ethical quality whilst anticipating issues in terms of integrity. In this respect, the ombudsperson of our institution, Dr Montserrat Esquerda, relies on this code and the Best Practices Committee to uphold and assure the integrity of the organisation.

The Code of Best Scientific Practices of Institut de Recerca Sant Joan de Déu (IRSJD) is aligned with the European Code of Conduct, the Code of Conduct of CERCA (the Research Centres of Catalonia) and the initiatives promoted by the Committee for the Integrity of Research in Catalonia, the collegiate body charged with advising research execution and funding agents within the research, development and innovation system about the promotion and consolidation of best practices in the field of research, and likewise about the analysis and prevention of conflicts of integrity in research.

1 The research protocol

1.1. Every research project must have a research protocol defining a clear objective and specifying the methods used, which should make it possible to address the issue posed by the objective with methodological rigour.

1.2. The research protocol includes: a definition of the working hypothesis, the background to the proposal and justification of the need to conduct the study, the objectives (one primary objective and other specific ones), measurement variables for each objective, the methodology that should be adopted, the work plan, the envisaged timetable (if the study involves the active participation of patients, the activities to be carried out at each visit), the available and necessary resources, the participating team, and in the case of studies involving humans or animals, the ethical considerations, safety precautions and a section setting out how patients' information shall be handled to ensure their privacy in accordance with Spanish Organic Act 3/2018, of 5 December, on Personal Data Protection and Digital Rights.

1.3. The research protocol must be identified with a title, a version and a date. This makes it possible to identify the latest approved version, and indeed the one each research team is working with. If changes are made to an approved research protocol, the version number and date must be updated to identify the latest approved version that must be used. This is particularly important if it involves potentially risky procedures affecting humans or animals, and it is also the case when the collection of biological samples or the use of pharmacological substances is needed. In all of these cases, the new version of the amended protocol must be re-assessed by the respective committees, as indicated in sections 3.1, 3.2 and 3.3.

1.4. Applications submitted to calls for funding do not constitute research protocols. In order to optimise the time devoted by research staff, whenever the aim is to conduct a research project it is advisable to draw up the comprehensive protocol. Using this document (which must be identified with a title, a version number and a date), it will be possible to copy the information that is required for each funding call the researchers wish to apply for. Likewise, it will be useful for presentation to the Ethics Committee.

1.5. It is advisable for any research protocol to be independently reviewed by third parties, except when this review is already a compulsory step and forms part of the institutional process.

1.6. It is not permissible for a research protocol to remain confidential in full or in part. Protocols may be subject to restricted disclosure owing to confidentiality and competition reasons, although this must not impact the fulfilment of best practice principles.

2 Information for the patient and informed consent (PIS/ICS)

2.1. The research protocol for research projects involving participation of patients (intervention studies) or use of clinical history data must be enclosed with the patient information sheet and informed consent sheet (PIS/ICS).

2.2. When the project involves the participation of minors, an information and consent sheet must be drawn up for the parents or legal guardians along with an information and assent sheet for minors over the age of 12 years, which must be drafted in simpler terms.

2.3. The informed consent sheet from the parents must be signed by both parents. If only one parent is signing, it will be necessary to check the box guaranteeing that the other parent agrees.

2.4. Only under exceptional circumstances may an exemption from seeking consent be permitted.

2.5. The PIS/ICS must be drawn up in separate documents to the research protocol and should

also be identified with a version number and date. They shall be updated as changes are incorporated into the originally approved versions.

2.6. The content of the PIS must include: notice that the patient is being asked to take part in a research study, the objective of the study, the activities that patients included in the study will need to perform, the time participants will need to devote, the known risks of taking part, the potential benefits for participants (if there are none, as is the case with an observational study, this must be clearly stated), the fact that patients may withdraw at any time with no detriment to their medical monitoring, information about the insurance policy taken out (if necessary), details about how biological samples will be processed during the study and after it concludes (if samples are collected; see point 4.4) and information about how the data will be processed to ensure patient privacy (the minimum requirements of Spanish Organic Act 3/2018, of 5 December, on Personal Data Protection and Digital Rights must be met).

2.7. The text must be drafted in a way that allows it to be understood by individuals who are not involved in medicine or health. Consequently, excerpts of the research protocol should not be copied into the patient information sheet because the vocabulary is too specialised.

3 Regulatory requirements of the research protocol or scientific report

3.1. The Research Committee (or similar body) of each institution must be aware of all research activity being carried out at said institution. In this respect, mechanisms are in place to enable research staff to secure approvals, certificates, etc., from the relevant committees.

3.2. Any research protocol that encompasses studies involving humans or the collection of people's data, or which involves the use of biological samples of human origin, must not begin until approval has been granted by the Drug Research Ethics Committee (CEIm, from the Catalan).[1]

To enable the CEIm to assess a research protocol, the following is needed: the research protocol (as per the requirements of point 2.2), the PIS/ICS when the study involves patients or use of patient data or indeed the usage of biological samples (as per the requirements of point 3) and the CV of the principal investigator. If funding has been secured, the financial report and details about the type of funding must be submitted.

3.3. Any research protocol involving experimentation with animals must not begin until approval has been granted by the Animal Research Ethics Committee (CEEA, from the Catalan).[2]

3.4. Any research protocol that involves the obtainment and/or storage of biological samples of human origin must ensure the confidentiality of donors, regardless of the level of identification applied to the samples stored. Clear written information must be provided to interested parties about how these samples are stored and what their final us will be. The obtainment, management and storage of biological samples for research must be carried out in accordance with the provisions of Spanish Royal Decree 1716/2011.[3] The patient information and consent sheet must make specific reference to the provisions of article 23 of said Decree. The content of this information will vary depending on whether samples are collected for a project or to be included in the Biobank. In the latter case, the HSJD Biobank version of the information and consent sheet must be used. It is advisable to use biobank services to ensure compliance with current legislation and to guarantee the traceability of samples.

When identifiable samples are kept to carry out genetic testing:

1 Spanish Royal Decree 1090/2015, of 4 December.
2 Spanish Decree 214/1997, of 30 July.
3 Spanish Royal Decree 1716/2011, of 18 November, laying down the basic requirements for the authorisation and operation of biobanks for the purposes of biomedical research and the processing of human biological samples, and regulating the operation and organisation of the National Biobank Register for biomedical research.

– Written consent must be sought anew every time new analyses are intended to be conducted provided these differ to those envisaged in the initial protocol – unless the patient has given consent for the samples to be stored in the Biobank. In the latter case, where possible, patients shall be informed about new studies carried out with their samples in case they wish to exercise their right for the samples to be destroyed or for their use to be restricted, although a specific consent form does not have to be signed by patients for every project.

– Upon obtaining the sample, the consent that was signed by patients must be reviewed in case they wished to exercise their right to be told the results of the analyses conducted and act accordingly.

3.5. Any research protocol that entails the obtainment, processing and/or preservation of biological material of human embryonic origin must benefit from the relevant authorisation from the Spanish Ministry of Health,[4] following approval from the relevant specific CEIm.[5]

3.6 Any research protocol that entails the use of institutional computerised files or the preparation of databases containing information about patients and/or their relatives must assure the anonymity of said individuals and adhere to current regulations in terms of data protection.[6]

3.7 The principal investigator and the collaborators on a research project involving human beings shall faithfully and exclusively adhere to what is laid down in the research protocol, especially with regard to obtaining informed consent from the participants and the confidentiality of the data, samples and findings.

4 Responsibilities of the members of the research team

4.1. The principal investigator on the project is in charge of ensuring that the research protocol adheres to all regulatory aspects.

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

4.3. The researchers must pursue their research adhering to the utmost level of scientific rigour.

4.4. The researchers must avoid any kind of plagiarism and must stick to the principles of intellectual property and co-ownership of data for projects carried out in cooperation with other researchers or supervisors. The validation of research findings through new studies does not constitute plagiarism provided the research that the study seeks to replicate is explicitly cited.

4.5. The researchers must uphold a critical perspective of their work and that of others whilst being prepared to accept constructive criticism from other researchers.

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

4.7. It is specifically incumbent on the principal investigator to assure the veracity of all aspects set out in the project report.

4.8. If it is necessary to use external facilities, central services such as laboratories and sample extraction, or equipment for a research project, approval must be sought from the director of the relevant institution, facility or equipment. If the scientific equipment or premises pertain

4 The Committee for the Guarantee of Donation and Use of Human Cells and Tissues, attached to Carlos III Health Institute and envisaged in the Act on Biomedical Research (currently under parliamentary review).

5 Within the geographical scope of Catalonia, the only relevant CEIm for these kinds of studies is attached to the Centre for Regenerative Medicine of Barcelona (CMRB), according to Spanish Decree 406/2006, of 24 October 2006, regulating the requirements and procedures for the accreditation of clinical research ethics committees (Official Journal of the Government of Catalonia-DOGC of 26/10/2006).

6 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). Spanish Organic Act 3/2018, of 5 December, on personal data protection and the guarantee of digital rights.

to the institution itself, prior permission must be sought from the director of the institution, or from the individual in charge of the team or facility. Detailed information must be provided about the nature of the project, about what the facilities will be used for and about the ethical aspects associated with the project. The project budget must envisage the cost that using those facilities may entail.

4.9. The principal investigator on a research project shall be responsible for regularly checking that the entire team are appropriately adhering to the research protocol, particularly when it comes to recording and storing data. The principal investigator and the collaborators shall be responsible for the quality of the information compiled and for safeguarding the data.

4.10. When drawing up the personal curriculum vitae, the author shall be responsible for the content of it. To demonstrate that this is the case, it is advisable for the curriculum to be signed.

4.11. Authorisation will need to be sought from the Research Committee for collaborations on projects that are external to the institution when they are conducted at the institution itself. In instances that entail studies involving humans, people's data or biological samples of human origin, approval will be required from the Drug Research Ethics Committee (CEIm).

4.12. Whether or not they are responsible for the clinical treatment of the individuals involved in the project, the principal investigator and the staff collaborating on research projects are required to not interfere in any aspect determined by the physicians treating these individuals.

5 Supervision of research staff

5.1. All staff who are training for any category or stage of education (pre-doctoral, post-doctoral, students on placements and others) shall be guided by a supervisor who shall be entrusted with their training over the envisaged period to allow them to attain the best scientific education possible in their field of research.

5.2. The functions of supervisors are as follows:

a. To hold regular meetings with the people undergoing training so they can gradually progress on the path to attaining suitable consistent maturity and scientific projection.

b. To individually and regularly interact with each person undergoing training who they are responsible for. Supervisors must encourage staff undergoing training and researchers working on the same research project to take part in regular meetings. This will ensure that all staff are familiar with the various tasks being carried out on the project and it will also allow the people undergoing training to learn new techniques from research staff with greater experience.

c. Their functions as trainers are as follows:
- To provide support when shaping the design of a research project.
- To thoroughly examine the methodological issues associated with the smooth unfolding of the design of the research project.
- To support the person undergoing training at times of difficulty, aiming at strengthening and providing stability in the endeavour needed to engage in the research process.
- To provide assistance in the analysis and publication of the research findings.
- To look more precisely into the general ethical aspects, but focussing in particular on those linked to the specific research being carried out by the person undergoing training.
- To ensure suitable working conditions for staff undergoing training, and to ensure they are suitably prepared in terms of occupational risk prevention.

d. The total number of people undergoing training for which a single supervisor is responsible should be appropriate and compatible with the scope of his/her obligations and commitments.

e. The staff undergoing training have different rights and obligations to the other people who are contractually linked to the institution. Institutions must have a document describing these rights and obligations. Supervisors must be particularly diligent with scientific staff undergoing training, preventing them from becoming involved in tasks that are unrelated to said training.

6 Collaborative projects

6.1. For collaborative projects between various groups from the same institution or from different institutions it is advisable to draw up a document setting out the terms of collaboration and the responsibilities.

6.2. Aside from the research protocol, the collaboration agreement must include: a description of the research plan of each group, the budget for each group, the criteria for project monitoring, the distribution of rights and obligations in each group, the plan for dissemination of the findings, the procedure for the storage and distribution of data and samples, the distribution of potential commercial rights or patents stemming from the research findings, and all aspects deemed suitable which could become the subject of a conflict.

6.3. Institutions shall encourage collaboration between groups from within said institution, between various groups at Sant Joan de Déu and between groups from varying institutions, since a multi-disciplinary approach brings about enhanced quality of research and constitutes an enriching component for both the researchers and the various institutions.

7 Recollida i emmagatzematge de dades de recerca

7.1. All the data and biological samples collected during a research project must be coded during collection if they belong to patients: any information allowing the patient to be identified should be deleted and the data must be assigned a code. The data collection sheet should never include information that would allow the patient to be identified. It is not acceptable to use a patient's initials to code personal data. Moreover, the date of birth, postcode, telephone number or email address should not be collected. This information will appear in the medical record but should never appear on the data collection sheet. The data collection sheet of each patient will be assigned a code. As long as a link is established between the code and the identity, this data will allow a patient to be identifiable. The file incorporating the link between the code and the identity of the patient must be safeguarded, albeit separately from the file containing the data collection sheets.

In the field of research the most common scenario is for data to be coded, but said data are neither anonymous nor anonymised. In order to anonymise a personal detail the file that contains the link between the code assigned and the identity of the patient would need to be destroyed. This makes the patient unidentifiable and, as a result, will not allow us to collect data thereafter if we have omitted to include a specific one.

Anonymous data refer to those that are directly collected from the patient and at no point is there a need to establish a link between the information compiled and the identity of the patient. This scenario is the least common in the field of research. Anonymous data may be used when conducting surveys if it is not necessary to undertake any subsequent monitoring.

7.2. Both the written and the electronic data shall be collected in accordance with a protocol put in place beforehand. Among other aspects, this protocol must specify the date on which the data are compiled and the individual compiling them. Whenever biological or chemical material is collected, a record must be prepared detailing the material collected. In all cases it is necessary to provide details of the storage and preservation of biological or chemical material and data.

7.3. The principal investigator must envisage the various formats that will be required for suitable safeguarding and preservation of documentation and biological or chemical material. A record will be kept for monitoring the data collection notebooks or record books.

7.4. In relation to data collected in electronic format, it will be necessary to incorporate a storage procedure and guarantee that access can be restricted to authorised individuals.

7.5. If the processes for collection and recording are undertaken at different times, the date of each event must be recorded. It will also be necessary to specify the date on which subsequent amendments are made to the original record, and if such changes are made, to note down the individuals who make those changes. To do this, suitable record books shall be used to make it possible to monitor the banks of biological or chemical material.

7.6. It is vital to uphold the principle of protecting individuals' privacy both when storing the data collected during the research process and when processing and disseminating the findings. In all cases it is necessary to adhere to current legislation.

7.7. All instruments that assist in obtaining the data (informed consent sheets, reports, images, analyses, questionnaires, etc.) must be stored using an identification system that allows those instruments to be recognised and linked to the data, while ensuring the privacy of such data (coding; see point 8.1).

7.8. It is important for the principal investigator or, by delegation, one of his collaborators to define and shape security mechanisms when it comes to the location and the way in which the data will be stored. Said individual should also establish mechanisms to protect the data in the event of risky incidents that could affect their integrity. In this regard, it is important for there to be a protocol in place setting out a specific plan for the storage and collection of back-up copies of records that are in electronic format. The data must be stored in a sufficiently clear and orderly manner to allow them to be regularly monitored and, if necessary, to enable retrospective auditing of them to be conducted.

7.9. If images are stored, whenever possible the originals must be kept and a digitalised copy of them should be made at the same time.

7.10. The principal investigator shall ensure that any member of the research team can have access to the data records and to banks of biological and/or chemical material associated with a specific research project at any time. This information shall also be made available to the remaining researchers at the institution so they can request to access and use the data provided no restrictions are put in place as a result of future commercial activities. The application for the transfer must be accompanied by a research protocol, which will be reviewed by a committee and the CEIm, who will need to approve the transfer of the samples. The applicant will be required to bear the costs of production and shipment.

7.11. All original and primary information along with the biological material collected must be kept for a period of at least five years following the initial publication of the findings, unless the law stipulates that a longer period applies. Any plans for use of the biological material will need to be approved by the principal investigator. It is advisable for any surplus samples to be incorporated into the Biobank so they may be used subsequently for other research projects.

7.12. All the documentation and biological material collected during a research project are the ultimate property of the institution, where they must be adequately safeguarded in accordance with the criteria established by the project's principal investigator. In the case of studies with sponsors from outside the institution, the ownership of the documentation and material collected may be defined in the relevant agreement signed.

7.13. If a member of the research team changes institution and needs information from the research project conducted as part of his research activity, the principal investigator can provide him/her with a copy of all or some of the documentation or some of the material collected depending on his/her participation in the research project and the purpose for which he/she is requesting this material. If the team member changing institutions is the principal investigator, any copies must be made under the supervision of the steering committee of Institut de Recerca Sant Joan de Déu and the scientific directors of the institution.

7.14. It is necessary to be particularly careful when it comes to all aspects of information about the purpose, the disruption, and the potential risks and benefits of the research project, and with regard to the obtainment of express specific consent in writing from the participants and the confidentiality of the data, samples and findings obtained. Moreover, given that in the field of clinical research the procedure for obtaining data is complicated and is not always likely to be repeated, the research team must focus in particular on the quality of this collection process and on the procedure for safeguarding the data.

7.16. The Best Scientific Practices Committee may review primary data records to ensure the traceability thereof.

8 Protection of equipment and use of hazardous materials

8.1. It will be incumbent on the governing council of each institution to work with their team leader and those individuals at the institution with authority in this area to examine the most suitable location for placing the equipment acquired. Before requesting any equipment it will be necessary to envisage its future location; therefore, it is vital to seek authorisation from the director in charge of research at each institution.

8.2. The researcher in charge of the equipment shall be responsible for ensuring it operates properly and must ensure it is made available to other research groups at the institution. Collaboration must be the prevailing standard in this regard.

8.3. The governing council of each institution must ensure to the extent possible that scientific equipment acquired by institutions is used in an optimal, effective manner. The person in charge of the equipment must give due consideration to potential internal and external scientific collaborations to maximise the use of said equipment. Alternatively, the potential for delivering external services may be examined.

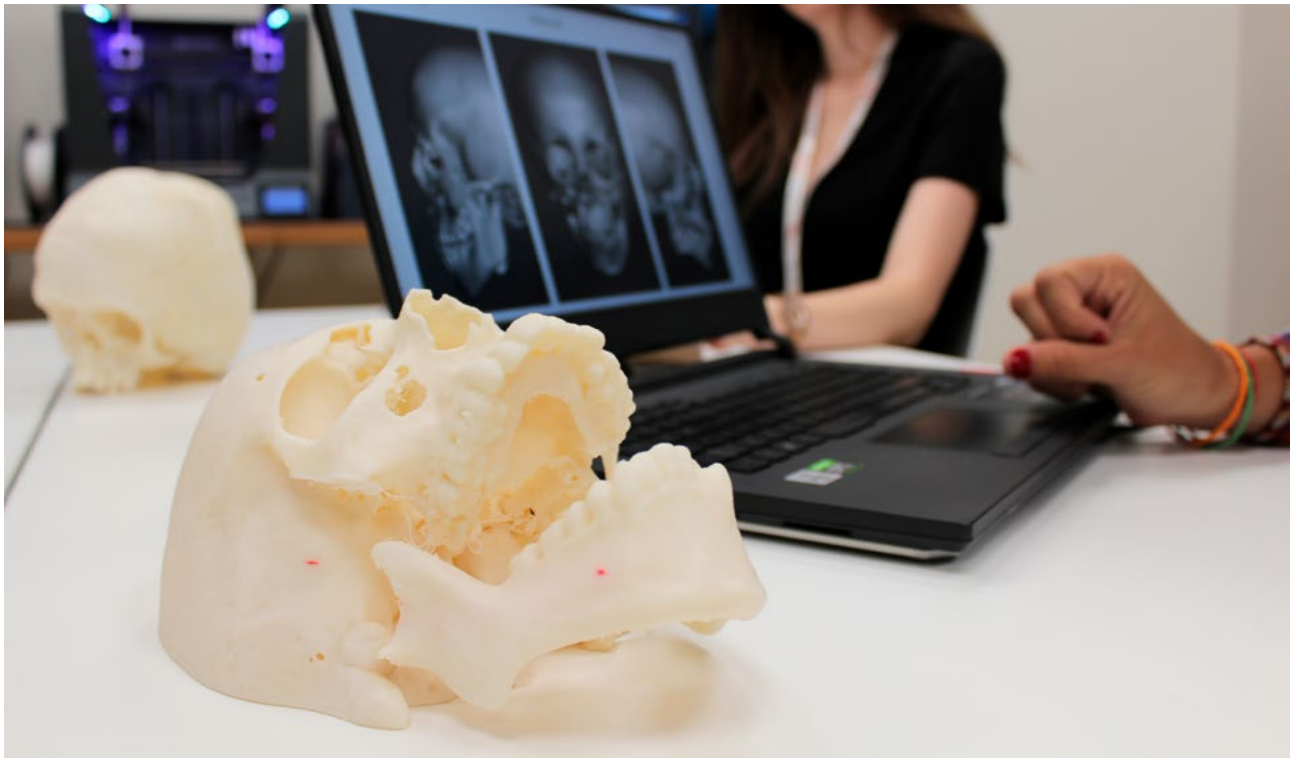
8.4. Each item of equipment shall benefit from protocols setting out the rules for its use, maintenance, protection and repair, as well as protocols to define prevention measures in the event of a fault.

8.5. The institution to which the equipment belongs shall be responsible for its maintenance and for training staff entrusted with handling the devices.

8.6. The protocols for handling devices are included in the occupational risk prevention plan established by the institution that owns the equipment.

8.7. Incidents involving data collection equipment must be recorded in writing to ensure they are suitably documented.

8.8. Professionals responsible for handling hazardous materials must be trained and monitored to prevent potential risks to themselves, to third parties and to the environment.



9 Dissemination of research findings

9.1. The research findings must be disseminated among the scientific community so they can be reviewed and assessed critically, and if necessary, so they may be verified by professionals with expertise in the subject.

9.2. Where possible, the dissemination of data shall be carried out starting with its publication in nationally and internationally renowned specialised journals.

9.3. An excessive delay in publishing the findings of a research project or failure to do so, as well as the overstatement of these findings, may be deemed misuse of the resources allocated. Moreover, efforts should be made to also publish findings that are negative or that differ from those originally expected.

9.4. The dissemination of research findings shall also be carried out at scientific meetings and conferences, and via any other media outlet that disseminates research findings to the scientific community and indeed to wider society, who will ultimately benefit from the research activity.

9.5. The authors of a paper must acknowledge and reveal any errors they have made in their scientific disseminations.

9.6. The transfer of the technology developed as part of research projects is essential and constitutes a means of ensuring society is better off. In all cases, currently applicable industrial and intellectual property laws must be respected.

9.7. The publication of a single research project broken down into parts is not acceptable. Fragmentation in this manner may only be justified due to restrictions on length.

9.8. Duplicate or redundant publication and self-plagiarism are considered unacceptable practices. Secondary publication may only be justified under the terms established in the Vancouver Recommendations.[7]

10 Publication policy

10.1. The individual with the highest level of responsibility over the research project shall grant permission for the findings to be published. This authorisation shall refer to both the content of any release and the publication medium or place.

10.2. The definitive publication of the research findings must clearly state the institutions or organisations to which the authors belong, the institutions that have enabled the research project to be conducted, the scientific method pursued, any legal aspects relevant to the project, the ethics committee that approved the research protocol and any financial grants received.

10.3. The dissemination of the findings among wider society must take place after they are disclosed in scientific publications. The early or premature publication or dissemination of findings may be justified under exceptional circumstances on the grounds of public health. In these circumstances, mechanisms shall be put in place so that the findings may be reviewed by independent researchers either before or at the same time as they are published. Any dissemination in this manner must be approved by the Best Scientific Practices Committee.

10.4. If other scientific papers have been used to conduct the research project, they must be explicitly mentioned.

7 See the criteria on "Acceptable secondary publication" in: 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.icmje.org/

10.5. The acknowledgments section should be comprehensive but strict. It shall be incumbent on the principal investigator to ensure that permission has been sought from the persons and institutions detailed in this section so they may be referenced therein.

10.6. All financial grants from public or private sources that the project or researchers have benefitted from must be specifically set out in all publications.

10.7. When publishing, priority must be given to the quality of the publications in which findings are released rather than the number of publications. Repetitive and redundant publications that do not add new findings to the research should be avoided. Secondary publication of findings shall only be acceptable under the terms established in the Vancouver Recommendations.

10.8. If the findings obtained in a research project have the potential to give rise to inventions or applications that could be subject to protection owing to their commercial interest, the leader of the research project is required to report this to the governing council of the institution and oversee the publication of the findings in scientific journals taking into consideration this potential scenario.

11 Publication authorship

11.1. The publication should include all researchers who have substantially contributed to the research (conception and design and/or analysis and interpretation) and who are aware of the full content of the publication. Authors will need to have contributed sufficiently to the research in order to be responsible for its dissemination.

11.2. In keeping with the recommendations of the International Committee of Medical Journal Editors (ICMJE), authorship should be based on meeting the following conditions:

- Substantial contributions to the conception or design of the work; or to the acquisition, analysis or interpretation of data.
- Taking part in drafting the work or reviewing it critically for intellectual content.
- Being involved in final approval of the version to be published.
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work have been appropriately investigated and resolved.

11.3. Authorship status is conferred owing to the contribution to the research project rather than due to the professional position held at the institution. Any person who asks to be listed as an author *ex officio* due to their hierarchical status will be breaching the principles of fairness. Leaving out a research participant from the list of authors constitutes misappropriation of authorship of the work.

11.4. Every author must give written acceptance of the final draft of the manuscript to be submitted for publication.

11.5. When it comes to the order of authorship, the guidelines applicable to the discipline of the published work shall be taken into consideration. In any event, when the contribution from each author differs, the following common practice recommendations will be followed:

- The first author shall be the individual who has made the most substantial contribution to the research project and prepared the first draft.
- The last author shall be the individual who is leading the research project or the individual who has the final say about the research protocol.
- The remaining individuals can be listed in order of contribution, and in certain cases, if their contributions are similar they may be listed in alphabetical order, specifying that this criterion has been applied.
- When two or more individuals have devoted the same effort to a project and shared the preparation of the manuscript, they will share the status of first authors. This circumstance must be clearly stated in the paper. The same criterion may also apply in the case of senior authors.
- The author who is primarily responsible for the entire editorial process and for future interactions arising as a result of the publication shall be in charge of correspondence.
- Where possible, the specific contributions of each author shall be detailed.

11.6. The publication of accounts, technical or work reports or any other brief addressed to third parties should always include a list of the authors behind the research or investigation, the institution or institutions with which they are affiliated and any subsidies received in the same manner that would apply to a patent or scientific publication.

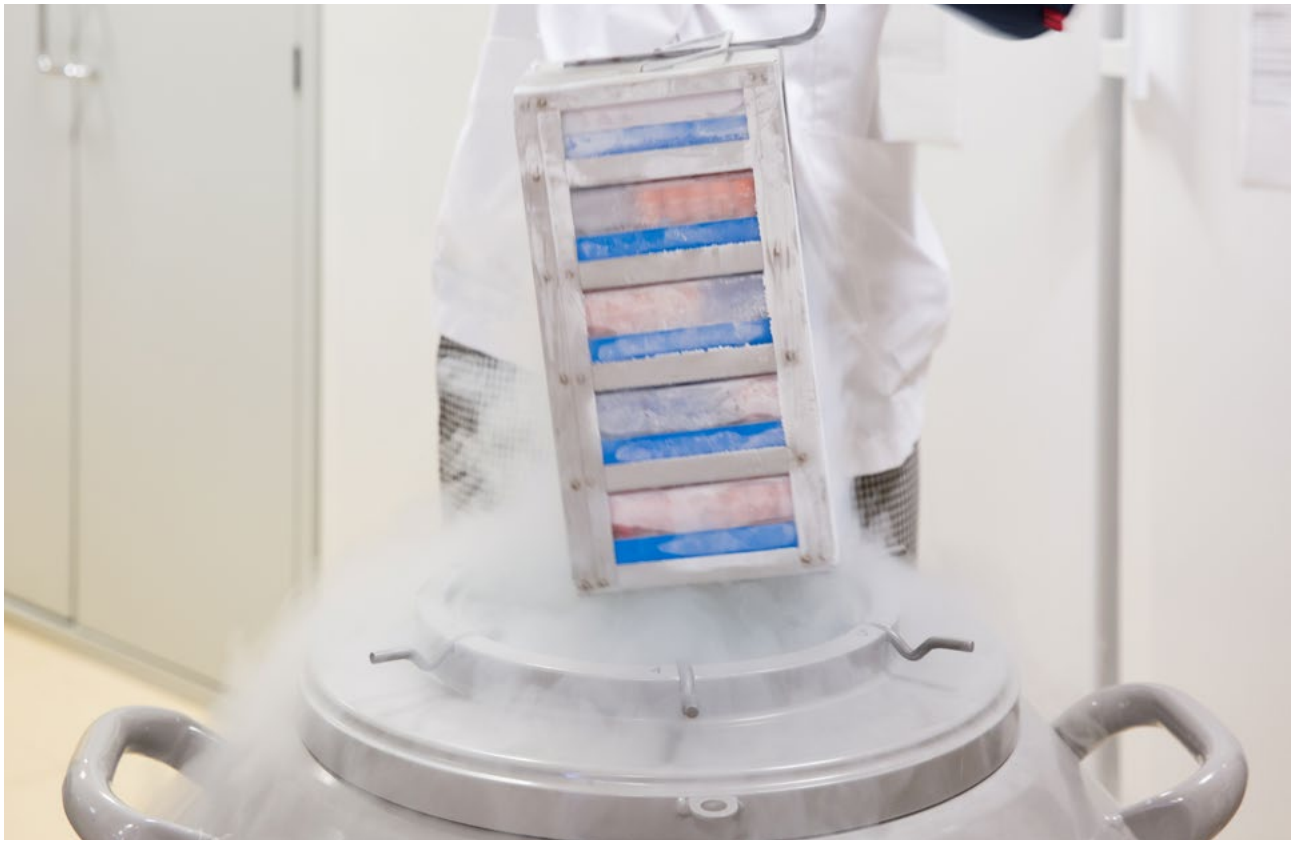
11.7. When preparing the curriculum vitae, the author shall be responsible for ensuring its content is accurate. Along these lines, he must always place his handwritten signature on the curriculum document given to him. If it is a collective paper, it only needs to be signed by the person responsible for the request for publication.

12 Peer review

12.1. Peer review shall refer to any task involving the review and critique by an expert or similar of either a paper submitted for publication, an account, an experimental clinical protocol or a report.

12.2. Reviews must be performed objectively and in good faith. A review must be discarded whenever the researcher may have potential conflicts of interest.

12.3. Reports and briefs undergoing review always constitute privileged and confidential information; consequently, they may not be subject to improper use (using the information reviewed for the benefit of the individual or disseminating the content to third parties without explicit consent). A review should never be delayed with a view to securing personal benefit.



13 Projects sponsored by the healthcare or pharmaceutical industry, or other for-profit organisations

13.1. One of the goals of investing in research is for the findings of this research to be transferred to industry, thereby enhancing the competitiveness of a specific region or country. Industry promotes technology transfer and can provide resources to enable institutions to conduct research.

13.2. Institutions must incentivise collaboration with industry, but agreements must be set up to regulate the intellectual property associated with the research.

13.3. All financial and intellectual property agreements, as well as all compensation that arises directly or indirectly from the research, must be set out in a single written agreement, which shall be signed by the institutions with which the researchers taking part in the project are affiliated. The financial covenants must be accessible to the bodies, committees and people with responsibility for the issues covered.

13.4. It is an ethical requirement to publish the findings stemming from research that has been sponsored. In the case of projects funded by external organisations, agreements may be established with the sponsor to enable said party to review the research findings prior to their dissemination, thus allowing a consensus to be reached on the sharing of intellectual property.

13.5. Research sponsored by the healthcare industry or other for-profit organisations must adhere to the same procedures and rules as all other research projects. Clinical trials involving healthcare products and medicines must be conducted in line with the specific applicable regulation (Spanish Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, ethics committees for investigation with medicinal products and the Spanish Clinical Studies Registry).

13.6. In instances where the sponsor only calls upon the institution's researchers to take part in data collection adhering to a protocol (such as clinical trials), the agreement signed by the institution and the sponsor shall include a covenant about the disclosure and publication of the findings obtained. It is essential that it is clearly pointed out that the findings will be disseminated regardless of the outcome of the research.

14 Research projects sponsored through donations from organisations or private parties

14.1. Research projects carried out through nominal donations from organisations or private parties shall follow the same procedures as all other research projects.

14.2. When disseminating the research findings, any grants received must be explicitly acknowledged.

14.3. It is inappropriate to accept donations or enter into business collaboration agreements with organisations whose activities pose a danger to public health.

15 The Best Scientific Practices Committee

15.1. The Best Scientific Practices Committee shall be appointed by the governing body of the organisation.

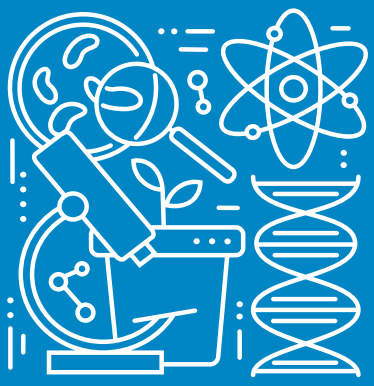
15.2. The Committee shall be formed by members of the various institutions that are signed up to this Code of Best Scientific Practices, and it shall include at least one representative per institution.

15.3. The goals of the Best Scientific Practices Committee are as follows:

- To ensure compliance with this code.
- To act as the arbitration body in the event of a conflict.
- To be receptive to issues and needs relating to good scientific conduct and to update this code when deemed appropriate.
- To report to and raise awareness among the scientific community of each institution about events, needs and guidelines relating to the ethical and moral aspects of biomedical research.
- To be alert and receptive to new issues relating to the integrity of the research.
- To act impartially in any decisions made.

15.4. The operation of this Committee shall be as follows:

- The Committee shall meet at least once a year, notwithstanding the fact that further meetings may be held if its members consider it suitable.
- The Committee shall meet ad hoc when any urgent issue needs to be resolved.
- The research staff of an institution or one of the institutions signed up to this code can directly address the Committee by formally writing to its chair.



SJD
Sant Joan de Déu
Institut de Recerca

Santa Rosa, 39-57
08950 Esplugues de Llobregat · Barcelona
T. 936 00 97 51
frecerca.info@sjd.es
www.irsjd.org