CÓDIGO DE BUENAS PRÁCTICAS CIENTÍFICAS DEL CSIC

CODE OF GOOD SCIENTIFIC PRACTICES OF CSIC

GOBIERNO DE ESPAÑA
MINISTERIO DE CIENCIA E INNOVACIÓN
CSIC

CÓDIGO DE BUENAS PRÁCTICAS CIENTÍFICAS DEL CSIC

CODE OF GOOD SCIENTIFIC PRACTICES OF CSIC

CSIC

CODE OF GOOD SCIENTIFIC PRACTICES OF CSIC

PREAMBLE

It would be difficult to imagine the actual world without the current levels that have been achieved in science and technology, as our life is now highly dependent on technological products. All scientific areas, both the natural and social sciences have contributed greatly to the advancement of knowledge and to improve the quality of life. However, we should not forget that science, as any other activity, must be based on sound ethical principles. These principles inspire the following Code of Good Scientific Practices, designed to provide an ethical basis for all scientific activity of CSIC.

The first of these principles is to consider freedom and autonomy of research. Science will be always under a particular human interest and always serve the welfare of mankind; the scientist and the science policy administrators are obliged to morally justify aims and priorities.

The second principle is respect to human dignity, particularly when human beings are the targets of the research. Whenever their health and rights are involved, it will be necessary to have a voluntary informed consent, with clear information about the risk and possible consequences of a wrong use of science.

The third one is the acceptance of responsibilities towards society, during scientific activity. Furthermore, the scientist is also responsible of his/her actions in relation to any living organism and the environment, avoiding any unnecessary damage and being aware of the integrity and correct function of our Earth System. This generation is responsible to the next ones, about the situation of the world, taking especially care to promote ethics, and allow that what derives from scientific research will contribute to improve life conditions in the near future.

The fourth principle is that research against human health or dignity including racism, holocaust denial or terrorism apology should not be supported, either in natural science or humanities. Although scientists or their institutions will not be directly responsible of the use that could be made of the knowledge they generate, they should reject to participate in projects and in the spreading of information to be used with awkward ends.

The fifth is that research must be transparent. The scientist should always be ready to answer about his/her work, understanding the

importance of peer review research evaluation and the social impact of his/her scientific activity.

All mentioned above indicates that scientific activity will be necessarily submitted to good practices. The scientists are obliged to adapt their activities to ethical principles. Good practices should involve procedures and results. The actual scientific development requires scientific teams, human and material resources, infrastructures and project management and programs with specific duties and responsibilities for each scientist. The honesty of the scientist, his/her vocation or own inventiveness is not enough to achieve good practices. Always observing the value of liberty and individual creativity, the full acceptance of good practice rules must be unequivocally explicit in the institution research contracts where they develop their research and with society that supports them.

The goal of CSIC is the acquisition of knowledge and the social welfare derived. Therefore, all its activities, rules and internal function of the Institution, should be focused, at all levels, to enhance scientific development. This mission should be done following the legality and the criteria of this good practices manual as defined in this Code, which should be updated or corrected, according to the experience developed from its application or to any new circumstance.

In this context, the CSIC Presidency, commissioned the Ethics Committee to design this Code of Good Scientific Practices, bringing together a set of rules, principles, compromises, declarations and/or recommendations applicable to any research kind. This Code calls for basic moral principles, helping its development and achievement. The Good Practices Code should be the instrument to generate and guarantee the integrity and ethical quality of scientific research developed in the CSIC.

INDEX

1. PRINCIPLES OF RESEARCH WORK

1.1. Exercising methodical doubt. Checking hypotheses

The basis of scientific knowledge is the capacity for wonderment or questioning about the reasons for facts or situations hitherto unsolved or not investigated. Science aims to attain objective knowledge we can assume to be true. To achieve this we follow a two-step process of reflection: methodical doubt and justification of an explanatory hypothesis. Methodical doubt implies independent opinion and not accepting any idea, from the scientific point of view, as absolute or definitive. This questioning attitude, which is the starting point of all scientific endeavour, must always stay with the investigator, because if the human capacity for wonder is endless, so is also the extent of possible knowledge, and so our certainty at any moment can only be provisional.

Likewise to justify a hypothesis we need tests or arguments to validate it and the researcher must always assume the mentioned attitude.

1.2. Designing good experiments

Observation and experimentation in the laboratory or in the natural environment must provide us with the right answers to scientific questions. Therefore, research must be performed following well-designed protocols that can be examined and understood by any expert researcher on a given field. Experiments and observations must be carefully designed in order to make the best use of the available resources and taking into account specific rules. More care and attention is needed when the object of research are human beings or their personal data, laboratory animals, or when human safety or the environment are at risk.

1.3. Managing data and resources

Experimental data and observations, and the materials used, are the basis of results and scientific research publications. So in case of doubt, others should be able to repeat and understand our experiments. The experimental

protocols and the original data must be kept by the researcher, the research team and the institution for at least five years.

The data remains the property of the Institution in which the scientific work has been carried out, so its source should be clearly cited.

In orden to allow any expert in a certain field to understand and reproduce an experiment, the Institution must provide researchers and trainees with suitable equipment to store the information.

1.4. Proper use of funding

The material and economic resources must be used effectively and efficiently, and carefully managed. This is especially important because economic and material resources are limited.

Consequently, the Institution's personnel must use resources responsibly, efficiently and economically, follow health and safety procedures and respect the environment. Government assets must always be managed in an austere way.

1.5. Misconduct in research activity

Science as the search for knowledge is by its very principles the enemy of fraud. Nevertheless, researchers may be tempted to stray from this in seeking undeserved credit, or financial gain either personally or for the Institution.

This sort of deviation is the biggest threat to good scientific practices and if it happens, the researcher is held accountable for it. Misconduct includes:

- Exaggerated interpretation of data.
- Falsification of data or tests to fit a hypothesis.
- Fabrication of data and discoveries.
- Plagiarism of the work of others.

Effective mechanisms for fighting this include:

- Requiring the researcher to submit any new contribution to peer review so other colleagues can check results.

– Disapproval and fight against fraud by the scientific community.

– Coordination among all stakeholders involved in scientific research to ensure the effectiveness of the fight against fraud.

2. THE RESEARCHER AS A SCIENCE PROFESSIONAL

2.1. Leadership and cooperation in the research team

The complexity of current scientific research requires working in teams and the use of shared methodologies, human resources and infrastructures such as projects or research programs.

The researcher who intends to lead a team must assume the responsibilities of leadership. These responsibilities and the composition of the research team should remain clearly established in the financial documents and be fulfilled by every member of the team.

The scientific work of other teams must not be hindered. The scientist must accept the critique, queries and comments of other colleagues.

2.2. Training and testing

Every researcher must take responsibility of educating and training other researchers.

- Obligations of directors and tutors include:
  - Providing trainees with resources and a proper scientific environment. Be aware of their needs and avoid undue pressure.
  - Providing information about safety and accident prevention rules that must be followed.
  - Encouraging them to observe the Code of Good Scientific Practices and to maintain a critical mind.
  - Ensuring that his/her own work is an example to be followed by the trainee.

- Being an expert in his field in order to educate and train others.
- To introduce the trainee to forums and scientific meetings, provide advice about the future.
- To recognize the trainee's work and to be rigorous and fair in authoring publications.

- Trainee's obligations include:
  - Compromise to work on the assigned research project.
  - Follow the tutor's advice and recommendations, and to inform him/her about initiatives and relevant new results. Any difficulties encountered when carrying out the work must be reported promptly.
  - Be aware of the observance of the safety rules and procedures, and the fulfillment of the Code of Good Scientific Practices.
  - Take part in scientific activities, forums, seminars, etc., relevant to his/her work.
  - Give credit for the tutor's contribution in oral or written publication of results.
  - Respect and value the work of management, and make good and careful use of materials and facilities.

2.3. Evaluation and appraisal

- Researchers are often called on to take part in evaluation of projects, publications and groups. In these activities it is important to consider:
  - The evaluation must be declined when there is a conflict of interest between the expert and the subject of the evaluation.
  - The evaluation shall be confidential and not be used for any purpose other than the evaluation itself. Internal deliberations of a given committee shall also be treated as confidential.
  - Information made available to committees shall not be disclosed or shared without previous and express written authorization of the owner.

- Acceptance of the appraisal must be made known to the institution and regulated by a formal agreement. This ensures that the researcher has the required knowledge and experience and avoids conflicts of interest.

2.4. Disclosure

A free society is one that has a high level of knowledge and a critical mind for making decisions, therefore the scientists have to:

- Disclose and communicate to society the results of their research, in order to contribute to the advancement of culture, the spread of knowledge, and to account for the resources involved.
- Make an effort to provide the public in general with the proper level of the knowledge and to avoid the premature disclosure of unconfirmed results to the media.

Criteria of truthfulness and scientific proof shall always be required.

2.5. *Curriculum vitae*

A *curriculum vitae* is a record of research work but must never be the aim of the researcher's endeavors.

It must document certain personal information about education and professional experience. Accuracy and clarity are essential.

The content of the *curriculum vitae* is the responsibility of the researcher.

All pages should be signed.

2.6. Collaboration with public and private entities. Contracted research. Conflict of interest

The public researcher should be willing to answer any factual questions posed to the Institution by either public or private entities.

Any collaboration with the different public or private entities which require written agreement shall be supervised and signed by the Institution´s legal

representative, so that all terms and conditions ruling the interests of the parties can be clearly stated. Furthermore, all adopted agreements entered into by the entity soliciting the work and the representatives in charge of the execution of the research shall be included in the abovementioned agreements.

Conflicts of interest must always be avoided whilst negotiating the agreements and/or during the publication and exploitation of the work done in collaboration with private entities.

2.7. Data protection management. Intellectual property, industrial property, Know-How

The Institution must foster and promote the suitable management of its results establishing guidelines for the correct implementation of intellectual and industrial property policies to allow its effective valuation, protection, appraisal and commercialization. Likewise, measures should be taken to increase the awareness and training of the researchers on intellectual and industrial property and its exploitation.

R&D projects developed either in collaboration or under contract, should safeguard all previous knowledge, information and know-how property of the Institution. Researchers will sign the contractual documents in which the different interests, tasks and contributions will be adequately defined. Furthermore, undisclosed and confidentiality obligations, the property in the results achieved during the course of the project, the likelihood of their legal protection and the conditions under which they can be exploited shall be stipulated.

If the results obtained are liable to legal protection due to commercial interest, these must remain undisclosed during their valuation process. Nonetheless delay in disclosure shall be maintained at the bare minimum.

3. SCIENTIFIC PUBLICATIONS. ORAL AND WRITTEN COMMUNICATION

Publication of all results obtained with the aid of public funds is a fundamental activity of any research work since it is the only way to submit the findings to the international scientific community for review.

3.1. Publication of results

- Researchers shall always make an effort to publish their results and their possible interpretations in an open, honest, transparent and exact manner. This includes the publication of those results not in line with the given hypothesis.
- Publications of fragments of the work or part of the work separately is only acceptable if the publisher so requires or by reason of extensions.
- Researchers shall not unduly withhold the publications of any finding from projects financed with public aid unless this can be justified by commercial arrangements or by the nature of its legal protection.
- Research results obtained under an agreement shall be published in accordance with the terms contained therein.
- Verbal communications of results shall follow the same rules as for publications, avoiding in each case to overstate the importance and practical applications of the results.
- In case an error is detected in a publication, it must be revealed in publications of the same standard and if serious, the publication must be withdrawn.
- The "open access" would take the same criteria than other kind of publications, but always in accordance with institutional policy. In this regard, in 2006, the CSIC joined the Berlin Declaration for the "open access" to knowledge (Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities), which favours and promotes the open access to scientific and academic output.

3.2. Authorship of publications

- In order to be credited as author of a publication the researcher in question needs to either (i) have participated in the proposal and work design, and/or (ii) have carried out the experimental part, and/or (iii) analyzed and interpreted the results and its debate on whether it is state of the art.

- All researchers who have participated significantly in the research work must appear as authors of the publication.
- All authors of a publication, unless otherwise specified, must know the text and be responsible for its content.
- The order of the mentioned authors shall be decided in accordance with the guidelines normally accepted in their field of work and must be known to all of them.
- The work and contribution of collaborators and technical staff contributions must be properly acknowledged.
- Besides the authors, the institutions or centers in which the research has been executed or those they belong to, must be mentioned. Grants, financial support or sponsorships must also be declared and thanked, except when declined.
- Likewise, any conflict of interests must be known.

3.3. Previous authors recognition

- The authors must mention and make reference in their publications to all the previous literature connected with such publications.
- Previous publications which are not essential for the research shall not be included.

3.4. *Peer review* of scientific publications

Peer review is a method used to validate written research in order to evaluate its quality and scientific rigor. This method opens the work to scrutiny, annotation or edition by other authors with similar knowledge to that of the researcher. Currently, scientific publications are only accepted for publication in scientific journals, after *peer review*.

- The scientist, as reviewer or publisher, must avoid any kind of conflict of interest (personnel, academic, commercial, etc.). Likewise, evaluations, reasonings and opinions must be clear and accurate, and subject to enough discussion in order to be impartial.

– The evaluation process must remain strictly confidential. Reviewers and publishers must not use the information which they might have accessed without previous, specific and express authorization by the author.

4. INSTITUTIONAL FRAMEWORK

4.1. Information on research conditions

– Institutions must stimulate scientific collaboration and the quality of the research. Likewise it must recommend models for the organization of research and encourage the relationships between the economic and social agents, and in particular offer its advise and experience in those research activities.

– The Institution must guarantee that all researchers have access to the Code of Good Scientific Practices of CSIC as well as to the updated legislation applicable to the different fields of science. Documents gathered in a specific document ("ad hoc") will be edited at CSIC´s web. In addition, the Institution will endeavour to make researchers aware of good research practice by means of giving adequate information through specific courses, leaflets and others. To this end and by virtue of what is stipulated in the statute, the Presidency set up an Ethics Committee.

– Researchers must make compatible the intellectual freedom with the engagement and loyalty to the Institution that provides them with the framework to develop their research efficiently. Researchers must get involved with the CSIC and know well all the activities that the Institution carries out as well as its role of service to society.

4.2. Evaluation criteria and promotion of personnel and units

– The Institution must establish clear evaluation and personnel promotion procedures, set clearly-defined criteria, and make them known in advance.

– The mentioned criteria shall be objective, clear, impartial and lasting and reflect the quality of the performed work.

– In order for any evaluation to be fair, it has to be objective. The evaluators shall make an effort to know well every candidate's capacity and interpret properly each and every document they submit. If the evaluation process includes a personal interview, this one must be stated in writing.

– Evaluators shall avoid any conflict of interest that might be related to kinship, friendship, enmity, professional implication or any other similar condition; the evaluators always have to be unbiased.

4.3. Non-discriminatory conditions

In accordance with the current regulation, the Institution will promote equal opportunities and prevent any discrimination on the basis of age, race, sex, religion, marital status, sexual orientation, opinion or any other condition or social circumstance, and mainly in relation to the:

– Access to training activities.

– Access to (i) become a member of the examining board and (ii) enter the personnel recruitment processes at all levels as well as any promotion competition and free access to job openings of different grade such as directive or management positions.

Furthermore, CSIC shall take all necessary measures in order for its workers not to be subjected to labour harassment, promote work conditions based on fair treatment and respect and ensure the implementation of instruments to detect and solve any potential desviation.

ANNEX I:
LEGAL TEXTS

A. Research with human beings

- Ley 14/2007, de 3 de julio, de Investigación biomédica.
- Ley 14/2006, de 26 de mayo, sobre técnicas de reproducción humana asistida.
- Real Decreto 1301/2006, de 10 de noviembre, por el que se establecen las normas de calidad y seguridad para la donación, la obtención, la evaluación, el procesamiento, la preservación, el almacenamiento y la distribución de células y tejidos humanos y se aprueban las normas de coordinación y funcionamiento para su uso en humanos.
- Real Decreto 65/2006, de 30 de enero, por el que se establecen requisitos para la importación y exportación de muestras biológicas.
- Real Decreto 223/2004, de 6 de febrero, por el que se regulan los ensayos clínicos con medicamentos.
- Real Decreto 120/2003, de 31 de enero, por el que se regulan los requisitos para la realización de experiencias controladas, con fines reproductivos, de fecundación de ovocitos o tejido ovárico previamente congelados, relacionadas con las técnicas de reproducción humana asistida.
- Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica.
- Ley 30/1979, de 27 de octubre, sobre extracción y trasplante de órganos
- Declaración de Helsinki de la Asociación Médica Mundial (Principios éticos para las investigaciones médicas en seres humanos).
- Convenio del Consejo de Europa relativo a los derechos humanos y la biomedicina, ratificado por España el 23 de julio de 1999.
- Declaración Universal de la UNESCO sobre el Genoma Humano y los Derechos Humanos.

B. Animal research

- Ley 32/2007, de 7 de noviembre, para el cuidado de los animales, en su explotación, transporte, experimentación y sacrificio.

- Real Decreto 65/2006, de 30 de enero, por el que se establecen requisitos para la importación y exportación de muestras biológicas.
- Real Decreto 1201/2005, de 10 de octubre, sobre protección de los animales utilizados para experimentación y otros fines científicos.
- Ley 8/2003, de 24 de abril, de sanidad animal.

C. Workers' protection

- Ley 7/2007, de 12 de abril, del Estatuto Básico del Empleado Público.
- Ley 54/2003, de 12 de diciembre, de reforma del marco normativo de la prevención de riesgos laborales.
- Ley10/1998, de 21 de abril, de Residuos.
- Real Decreto 665/1997, de 12 de mayo, sobre la protección de los trabajadores contra los riesgos relacionados con la exposición a agentes cancerígenos durante el trabajo.
- Real Decreto 664/1997, de 12 de mayo, sobre la protección de los trabajadores contra los riesgos relacionados con la exposición a agentes biológicos durante el trabajo.
  - Guía técnica para la evaluación y prevención de los riesgos relacionados con la exposición a agentes biológicos.
- Ley 31/1995, de 8 de noviembre, de Prevención de Riesgos Laborales.

D. Environment protection

- Ley 42/2007, de 13 de diciembre, del Patrimonio Natural y de la Biodiversidad.
- Ley 30/2006, de 26 de julio, de semillas de vivero y de recursos fitogenéticos.
- Real Decreto 178/2004, de 31 de enero, por el que se aprueba el Reglamento general para el desarrollo y ejecución de la Ley 9/2003, de 25 de abril.
- Ley 9/2003, de 25 de abril, por la que se establece el régimen jurídico de la utilización confinada, liberación voluntaria y comercialización de organismos modificados genéticamente.
- Ley 43/2002, de 20 de noviembre, de sanidad vegetal.

- Real Decreto 58/2005, de 21 de enero, por el que se adoptan medidas de protección en la introducción y difusión en el territorio nacional y en la Comunidad Europea de organismos nocivos para los vegetales o productos vegetales, así como para la exportación y tránsito hacia países terceros.
- Real Decreto 39/1998, de 16 de enero, por el que se modifica el Real Decreto 401/1996, de 1 de marzo.
- Real Decreto 401/1996, de 1 de marzo, por el que se establecen las condiciones para la introducción en el territorio nacional de determinados organismos nocivos, vegetales, productos vegetales y otros objetos, con fines de ensayo, científicos y para la actividad de selección de variantes.
- Convenio sobre la Diversidad Biológica – Protocolo de Cartagena sobre Seguridad de la Biotecnología del Convenio sobre la Diversidad Biológica.
- Tratado Internacional sobre los Recursos Fitogenéticos para la Alimentación y la Agricultura.
- Tratado Antártico sobre Protección del Medio Ambiente (Protocolo de Madrid, BOE de 18 de febrero de 1998).

E. Personal Data protection

- Real Decreto 1720/2007, de 21 de diciembre, por el que se aprueba el Reglamento de desarrollo de la Ley Orgánica 15/1999, de 13 de diciembre.
- Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal.

F. Other legal texts

- Constitución Española de 1978.
- Ley 30/1992, de 26 de noviembre, de Régimen Jurídico de las Administraciones Públicas y del Procedimiento Administrativo Común.
- Ley Orgánica 3/2007, de 22 de marzo, para la igualdad efectiva de mujeres y hombres.
- Real Decreto legislativo 1/1996, de 12 de abril, por el que se aprueba el texto refundido de la Ley de Propiedad Intelectual.

- Real Decreto 1730/2007, de 21 de diciembre, por el que se crea la Agencia Estatal Consejo Superior de Investigaciones Científicas y se aprueba su Estatuto.

Remark

As the above mentioned legal texts do not constitute a complete clearly-defined list, other rules could be enforced. The list of regulations issued by local and autonomous regions is extremely long and detailed and so has been omitted.

GOBIERNO DE ESPAÑA
MINISTERIO DE CIENCIA E INNOVACIÓN

CSIC