CODI DE BONES PRÀCTIQUES EN **RECERCA** CÓDIGO DE BUENAS PRÁCTICAS EN **INVESTIGACIÓN** CODE OF GOOD **RESEARCH** PRACTICES

NORMATIVES I DOCUMENTS



CODE OF GOOD RESEARCH PRACTICES

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1. Introduction

As stated in its Statutes, one of the University of Barcelona's (UB) priority objectives is to carry out the highest level of research. This quality research should contribute to the following: progress in all knowledge areas, quality-of-life improvements, environmental preservation and improvement, the promotion of peace, the elimination of social and economic inequalities between individuals and peoples, and scientific and artistic progress in general. The equal opportunities of women and men are respected in all of these areas. The University does not participate in research projects that are incompatible with this objective. In particular, it does not take part in projects that could contribute to the arms race.

The UB ensures that all of its research is of a high quality. To achieve this, it evaluates studies undertaken by individuals, research groups and any other forms of research collaboration (Article 100.6, University of Barcelona Statutes).

The entities in the UB Group are responsible for ensuring that all of their research is undertaken in accordance with the current legislation and using good scientific practices.

2. Objectives and scope

The Code of good research practices establishes guidelines on how to carry out research activities.

Its objectives are to:

- improve the quality of research in all fields;
- set up mechanisms for ensuring honesty, responsibility and rigour in research:
- ensure that researchers-in-training acquire good scientific practices.

This document is applicable to all the members of the UB Group who carry out research activities of any kind.

3. Honesty, responsibility, rigour and conflicts of interests

3.1. Honesty

Researchers must be honest about their own research activities and in relation to other researchers' activities. This principle must be applied to all research, including experimental and field studies. It must be upheld in the initial formulation of the hypothesis, the design of the method, the data analysis, the publication of results, the recognition of the contribution of other researchers and the evaluation and review activities that are carried out on request. The researchers must not infringe intellectual property rights, plagiarise or manipulate results.

3.2. Responsibility

Researchers must ensure that studies are carried out in accordance with the terms and conditions defined by the funding body and/or those agreed by the UB and the funding organizations. The following must be assured:

- a) The research is carried out as stated in the original proposal that was presented to the funding organization, except in cases in which amendments have been agreed.
- b) The funding is only used for the planned objectives, except in cases in which authorization has been obtained for other uses.
- c) The reports should accurately reflect the work that has been carried out and should be presented within the planned period.
- Publication, authorship and intellectual property conditions must be met.

3.3. Rigour

The researchers must have undertaken an accurate process of discovery and interpretation. This requires a detailed review of the results before they are published. If errors are identified after publication, a correction must be published as soon as possible.

3.4. Conflicts of interest

The researchers must avoid conflicts of interest that could compromise the validity of their research results.

4. Research team leadership and organization

At least one person must be in charge of a research team and act as the leader and public representative. Research team leaders must foster a working environment in which team members can train and develop their skills, knowledge exchange is promoted, and common research objectives are attained.

Research team members must participate actively in the tasks that are proposed and organized.

The following must be clearly established in the organizational structure of the research teams: the lines of authority, the communication channels between members, and members' responsibilities for the research tasks.

The leaders must promote cooperation with other research teams to foster the exchange of ideas among researchers.

5. Project planning and monitoring: research protocols

All research must be formulated in a written document (the research protocol). The text of the protocol may coincide with the report drawn up to apply for research funding in a public call for applications.

A research protocol must include at least the following information: background, specific objectives, proposed method and the participating team. It must also include a work plan with a proposed schedule for each stage of research. This plan must indicate the human and material resources that are expected to be used in each stage. Depending on the type of study, ethical and legal aspects must also be included, as well as risk assessment. If the research directly involves people, material of human origin or animal experiments, the document must first be assessed by the corresponding committee (Clinical Research Ethics Committee, Bioethics Committee or the Animal Experimentation Ethics Committee).

The implementation of research projects or protocols should be monitored to ensure that the activities are carried out appropriately according to the plan and that any relevant changes are made, if necessary.

6. Competences and supervision of researchers-intraining

All research staff must have the necessary competences to carry out their assigned activities. Students and staff-in-training must be appropriately supervised to ensure the quality of their results.

All individuals who are associated with the University of Barcelona via a contract or grant in order to receive some form of training shall be assigned a mentor (director or supervisor), who must accept this task in writing.

Mentors are responsible for the training process and must take into account the objectives that are set and the time allocated to attain them. Thus, mentors must provide the best possible conditions for the development of the future scientific careers of research staff-in-training.

The person-in-training is responsible for meeting the conditions established in the contract or grant and for following the recommendations of his/her mentor, in accordance with the planned training process.

The mentor must:

- a) interact personally and regularly with the staff-in-training for whom they are responsible, supervise their assigned tasks, and ensure that tasks are completed;
- b) organize meetings to discuss progress on the assigned tasks and contribute to the scientific and technical development of the personin-training;
- c) ensure that research is carried out in safe conditions;
- d) provide all of the necessary information on current legal regulations that affect research activities (see Sections 9, 10 and 11);
- reach agreement on participation in research projects, periods of study abroad, courses, etc.

7. Procedures and methods

All of the methods used in protocols or research projects must come from sources of proven reliability (reference methods, scientific publications, regulations, etc.). If the research requires the use of a new method, the process of perfecting and validating this method shall form part of the research protocol and the researchers must provide evidence of its reliability.

All of the procedures and methods used in a research protocol must be appropriately referenced and/or documented, so that it is possible to accurately recreate how the method was carried out. Documents must include at least the researchers' original research results. Depending on the nature of the research, it may be more appropriate to document the methods in the research protocol or in specific procedures. If methods are described in specific procedures, the copies of this document must be controlled to ensure that all of the researchers have the same version of the documents.

8. Facilities and equipment

All of the facilities must have been equipped for the planned research activities, to ensure the safety of the people who work there and the quality of the results.

When equipment is used for research activities, the researchers must ensure that it is suitable for the planned activities and that the people who operate it have been given appropriate instructions to ensure its correct use. In cases of complex equipment, these instructions should be available in the form of documented procedures.

Any equipment that is used in research activities must be maintained regularly to ensure that the results are not affected by malfunctioning. In addition, the researchers must at all times ensure the reliability of the measures made using the equipment.

9. Obtaining, recording, storage, custody and conservation of materials and results

Researchers must record all research data and observations (including preliminary, negative, unexpected or conflicting results) permanently and with enough clarity to ensure that others can reproduce the study. The records must include information about the person who obtained the results and the date on which they were produced. The date of any amendments and the person who made the changes must also be noted. Appropriate records and ways of identifying data are required to illustrate the study, and may be particularly important for intellectual property protection.

All data must be kept for at least 5 years from the date of publication (except in cases in which a longer period has been agreed), so that

the integrity and safety of the research is ensured and unauthorized modifications are prevented. If data is stored in electronic media, a system of backup copies is required. Suitable data recovery should be guaranteed according to the length of data storage.

All data that contain personal information must be obtained and stored in a way that complies with the data protection act.

All of the materials that are the object of research activities and any derived products must be clearly and permanently identified. The project or protocol that produced the materials must be clearly indicated. Materials must be stored to ensure that they are in good condition, conserved and traceable for the established period of time. If the storage conditions are critical (temperature, humidity, etc.) the corresponding records are required. Any exchange of materials with other institutions can only occur once the parties have signed a protocol on the corresponding transfer.

10. Dissemination of results, authorship and intellectual property

The dissemination of results is one of the main objectives of research at the UB. The UB considers that the publication of original, previously unpublished, peer-reviewed results in journals or other media is one of the best ways to disseminate research results.

To fully meet the criteria of author of a published paper, the individual must have: a) contributed substantially to the conception and/or design of the study or to the analysis and interpretation of the data, b) contributed to the preparation of the resulting document, and c) be able to present in detail his/her contribution to the research and to discuss the main aspects of the study. Any person who has collaborated on the paper in any other way should be recognised in the Acknowledgements section.

Researchers must clearly state their affiliation with the University of Barcelona in the papers that they publish. If researchers are attached to other research structures (institutes, observatories, etc.), they must also clearly indicated their affiliation with the University of Barcelona.

All published papers should also explicitly state the independent ethical committees that supervised the research protocol, as well as details of all the subsidies, grants and sponsorship received from public and private sources. If UB research support services were used in the study, the specific service should be mentioned.

Researchers must be aware of the UB's policy on intellectual property protection and the promotion of assessing and marketing research results.

11. Safety, health and the environment

Researchers must be fully aware of the safety, occupational health, and environmental protection measures that should be taken into account in research activities.

The UB ensures that the safety and health of research staff and respect for the environment are integral to the research that is carried out in the University (University of Barcelona Statutes, Article 100.8).

Research groups must ensure that their activities are in line with the UB's policies on the prevention of occupational hazards and environmental protection (University of Barcelona Statutes, Article 108.4).

All UB research staff have the right to safety and health information and effective protection in their workplace (University of Barcelona Statutes, Article 138.1i).

All University of Barcelona research staff have a duty to know the safety regulations for their centre and to appropriately use the resources, means, installations and services that the University of Barcelona provides (University of Barcelona Statutes, Article 138.2f).

12. Research on human subjects

Researchers who carry out studies on humans or who use biological samples of human origin must ensure that they comply with the corresponding regulations.

When a research project involves human subjects or biological samples of human origin, the University of Barcelona Bioethics Committee (CBUB) must be asked to draw up a report. The report must be favourable for the research to proceed.

When a clinical trial is carried out or forms part of a research project, authorization must be applied for and obtained from the Clinical Research Ethics Committee (CEIC) at the centre/s in which the trial will take place.

Researchers must know and comply with the recommendations of the European Charter for Researchers (EU, 2005).

Researchers must request and obtain the express consent of those who provide biological samples or from the research project participants

(or their legal guardians/powers or attorney, if applicable). In these cases, information must be provided on the proposal and length of the study, the potential benefits (either to the subject or to other people), the potential risks and discomfort, the criteria of exclusion/inclusion in the project, the method and the criteria for ending the project.

Researchers must be clearly committed to maintaining the confidentiality of all of the information they gather about project participants, in accordance with personal data protection regulations. In general, it is essential to ensure the anonymity of participants during the project and when data is recorded and stored.

The researchers must make a clear commitment not to transfer data or biological samples to other projects or researchers without the authorization of the provider of the sample and the corresponding ethical research committee.

The researchers must specify, if applicable, any financial compensation that was awarded to the subjects who participated in the project.

If students participate in a project, they must be included of their own free will and measures should be taken to ensure that those who refuse to participate or withdraw are not penalized.

13. Research on experimental animals

All research activities that involve experimental animals should be carried out in accordance with current legislation.

Staff who participate in research activities involving animals for experimentation or other scientific purposes must have the required credentials as a researcher or experimenter. In addition, researchers must apply for and obtain authorization from the Animal Experimentation Ethics Committee (CEEA) for each of the experimental procedures that are undertaken with animals for experimentation or other scientific purposes. The CEEA provides the information and support that is required for researchers to comply with current legislation.

Research activities that use animals for experimentation and other scientific purposes must be governed by the "Three Rs Principle": Replacement, to ensure that when possible, animal experiments are replaced by others that do not involve animals; Reduction, to limit the number of animals to the minimum required to attain valid conclusions; Refinement, to use experimental procedures in which measures are implemented to reduce the suffering of the animals.

Appendix I. References and current regulations

- University of Barcelona Research Regulations (http://www.ub.edu/aj/index11.htm)
- University of Barcelona's gender equality plan (http://www.ub.edu/genere/index.html)
- Personal data protection law
 Royal Decree that approved the implementing rules for Organic Law 15/1999
 of 21 December on personal data protection html, Royal Decree 1720/2007 of
 21 December (BOE no. 17, 19.01.2008). Law on personal data protection html
 Organic Law 15/1999 of 13 December (BOE no. 298, de 14.12.1999).
- The Agency for Assessing and Marketing Research Results (AVCRI): http://www.pcb.ub.es/acri/index.php?option=com_content&task=vie w&id=25<emid=102&lang=ca_ES
- Health, Safety and Environmental Issues (OSSMA): http://www.ub.edu/ ossma/info/index.htm
- Regulations on research involving human subjects: (http://www.ub.edu/recerca/Bioetica/enormat.htm).
- European Charter for Researchers recommendations (EU, 2005) (http://ec.europa.eu/eracareers/index_en.cfm?l1=29&CFID=133 80938&CFTOKEN=dd2d4b487dd2a08c-16B85352-F54B-C081-6C7C41D65B5DA60F
- Regulations on research involving experimental animals:
 Council Directive 86/609/CEE of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimentation and other scientific purposes.
 Law 32/2007 of 7 November for the care of animals during their exploitation, transport, experimentation and sacrifice (BOE of 8 November 2007).
 Law 5/1995 of 21 June on the protection of animals used for experimentation and other scientific purposes (DOGC 2073, 10.7.1995).
 Decree 214/1997 of 30 July on the use of animals for experimentation and other
- scientific purposes (DOGC 2450, 7.8.1997).

 Animal Experimentation Ethics Committee
- Biosafety Committee (currently being set up)

(http://www.ub.es/ceea/).

Appendix II. Other references

- Buenas prácticas para la gestión de los derechos de propiedad industrial e intelectual (IPR) en las relaciones de I+D+I entre los centros públicos de investigación y las empresas.
 - Cuadernos Técnicos RedOTRI (http://www.redotrouniversidades.net)
- Code of good scientific practices. Barcelona Biomedical Research Park (http://www.prbb.org/eng/part01/p06.htm).
- Codi deontològic del psicòleg http://www.copc.org/content/category/18/37/83/
- Good Research Practice. University of Cambridge (http://www.rsd.cam.ac.uk/about/policies/practice).
- Code of Good Practice in Research. University of Reading (http://www.rdg.ac.uk/UnivRead/vb/RES/gar_public/index.htm).

Appendix III. Glossary

Risk assessment

The overall process of estimating the magnitude of risk and deciding whether the risk is tolerable (OSHAS 18002:2000).

Conflict of interests

Situation in which the judgement of the researcher with respect to his/her primary interest—the integrity of the research—tends to be unduly influenced by his/her secondary interest, which is generally financial or personal.

Express consent

Statement of a person's free, unequivocal, specific and informed consent to be included in a research project. The document must include the requirements of free will, information and comprehension.

Controlled copy

Copy of a document that is distributed in such a way as to ensure that the recipient always has the latest version.

Research team

Group of researchers who work together in an organized way under the leadership of at least one person to undertake research activities.

Mentor

Researcher linked to the home institution who is responsible for supervising or guiding a researcher-in-training.

Plagiarism

This is an infringement of an author's copyright for any kind of work. It occurs when a work is copied without the authorization of the author or the copyright holder and presented as an original work.

Intellectual property

Any property that, by common agreement, is considered to be of an intellectual nature and worthy of protection, including scientific and technological inventions, literary or artistic output, brands and identifiers, industrial drawings and models, and geographical indications (WIPO, 2000).

Research protocol

Written document that describes a research proposal before it is implemented and contains the following: background, objectives, planned method, the research team, the work plan, planned schedule, the available and required resources, and any other document that is required.

Materials transfer protocol

Document that specifies the terms and conditions for the exchange of samples or materials with researchers from other institutions.

Traceability

The ability to identify and trace the history, distribution and application of all the items under consideration (ISO 9000:2005).