

Code of Good Scientific Practice



Barcelona
Biomedical
Research
Park

Research centres

Hospital del Mar Medical Research Institute
www.imim.es

Dept. of Experimental and Health Sciences of the UPF
www.upf.edu/cexs

Centre for Genomic Regulation
www.crg.eu

Centre of Regenerative Medicine in Barcelona
www.cmr.b.eu

Barcelona Institute of Global Health
www.isglobal.org

Institute of Evolutionary Biology
www.ibe.upf-csic.es

Pasqual Maragall Foundation
www.fpmaragall.org

**Code of Good
Scientific Practice**



Foreword

The public entrusts the scientific community with the responsibility for undertaking high quality scientific research. In hand with this responsibility comes the expectation that this research work is always done in good faith, with honesty and integrity. The Code of Good Scientific Practice of the centres of the Barcelona Biomedical Research Park (PRBB) represents a set of recommendations and commitments governing scientific activities. The aim is to create an environment conducive to high-quality research and prevent problems from arising in relation to the integrity of scientists in their work. The recommendations complement current legal regulations.

The Code of Good Scientific Practice constitutes a framework for self-regulation. The content has been supervised and updated as part of the remit of the PRBB Good Scientific Practice Working Group (GSP Working Group). The GSP Working Group¹ is made up of nominated representatives of all PRBB Centres².

In the event of enquiries concerned with good scientific practice, each PRBB Centre has nominated two contact individuals (GSP Centre Contacts)³. Any member of staff working in a PRBB Centre who has an enquiry regarding good practice should contact the Centre Contact of their affiliated institution in the first instance⁴. In the rare event of an issue that cannot be resolved by the centre, an ad-hoc committee with representation from all PRBB Centres may be constituted under the leadership of the Director of the PRBB.

As evidence of the acceptance of the contents of the updated Code of Good Scientific Practice, the directors of the PRBB Centres have signed an original copy and have committed to promoting dissemination and adherence to its contents within their centres.

¹ See Section 9

² The term “PRBB Centres” is used to refer to the following institutes collectively: the Hospital del Mar Medical Research Institute (IMIM), the Department of Experimental and Health Sciences of the Pompeu Fabra University (CEXS-UPF), the Centre for Genomic Regulation (CRG), the Centre of Regenerative Medicine in Barcelona (CMRB), the Barcelona Institute of Global Health (ISGlobal), the Pasqual Maragall Foundation (FPM) and the Institute of Evolutionary Biology (IBE).

³ For current GSP Centre Contacts for all issues related to good scientific practice please see:
<http://goodpractice.prbb.org>

⁴ In the exceptional circumstance of conflicting interest with both Centre Contacts, individuals may contact the Director of the PRBB or the Chairperson of the GSP Working Group.

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1. Supervision of researchers in training

1.1. Assignment of a supervisor All individuals linked to a PRBB Centre either through a contract or grant in order to receive some form of training⁵ will be assigned a supervisor⁶.

⁵ Training as a scientist; this includes undergraduate students, postgraduates, individuals with diploma-level education and others.

1.2. Responsibilities of supervisors The supervisor defines the objectives and takes responsibility for the education of the individual in training, and should advise and guide the individual in order that the expectations of the initially proposed training may be fulfilled within the time allotted. Furthermore, the supervisor must provide the individual with the best possible conditions for the development of his or her future scientific career.

⁶ The term supervisor also refers to a tutor or thesis/project supervisor.

1.3. Limits to the number of individuals assigned to a single supervisor The total number of trainees for whom a single supervisor is responsible should be appropriate and compatible with the extent of the supervisor's obligations and commitments.

1.4. Rights and obligations of individuals in training Trainees have rights and obligations that differ from those of contracted individuals in the centre. The supervisor should be especially diligent in ensuring that trainee scientists are not involved in performing tasks outside those prescribed by their training. Trainees should not participate in projects with commercial restrictions on the publication of results. Trainees should commit to taking full advantage of the educational opportunities offered by supervisors, centres and the PRBB community.

1.5. Obligations of supervisors The specific obligations of supervisors are as follows: a) to interact personally with trainees for whom they are responsible on a regular basis in order to supervise the tasks with which the trainees are entrusted and ensure that those tasks are completed; b) to encourage regular meetings to discuss the progress of the assigned tasks and contribute to the scientific and technical development of the trainees; c) to monitor the working conditions of trainees and ensure that they receive appropriate health and safety training; d) to provide trainees with up-to-date information regarding legal requirements affecting scientific activities (see Section 8).

2. Preparation of research plans

2.1. Written projects subject to scrutiny by outside parties

All research projects that directly involve humans, experimental animals, or human embryonic material, must be formulated in a written research plan prior to their initiation. The text of the written plan must have been independently assessed



by an ethics committee on clinical research and/or animal experimentation⁷. This text generally coincides with the written proposal necessary to obtain approval and funding⁸.

⁷ See Section 8.

2.2. Unacceptability of secret research Under no circumstances should a research plan, or any part of such plan, remain secret. This stipulation differs from temporarily restricted access to certain research plans or parts thereof for reasons of competition and confidentiality.

⁸ A project proposal includes as a minimum requirement, the background to the project, specific objectives, proposed methods, a work plan including a predicted time scale, available and necessary resources, and the names of persons in the participating team. According to the type of study to be undertaken, the project proposal may also include ethical, legal and safety provisions, as well as a plan for the communication of the results of the study.

2.3. Extension or modification of the research plan In research involving humans, or experimental animals, or in some cases where there is extension or alteration of the primary objectives of the research⁹, the development of an unexpected or additional research question may require preparation of a corresponding complementary written plan prior to initiating research in that direction. If the implications of the new research question so require, the revised research plan must follow established procedures for external authorisation and supervision.

⁹ This would be the case, for instance, when stored biological material that is associated with identifying information on the source individuals is used for purposes other than those predicted in the original project proposal.

2.4. Exceptionally urgent research When situations relating to public health or safety require the immediate establishment and implementation of a research project, the start of research activities must nevertheless be supported by a research plan describing the procedures involved, albeit in a simplified form; this is especially applicable when that research involves human subjects or experimental animals. As far as possible, simplified research plans to be initiated urgently should nevertheless be externally reviewed and processed according to the normally required procedures for research plans.

¹⁰ An appendix to the research project proposal might include the following: criteria defining the relationships between the different researchers involved and governing the exchange of information during the course of the project; the explicit distribution of responsibilities, rights, and obligations of the participating groups both in relation to the tasks to be undertaken and the results obtained; a plan for the presentation and communication of the results; procedures for the storage and distribution of data and samples; prediction of possible commercial implications; stipulations relating to funding and resolution of conflicts.

2.5. Use of external equipment or facilities In order to ensure appropriate use of resources, all research plans that involve the use of health service facilities or equipment designated for patient care, or of any research facilities or equipment not designated for the exclusive use of the research group, will require prior consent from the individual responsible for the facility or equipment that is to be used.

2.6. Collaborative research When a planned research project involves the participation of several groups from the same or different centres, it is recommended that the limits and terms of the collaboration be formalised in writing before initiation of the definitive project¹⁰.

2.7 Registration of research involving human participants All research projects involving human participants initiated after October 2013¹¹ should be registered in a publicly accessible database before recruitment of the first subject.

3. Recording, documentation, storage, custody, and sharing of data and biological or chemical materials arising from research

3.1. Data collection and storage All research plans must include a system for collection of data, registries, and biological or chemical material arising from the research, along with a plan relating to their custody and storage.

3.2. Recording of data and alterations Without exception, all data arising from experiments or research observations must be recorded. That information must remain permanently recorded in databases, registered notebooks, or other appropriate format, in a condition that facilitates external review. The records must also include changes, errors and negative, unexpected, or conflicting results, as well as an indication of the person who performed the experiment or made the observation.

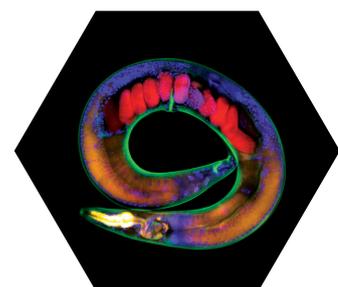
3.3. Storage of data The necessary means and infrastructure must be provided for correct storage and safekeeping of all documentation and biological or chemical material resulting from a research project. In the case of data recorded on electronic media, a specific plan will be included for the preparation and physical storage of backup copies.

3.4. Custody and access to collected data All individuals who belong to the research group must be able to access information on the data obtained and their interpretation. The individual responsible for the research will have a single record accessible to third parties, of the locations of all samples and data-collection instruments (registered notebooks, databases, etc).

3.5. Ownership of data and samples All primary documentation (registered data-collection notebooks, databases, etc.) and biological or chemical material obtained in the course of a research project is the property of the centre to which the person responsible for the research is affiliated¹². Recording, storage, and safekeeping of that material are the responsibility of the individual responsible for the project. Should a researcher change institutions, the individual responsible for the project may make available a photocopy of part or all of the records, a copy of the existing electronic information, a photocopy of the data-collection notebooks, or aliquots of available biological or chemical materials, provided such sharing is necessary. A Material Transfer Agreement must be signed for all human biological samples (blood, serum, DNA, tissues etc). When the change involves the person responsible for the research, the director of the centre will take responsibility for supervising this process.

¹¹ World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. *JAMA*. 2013;310(20):2191-2194. doi:10.1001/jama.2013.281053

¹² This includes human tissue samples donated for research purposes. Although the tissue donor maintains the right to instruct if or when the tissue be destroyed, the material is the property of the research institute.



3.6. Sharing of data and samples with outside parties Data and materials arising from a research project must be publicly available and in a condition to be shared with outside parties, except in cases where restrictions have been established on the basis of possible future commercial use. Provision of data or materials will require that information be provided on the intended use by the person who has requested them, that the research group is aware of the request, that there is a material or data transfer agreement with the approval of the individual responsible for the research, and that the person making the request is willing to pay all possible costs of production and shipping. Sharing may be restricted for reasons of availability, competition, or confidentiality. Material or data obtained from human subjects must be shared in such a way that the subjects cannot be identified; if identification of individual subjects is possible, those individuals must first consent.

3.7. Length of storage of data and samples All original primary information and biological and chemical material arising from a research project must be stored for a minimum of 5 years from the date of the first publication of the results, except in those cases in which the law allows shorter storage periods or requires longer periods to be applied. If the centre allows, the primary information and material may remain stored for longer periods, provided their final destination meets the approval of the person responsible for the research.

3.8. Falsification and fabrication Falsification and fabrication of data are research misconduct and serious offences. Falsification is the modification, incomplete or inaccurate reporting of findings in order to deceive. Fabrication is the intentional misrepresentation of research results by invention of data, findings or procedures that were not conducted.

4. Research projects funded by the healthcare industry or other commercial enterprises

4.1. Transparency When knowledge and technology is exchanged or provided to private enterprises, public interests must always take priority, and therefore, complete transparency must be maintained in all agreements.

4.2. Priority of interests It is recommended that directors of the PRBB Centres establish a conflict of interest policy that includes guidance for their researchers on protection of intellectual freedom and avoidance of excessive confidentiality agreements or unjustified publication restrictions.

4.3. Intellectual property rights and economic compensation When researchers participate in a project promoted by industry and make essential contributions to its design and execution, they must inform their affiliated centre and seek technology transfer advice to ensure that appropriate intellectual property rights agreements are negotiated. Such agreements also include all aspects of economic compensation directly or indirectly relating to the research and should be accessible to all parties involved in the agreement.

5. Publication and communication practices

5.1. Publication and peer review of results It is an ethical imperative that researchers make all reasonable efforts to publish their work in a peer reviewed publication. Publication of results in journals or other media that apply a process of peer review is an essential part of a research project.

5.2. Protection of results with possible commercial interest

If the results of research could lead to inventions or applications that may be subject to protection on the basis of their commercial interest, the individual responsible for the research project should communicate this information to the directorate of their centre and manage the publication of the results in scientific journals accordingly.

¹³ For more detail on acceptable secondary publication see current ICMJE Recommendations, International Committee of Medical Journal Editors, <http://www.icmje.org>

5.3. Unpublished results Failure to publish results of research, or excessive delay in publishing, should be avoided.

5.4. Negative results In clinical studies and certain epidemiological studies it is both necessary and important to make every reasonable effort to publish negative results or results that differ from those predicted in the research project.

5.5. Fragmented publication In clinical studies and certain epidemiological studies, fragmented publication of a single piece of research should be avoided. Fragmentation is only justified by extension of the research.

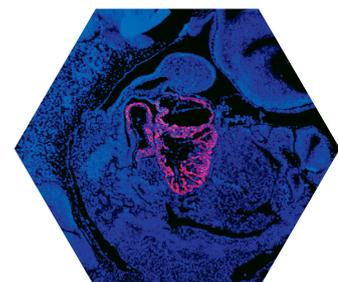
5.6. Duplicate publication Duplicate or redundant publication is an unacceptable practice. Secondary publication is only acceptable under the terms established in the guidelines of the International Committee of Medical Journal Editors ('Vancouver Group')¹³.

5.7. Plagiarism and bibliographic references to third parties Plagiarism, defined as the use or copying of ideas, text or data from other sources without acknowledgement, is research misconduct and unacceptable. Both in publications and in patent applications or utility models, it is necessary to cite all work directly related to a given piece of research and, in turn, to avoid unjustified or honorary citations. Reference to the work of others must include sufficient recognition of the value of that work.

5.8. Acknowledgements The Acknowledgements section of a publication must follow strict principles. The individuals or institutions mentioned have the right to deny permission to be included. Some journals require that written authorisation be obtained from individuals acknowledged. The same principle is applicable to references to 'personal communication'.

5.9. Institutional affiliation and acknowledgement of support

In conference presentations and all other types of presentation of results, the following must be declared: a) the institutions or centres to which the authors belong, or belonged, and in which the research was undertaken; b) whenever applicable, the independent ethics committees who supervised the research protocol and the specific permission obtained; c) details of all funding received.



5.10. Presentation in the mass media The presentation of results in the mass media must always include an appropriate level of explanation for a non-specialist audience or a part of the presentation that has been adapted for the general public. In such presentations, the names of the authors must always be linked to their institutions and, wherever possible, financial support and help received should be mentioned.

5.11. Premature communication through the media All research results should be scrutinised by other scientists through peer review in scientific publications or scientific conferences prior to their communication in the media.

5.12. Urgent reporting The early or premature reporting or publication of results is only justified in exceptional cases on public health grounds. In such cases, the authors must ensure that the results will simultaneously be under rapid review for scientific publication. Likewise, they should inform the editors of the journals in which definitive publication of the results is intended, of the scope of the prior communication.

5.13. Use of publication record for purposes of research assessment In assessments of individuals or groups involving analysis of scientific publications for the purposes of promotion or other forms of compensation, evaluation will always be based on the quality and potential importance of the scientific output, not simply on the number of publications.

6. Authorship of scientific articles, other publications, and patents

6.1. Who may be an author? The status of author is not dependent upon belonging to a given profession or on hierarchical position, nor to employment status, but rather to the contribution made by the individual to the research.

6.2. Who should be an author? To fully meet the criteria of author of a publication or patent, an individual must a) have made a substantial contribution to the creative process, that is, to the conception and design of the study, or to the analysis and interpretation of the data; b) have contributed to the preparation of the communications, reports, or publications that have arisen; c) be able to present in detail his or her contribution to the project and to discuss the main aspects of the overall research. All authors should confirm in writing their agreement with the final version of original manuscripts submitted for publication or registration.

6.3. Provision of data, expert reports, or experimental subjects Mere participation in obtaining resources or in data collection, such as, for example, the provision of routine data or experimental subjects, does not necessarily justify the condition of author, although such involvement should be recognised in the Acknowledgements section. In studies involving the use of samples, analysis, or expert reports provided by third parties, it is advisable to establish a prior plan relating to communication and authorship in which the potential intellectual contribution to the project is taken into account along with any other elements relating to rights to authorship.

6.4. Honorary and ghost authorship Any person linked to a research group who requests inclusion as an author on the basis of hierarchical position or professional relationship violates the principles of academic freedom and commits an act of injustice, if not abuse of authority. Likewise, the omission of names of any individuals who have made proven contributions according to the criteria in Section 6.2 represents an

act of misappropriation of intellectual property on the part of the other authors.

¹⁴ For more detail on conflict of interest see ICMJE Recommendations, International Committee of Medical Journal Editors, <http://www.icmje.org>

6.5. Indication of authorship in reports The preparation of memoranda, technical or work reports, or other written documents for the attention of outside parties must always indicate the authors of the research, the centre or centres with which they are affiliated, and the support received, in the same way as if the document were a scientific publication or patent.

6.6. Order of authorship As a general rule, the order in which authors appear in scientific publications should be as follows: a) the first author should be the person who has made the greatest contribution to the study and has prepared the first draft of the article; b) the senior author who directed or has final responsibility for the research project appears as the last author; c) the remaining authors may appear in order of importance and, in certain cases, in alphabetical order. The corresponding author is responsible for dealing with the editorial process and future correspondence arising from the publication of the study.

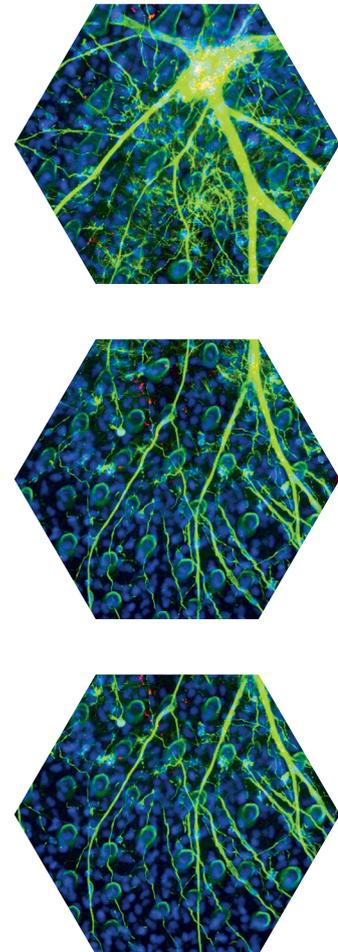
6.7. Shared main authorship The right exists in scientific publications to justify the order in which authors appear and some journals request this as a condition of publication. When two or more authors have made an equal contribution to the same study and have shared responsibility for preparation of the manuscript, they will be considered as equal first authors. This condition will be made clear in the publication of the article. The same criteria may be applied to intermediate or senior authors.

6.8. Curriculum vitae should be signed In the preparation of a personal Curriculum vitae, the author is responsible for the accuracy of its content. Consequently, it is advisable that such a document should be signed by the individual who presents it. In the case of a group CV, it is sufficient for the document to be signed by the individual responsible for presenting it.

6.9. Conflict of interest declarations Conflicts of interest may be financial or personal and where possible should be avoided. If it is impossible to avoid them, conflicts of interest should be declared by all authors of an article.¹⁴

7. Peer review

7.1. The concept of peer review Peer review is understood as all requests to an individual in their position of expert or similar status to undertake a specific assessment, examination, or evaluation of a manuscript submitted for publication, an individual or group grant proposal, a clinical or experimen-



tal protocol subject to assessment by an ethics committee, or a report arising from an on-site visit to a laboratory or centre.

7.2. Conflicts of interest Reviews must be objective and based on scientific criteria rather than personal opinion. Reviews should be declined in the event of a conflict of interest—for instance, when there is a direct relationship between the author(s) and the reviewer or when the reviewer is in direct competition with the authors—or if the invited reviewer does not consider that he or she is sufficiently prepared to perform the review¹⁴.

7.3. Use and fate of documentation submitted for assessment Reports and written documents that are subject to review are always confidential and represent privileged information. As a consequence, such documentation a) may not be used for the benefit of the reviewer until the information has been published; b) may not be shared with other colleagues except in specific circumstances or with the explicit permission of the editor or research organisation; c) may not be retained or copied except where this is allowed by those responsible for the editorial process or the research organisation for whom the review is requested. Common practice is to destroy or return the material once the review process is completed.

8. Main legal requirements affecting scientific activities

8.1. Responsibilities of the PRBB Centres The directors of the centres must provide assurances to personnel that the infrastructure complies with legal requirements and that they have the relevant authorisation to undertake any scientific activity that is subject to specific regulations. Centres will keep up to date with relevant legislation and regulations in the following areas: scientific research involving human subjects, human embryonic material and storage of human biological samples in biobanks; the use of animals in scientific research; the use of, exposure to, and storage of radioactive material, genetically modified organisms, or any other potentially dangerous biological agent; the use of geolocation and other individual identification data.

8.2. Research involving human subjects All research protocols involving the direct participation of human subjects or based on any form of information or biological samples obtained from such subjects must always have received, as a minimum requirement, approval from the corresponding clinical research ethics committee. When research involves patients, members of the research team who are not responsible for treating the study participants must collaborate and not interfere with any decisions made by the physician responsible for treatment.



8.3. Common requirements in all research involving human subjects and/or human biological samples Particular diligence is required in relation to all information regarding the purpose, potential discomfort/inconvenience and risks, and the benefits of the research, in obtaining the express, specific, and written consent of the participants, and in attending to the confidentiality of data, samples, and results obtained. In addition, given that in clinical research the process of data collection is complex and cannot always be repeated, the research group must pay particular attention to the quality of data collection and the procedures for data storage.

8.4. Genetic research All research protocols that include the collection, manipulation, and/or storage of biological samples for the purposes of genetic analysis will be prepared according to the current legislation. In particular, the privacy of the subjects and their right to be informed about their personal results must be guaranteed. The consent of the participating subjects can foresee the use of samples in other projects related to the initially proposed research. Consent must be renewed whenever biological samples are to be used for purposes other than those indicated at the time they were donated.

8.5. Research involving human embryonic material All research plans that involve collection, manipulation, and/or storage of human embryonic material must receive the corresponding permission from the Spanish Ministry of Health, following acceptance by the appropriate ethics committee for clinical research.

8.6. Research with human biological samples All research involving the use of human tissue or other biological samples derived from humans requires the specific informed consent of the donor. Specific donor consent must also be given before research may be done on samples obtained as part of diagnostic or health care procedures.

8.7. Human samples Storage, use and sharing of human biological samples of any kind, collected as part of a research project must comply with current legislation on biobanks and treatment of human biological samples for biomedical research. Where applicable, collections must be registered at the National Register of Biobanks of the Instituto de Salud Carlos III.

8.8. Protection of personal data All research plans that involve the use of institutional computer records or the preparation of databases containing information relating to individuals must guarantee the anonymity of the participants and be subject to current regulations on data protection.

8.9. Research involving experimental animals In accordance with national and European regulations, all procedures using animals must be previously approved by the Ethical Committee for Animal Research (CEEA-PRBB). All animal protocols must be carried out in an accredited animal facility.

8.10. Biosafety All procedures involving the use of genetically modified organisms (GMOs) or biological agents or chemicals of special hazard should be presented for approval to the PRBB Biosafety Committee (CBS-PRBB) which will undertake a risk assessment of the experiment within the context of the proposed research setting and equipment.

8.11. Good laboratory practice Non-clinical studies intended to test health or environmental safety and in which results must be presented to the competent regulatory authorities must be performed in accordance with current legislation on good laboratory practice.

9. The PRBB Good Scientific Practice Working Group

9.1. Definition The GSP Working Group is made up of nominated representatives of all PRBB Centres. The aim of the group is: *To actively share learning and good practice in scientific integrity amongst PRBB institutes, to catalyse the development of cross-institute educational initiatives and to act as an independent support and resource for PRBB institutes in cases of serious misconduct*¹⁵.

¹⁵ Full Terms of Reference and membership of the GSP Working Group can be consulted at <http://goodpractice.prbb.org>

9.2. Contacting the PRBB GSP Working Group The GSP Working Group Chairperson and Secretary can be contacted at goodpractice@prbb.org.

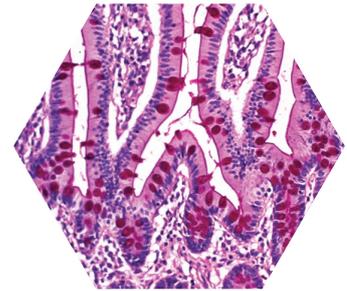
10. Commitment to dissemination and implementation

10.1. Dissemination The directorate of each PRBB Centre will distribute a copy of the new PRBB Code of Good Scientific Practice to all personnel and will provide a copy to any new members when they join the centre. In both cases, individuals will be required to confirm receipt of their copy. The PRBB Centres will maintain a record of the provision of the Code of Good Scientific Practice, including the date of receipt and the name of the individual. Likewise, the PRBB Centres will post a link to the current contents of the Code of Good Scientific Practice on their website so that they will be readily available and can be freely consulted.

10.2. Implementation The PRBB GSP Working Group will oversee the regular review and discussion of the contents of the Code of Good Scientific Practice as part of postgraduate studies and activities undertaken by trainee scientists and other staff affiliated with PRBB Centres.



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