The Regulations governing the research and innovation ethics bodies of the URV

Approved by the Governing Council on 11 July 2019-

PREAMBLE

Research is an essential function of the Universitat Rovira i Virgili (URV), as is stated in article 122 of its Statute. To this end, one of the objectives of the URV is to undertake scientific, technical, humanistic and artistic research and it is committed to ensuring freedom of research with no limitations other than those established by the deontological laws and codes and the good practices approved by the scientific community.

The great scientific and technical progress of the last century and its social implications mean that there are many measures for guiding the process and application of research whilst also guaranteeing scientific production, the freedom to think and be creative, and an equilibrium with other values and rights that may be affected. These measures are aimed primarily at research that involves interventions in people, samples or data, animals, biological protection and safety, including occupational risks, and research with social and environmental implications.

In this regard, in recent years various universities and research centres have created research and innovation ethics committees, terms that cover all phases of the scientific process (from basic and applied research to the dissemination of knowledge in general, including knowledge and technology transfer, technological development and the innovation of products and services) and that are identified with the concept of 'R+D+I'. This trend has been strengthened by various circumstances. The first is that, for several years, calls for R+D+I funding have required that projects with ethical implications must be evaluated by an independent committee that analyses a project's compliance with the methodological, ethical and legal requirements. The second is that the increasing number of editorial councils at scientific journals require these validations as a prerequisite before they will publish the scientific results obtained from a project. Regardless of these trends, the move towards the creation of these university bodies has been pushed by a series of sectoral regulations that stipulate the need to conduct an evaluation prior to undertaking certain R+D+I activities and teaching activities. This is the case with Law 14/2007, of 3 July, on biomedical research, and Royal Decree 53/2013, of 1 February, on regulations to protect animals used for scientific purposes, including teaching.

The ethics committees guarantee that the R+D+I activities and teaching carried out in universities and research centres respect the methodological, ethical and legal requirements set out in the regulations.

At the URV, the Ethics Committee was created in 2003 in order to establish the manner in which teaching and research staff undertake works of transfer and provide services and to offer certain general directives to foster best practice.

Prior to this, in 1999 and 2000, the Animal Room of the Faculty of Chemistry and the Animal Room of the Faculty of Medicine and Health Sciences had been registered as users of experimental animals in the Registry of Breeding Centres, Suppliers and Users of Experimental Animals of the Department of Agriculture, Livestock Farming and Fishing of the Catalan Government. The registry entry listed the specialized staff qualified, in accordance with article 17 of Decree 214/1997, to assess animal welfare, the staff responsible for caring for the animals and the members of the Ethics Committee on Animal Experimentation, the current composition of which dates from 2018.

Several years later, in the same vein of continuous improvement, the URV implemented a quality management system which is certified as complying with the requirements of ISO 9001 regarding research, development, innovation and transfer of knowledge and technology, which initially affected around twenty scientific and technical research groups (2007). The certification was renewed

annually until 2018. The URV also approved the Regulations governing transfer in ambits of special public sensitivity (2008). In the same year, the URV signed up to the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers, which establish, particularly in the former, the rights and professional and ethical responsibilities of research staff and of the contracting entity.

Subsequently, during the following decade, the URV has continued to develop its ethical commitment to R+D+I through various documents, such as the Code of good practice in research, research training, development and innovation; the Manual for workplace risk management; and the Internal Regulations of the Health and Safety Committee (all from 2013). The URV also received the HR Excellence in Research Award in 2014. More recently, in 2017, the URV published three guides on the prevention, detection and treatment of plagiarism in teaching, which were aimed at the University's students, teaching staff, faculties, schools and departments. These had originally been approved by the Governing Council on 28 April 2011 in its agreement on the prevention and treatment of plagiarism.

Coinciding with these developments, since its creation in 2005 the Pere Virgili Health Research Institute has had evaluation forms from the ethics committees of the Sant Joan Hospital in Reus and the Joan XXIII University Hospital in Tarragona, which deal with the methodological, ethical and legal aspects of the R+D+I activities carried out by health professionals, whose resources it manages.

In 2016, the Ethics Committee on Research into Medicines of the Pere Virgili Health Research Institute was accredited after having been created from the merger of the Ethics Committees of the Sant Joan XXIII Hospital in Reus and the Joan XXIII University Hospital in Tarragona. The aim of the new committee is to protect the dignity, rights, safety and welfare of individuals who participate in biomedical research and to ensure that the regulations on clinical good practice are followed, specifically those relating to methodological, ethical and legal aspects.

These committees are tasked with evaluating and writing an initial, preceptive and binding report on the methodological, ethical and legal aspects of the R+D+I and with monitoring them. These bodies are notable for the technical capacities and professional skills of their members and for their impartiality and independence.

These qualities of the committees mean that the most recent regulations, such as the aforementioned ones on biomedical research and the protection of animals used for scientific purposes, recognise their evaluations not only as an internal matter of the entities to which they provide a service but also as a function that is given to them by the public administration and society in general. Consequently, the committees' contribution is vital to ensuring that advances in science and technology are made in balance with fundamental rights and the common good. By the same token, the public administration has to ensure this equilibrium through the evaluation and monitoring of the R+D+I activities.

The ethics committees also have the objectives of promoting activities for training, informing and disseminating in their areas of competence, making recommendations, establishing guidelines, providing advice in resolving disputes relating to the integrity of R+D+I activities and carrying out anything else that helps to facilitate the tasks of the teaching and research staff and the administrative and services staff, in particular anything that refers to the monitoring undertaken by the competent authorities regarding the methodological, ethical and legal aspects of their activities.

In the light of these developments and aware of the commitment of staff who work in R+D+I, the scientific community and society in general, the URV has drawn up the present regulations for the Ethics Commission for Research and Innovation (CERI), the Ethical Commission for Integrity in R+D+I (CEIR), and the three evaluation and monitoring committees (the Ethics Committee for Research into Medicines (CEIm-IISPV), the Ethics Committee on Animal Experimentation (CEEA), both in collaboration with the Pere Virgili Health Research Institute (IISPV), and the Ethics Committee on Research into People, Society and the Environment (CEIPSA)).

CHAPTER 1. ETHICS BODIES FOR RESEARCH AND INNOVATION

ARTICLE 1. ETHICS BODIES FOR RESEARCH AND INNOVATION

The Ethics Bodies for Research and Innovation of the URV are:

a) The Ethics Commission for Research and Innovation (CERI)

b) The evaluation and monitoring committees:

- The Ethics Committees for Research into Medicines (CEIm-IISPV)
- The Ethics Committee on Animal Experimentation (CEEA)
- The Ethics Committee on Research into People, Society and the Environment (CEIPSA)

c) The Ethics Commission for Integrity in R+D+I (CEIR)

ARTICLE 2. OBJECTIVES AND STRUCTURE

1. The common objectives shared by these bodies are to:

a) Ensure that all R+D+I activities at the URV are carried out in accordance with the methodological, ethical and legal requirements, notwithstanding any reports that have to be issued by the university legal services when the general or university regulations so require. Each body acts within its own area of competence.

b) Ensure that all R+D+I activities pass the necessary evaluations.

c) Certify to the corresponding authorities that the previous objectives have been met.

2. The vice-rector competent in scientific policy will ensure the correct functioning of these ethics bodies for research and innovation.

ARTICLE 3. SCOPE

The scope of these bodies are all R+D+I activities that are undertaken at the URV and that involve the actions specified below.

1. The scope of the Ethics Commission for Research and Innovation (CERI) is to ensure ethical practices in R+D+I activities at the URV and to facilitate and coordinate the activities of the evaluation and monitoring committees and the Ethics Commission for Integrity in R+D+I.

2. The scope of the evaluation and monitoring committees includes the following activities:

a) Ethics Committee on Research into Medicines: Biomedical research on human beings, which involves i) research projects that use personal health data, observational studies or the use of human biological samples, ii) clinical trials with medicines, iii) clinical research with healthcare products and iv) observational post-authorization studies using medicines.

b) Ethics Committee on Animal Experimentation: Use of animals for experiments and other scientific purposes, including teaching. This committee will collaborate with the IISPV.

c) Ethics Committee on Research into People, Society and the Environment: Research involving i) human beings (including the handling of personal data), ii) the use of biological agents, genetically modified organisms and significant risk factors for individuals, society and the environment, and iii) the study of social and environmental issues. When the research involves the handling of personal health data, point 2.a. will be applied.

3. The Ethics Commission for Integrity in R+D+I deals with any actions that are contrary to the general principles and requirements established in the European Charter for Researchers, which are applicable both to staff (teaching and research staff and administrative and services staff) and to the URV itself.

ARTICLE 4. TECHNICAL AND HUMAN SUPPORT

The designated Vice-Rector must use its own resources to provide the Commission, the three evaluation and monitoring committees and the Ethics Commission for Integrity in R+D+I with the human, material and technical resources necessary to carry out the tasks and functions.

CHAPTER 2. ETHICS COMMISSION ON RESEARCH AND INNOVATION

ARTICLE 5. DEFINITION AND OBJECTIVES

The Ethics Commission on Research and Innovation (CERI) is the body that promotes ethics in R+D+I activities at the URV and facilitates and coordinates the activities of the evaluation and monitoring committees and the Ethics Commission for Integrity in R+D+I.

ARTICLE 6. COMPOSITION

1. The CERI consists of at least the vice-rector competent in the matter, or delegated individual; the presidents of the three evaluation and monitoring committees; the president of the Ethics Commission for Integrity in R+D+I and the person responsible for providing technical support for the Commission.

2. The CERI may request, if necessary, the advice of experts from the URV or from external organisations.

ARTICLE 7. FUNCTIONS

The CERI has the following functions:

a) To provide support for the three evaluation and monitoring committees and the Commission for Integrity in R+D+I, without detriment to the independence of these bodies.

b) To approve the rules of the three evaluation and monitoring committees and the Commission for Integrity in R+D+I, notwithstanding the competencies held by any other authorities external to the URV. The regulations have to include at least aspects relating to the composition of the committees (positions, functions, selection process, format of members' CVs, renewal, presidency, termination and conflict of interests), working methods (meetings, R+D+I evaluation system), complaints mechanisms and procedures for reviewing the decisions adopted by the aforementioned bodies, training activities, recommendations, monitoring models and the annual report.

c) To detect, in the ambits in which the URV operates, any needs relating to the aforementioned bodies' knowledge and compliance with the regulations regarding the methodological, ethical and legal aspects of R+D+I activities and to propose the most appropriate measures for responding to these needs.

d) To facilitate relations with the authorities competent in the ambit of these regulations.

e) To coordinate its activities with similar commissions or R+D+I ethics committees from other institutions.

f) To produce the Annual Report, which must include data on activities, an evaluation and the overall state of affairs.

CHAPTER 3. EVALUATION AND MONITORING COMMITTEES

ARTICLE 8. DEFINITION AND OBJECTIVES

The Evaluation and Monitoring Committees are bodies which, in accordance with the current legislation and with impartiality and independence, evaluate the methodological, ethical and legal aspects of the R+D+I activities that are carried out at the URV.

ARTICLE 9. SCOPE

1. The URV's evaluation and monitoring committees act in the following areas:

a) The Ethics Committee for Investigation into Medicines (CEIm-IISPV) evaluates the R+D+I activities in biomedical research involving humans and which mean working on i) research projects that use personal health data, observational studies or human biological samples, ii) clinical trials with medicines, iii) clinical research with healthcare products and iv) observational post-authorization studies using medicines. The CEIm-IISPV is an official body consisting of members from the health institutions affiliated with the IISPV, the URV and other bodies external to these two entities.

b) The Ethic Committee on Animal Experimentation (CEEA) evaluate R+D+I activities involving the use of animals. The CEEA is a shared official body involving those departments of the URV that undertake animal experimentation and the IISPV.

c) The Ethics Committee for Research into People, Society and the Environment (CEIPSA) evaluates those R+D+I activities that involve i) human beings (including the processing of personal data), ii) the use of biological agents, genetically modified organisms and significant risk factors for individuals, society and the environment, and iii) the study of social and environmental issues and phenomena. If the research involves the processing of personal health data, point 1.a will be applied.

2. Each of these committees is governed by the present regulations, by the corresponding regulations and by current specific applicable legislation.

ARTICLE 10. APPOINTMENT OF MEMBERS

1. The URV members of the evaluation and monitoring committees are selected from among the full-time teaching and research staff and the administration and services staff that have been put forward. They are appointed by the rector at the proposal of the vice-rector competent in the matter after the Governing Council has been informed. They are appointed for a period of four years, renewable for another four years, respecting the criteria of parity as far as possible.

2. Given that both the CEIm-IISPV and the CEEA participate in the IISPV, the URV must ensure that, at least a third and a half, respectively, of the members of these committees belong to the full-time teaching and research staff of the University.

3. To ensure the continuity of the tasks, every two years each committee must partially renew a maximum of one third of the members.

4. The committees may request advice from experts in the matter from the URV or from external organisations.

ARTICLE 11. IMPARTIALITY, INDEPENDENCE AND DUTY OF CONFIDENTIALITY.

1. The members of the committees act with total impartiality and independence when undertaking their tasks of evaluation. To guarantee these values, situations of conflict of interest are defined in the regulations for each committee. Thus, when a member has a conflict of interest, they must not receive the documentation or participate in the evaluation of the corresponding R+D+I activity. Furthermore, they must not attend the meeting and this must be recorded in the minutes.

2. The committee members, the experts and all those who can participate in the activities of the different bodies must maintain complete confidentiality regarding everything that comes to their knowledge as a result of their participation.

ARTICLE 12. EVALUATION REQUESTS

1. Notwithstanding the projects that a certain committee is required to evaluate, a formal request must be made for the evaluation of the R+D+I activities included in the ambit mentioned in article 2. This must be done by presenting the corresponding application and documentation to the relevant committee.

2. Once the documentation has been checked and found to be in order, the person who provides technical support to the committee will register the request and, if required by the research project's funding agreements, the committee secretary will certify that it is being evaluated.

ARTICLE 13. ETHICS COMMITTEE FOR RESEARCH INTO MEDICINES (CEIm-IISPV).

1. Definition and aims

1. The Ethics Committee for Research into Medicines (CEIm-IISPV) is an entity that belongs to the IISPV and acts to safeguard the dignity, rights, safety and welfare of individuals who participate in biomedical research.

2. The CEIm-IISPV ensures that R+D+I activities of any type and that any collection of human biological samples in its scope follow the norms of good clinical practice and in particular the specific methodological, ethical and legal requirements. The CEIm-IISPV also monitors these activities in the centres that fall under its scope.

3. Furthermore, it promotes improvements in the ethical aspects of the research that is conducted at supervised centres.

4. The committee has complete independence in terms of its composition, procedures and decisions and from any influence that may prevent it from providing competent, objective and opportune evaluation of the ethics of the studies proposed.

5. Both the composition and the procedures comply with Royal Decree 1090/2015, of 4 December, which regulates clinical trials with medicines, the Ethical Committees for Research into Medicines and the Spanish Register of Clinical Studies, and with Decree 406/2006, of 24 October, which regulates the requirements and procedure for accrediting ethical committees on clinical research, and with the European Union's current good clinical practice protocols (CPMP/ICH/135/95).

6. It is governed by principles established by the Helsinki Declaration of 1996 and subsequent revisions regarding ethical principles for biomedical research on humans. Likewise, any review of biomedical research projects, collections of biological samples and any research using human biological samples is subject to Law 14/2007, of 3 July, on biomedical research, and Royal Decree 1716/2011, of 18 November, which establishes the basic requirements regarding the authorising and functioning of biobanks for the purposes of biomedical research and the handling of human biological samples. The committee will also take into account the Oviedo Convention regarding human rights and biomedicine, signed on 4 April 1997.

7. The URV understands that competence for the evaluation of the aforementioned R+D+I activities belongs to the Ethics Committee for Research into Medicines CEIm-IISPV, which it recognises as its own entity.

8. In accordance with article 16.4 of Royal Decree 1090/2015, of 4 December,[1] any expert assistance will be requested by the technical secretaries and the president of the committee and the reason for this must be documented in the minutes of the meeting. Furthermore, documents demonstrating the expert's qualifications, their confidentiality commitment and any conflict of interests must be stored.

[1] Royal Decree 1090/2015, of 4 December, article 16.4: "If the CEIm does not have the knowledge and experience necessary to evaluate a certain clinical study, it must request assistance from at least one expert who is not a member of the committee. This expert must respect the principle of confidentiality.

2. Composition

1. According to article 15 of Royal Decree 1090/20015 of 4 December, the CEIm-IISPV is composed of a minimum of ten members and has the following structure:

a) One person who represents the interests of the patients, who is external to the biomedical research and clinical assistance, and who does not work in a health institution.

b) At least three care-providing individuals (doctors).

c) On person specialized in clinical pharmacology.

d) One hospital pharmacist or primary healthcare provider.

e) One person with a diploma or degree in nursing.

f) One person from the Research Commission and one person from the Ethical Care Committee, if there is one at the centre.

g) At least two people from outside the health professions, one of whom must hold a degree in law.

h) At least one of the individuals must have accredited training in bioethics.

i) At least two people must be independent of the centres where the research is being carried out.

2. Members who have no working relationship or direct or indirect interests with the institution are considered to be independent. This independence must be documented.

3. The composition of the CEIm-IISPV must ensure the independence of its decision making, competencies and experience regarding the methodological, ethical and legal aspects of the research, the pharmacology and the clinical and care practices in the hospital and extra-hospital medicine.

4. The CEIm-IISPV must consist of a president, vice-president and a technical secretary who must have the status of committee members.

5. The president represents the committee and must be elected by voting members in order to ensure independence.

6. The vice-president must be elected in a similar manner and must act as president if the president is absent or ill or the presidency becomes vacant.

7. The technical secretary will have a degree and knowledge of medicine, research methodology, bioethics, pharmacology, regulation of medicines and medical research in general.

8. The votes of all committee members have the same value, except for the technical secretary, who has a voice but who may not vote.

3. Functions.

Regarding biomedical research involving humans, the CEIm-IISPV has the following functions:

a) To evaluate the methodological, ethic and legal aspects and the substantial modifications of clinical trials with medicines, in accordance with Chapter 5 of Royal Decree 1090/2015, and to issue the corresponding reports.

b) To evaluate the methodological, ethic and legal aspects and the relevant modifications of clinical investigations with healthcare products, of post-authorization studies with medicines, of pharmacogenomic and pharmacogenetic studies, and of other biomedical research projects and collections of human biological samples.

c) To monitor all evaluated and authorized biomedical research.

d) To act as an Ethics Research Committee for Biobanks in the centres included in its scope, evaluating applications to create collections, applications for biological samples and carrying out the functions established in article 15.3 of Royal Decree 1716/2011.

e) To develop recommendations, good practice guides and training activities for teaching and research staff and administrative and services staff regarding the ethics of biomedical R+D+I involving humans.

f) All those functions that are specified in the current regulations.

ARTICLE 14. ETHICS COMMITTEE ON ANIMAL EXPERIMENTATION (CEEA)

1. Definition and aims

1. The Ethics Committee on Animal Experimentation (CEEA) is the body responsible for evaluating the methodological, ethical and legal aspects of the R+D+I activities carried out at the URV and that involve the use of animal for experimentation and for other scientific purposes, including teaching. The URV departments that carry out animal experimentation and the IISPV participate in the CEEA.

2. This committee has to ensure compliance with the current regulations regarding the protection of animals used in experiments and for other scientific purposes; specifically, it must carry out the functions assigned to it by Royal Decree 53/2013, of 1 February, or the relevant regulations.

3. The fact that the CEEA carries out its evaluation does not eliminate the obligation for R+D+I activities that use animals for experimentation or other purposes, including teaching, to be evaluated by the competent body.

2. Composition

1. The CEEA consists of at least six members, of whom at least half are members of the URV's full-time teaching and research staff, whilst maintaining the representation of the URV departments that carry out experiments using animals. They are appointed by the rector at the proposal of the vice-rector competent in the matter, whilst respecting at all times the criteria of parity as far as possible.

2. The CEEA has an interdisciplinary composition and its members are elected on the basis of their competence, professional experience and demonstrated interest in ensuring the welfare and care of animals in research.

3. The CEEA must always have the following members:

a) A veterinarian with experience in experimentation with laboratory animals and animal welfare, who is responsible for on-site monitoring of the animals' condition and the care provided for them.

b) A person responsible for the animal rooms of the URV who also carries out technical support duties for the Committee.

c) A representative of the entity's quality assurance unit, if there is one, or, if not, a researcher from the entity who is not directly involved in the procedures on which he/she has to report.

d) At least two members of the URV's full-time teaching and research staff with accredited experience in animal experimentation and who represent the different URV and IISPV units and departments that undertake research and/or teaching using experimental animals.

e) A member of the URV's full-time teaching and research staff with demonstrated experience in research areas that have no relation with those that are under the competence of this committee.

4. Furthermore, if necessary in order to take decisions, the CEEA may request the advice of experts from the URV or from external organisations regarding technical, ethical or legal issues.

3. Functions.

Regarding R+D+I activities that use animals, the CEEA has the following functions:

a) To evaluate these activities correctly and with equanimity, respect and efficiency. Prior to any activities, the CEEA must issue a favourable preceptive report, notwithstanding any other reports that have to be emitted. Any significant subsequent modification after the publication of the CEEA's favourable report must also include a favourable report from the Committee.

b) To monitor the R+D+I activities related to the favourable reports in the initial evaluation. The CEEA must establish the procedures and guidelines for carrying them out in accordance with the current legislation and the scientific community.

c) To propose recommendations, good practice guides and training activities in ethical matters regarding research using animals that facilitate the work of the teaching and research staff and the administrative and services staff.

d) All those functions that are specified in the current regulations and that the governing bodies of the URV consider necessary and opportune.

ARTICLE 15. ETHICS FOR RESEARCH INTO PEOPLE, SOCIETY AND THE ENVIRONMENT (CEIPSA)

1. Definition and aims

1. The Ethics Committee for Research into People, Society and the Environment (CEIPSA) is responsible for evaluating the methodological, ethical and legal aspects of the R+D+I activities carried out at the URV that involve i) human beings (including the handling of personal data), ii) the use of biological agents, genetically modified organisms and significant risk factors for individuals, society and the environment, and iii) the study of social and environmental issues.

2. If the research involves the processing of personal health data, this must be evaluated and monitored by the Ethics Committee for Research into Medicines of the Pere Virgili Health Research Institute (CEIm-IISPV).

3. If the research involves the handling of genetically modified animals, this must be evaluated and monitored by the Ethics Committee on Animal Experimentation (CEEA).

4. This committee must ensure compliance with the current regulations regarding personal data protection, protection and biological security, including the prevention of occupational risks, and any issues that affect the balance between economic development, the welfare of society and the environment.

2. Composition

1. The CEIPSA must have at least five members. They are chosen from among the full-time URV teaching and research staff and administrative and services staff who are put forward. They are appointed by the rector at the proposal of the vice-rector competent in the matter, whilst respecting at all times the criteria of parity as far as possible.

2. The CEIPSA has an interdisciplinary composition and its members are elected on the basis of their competence, professional experience and demonstrated interest in guaranteeing the protection of personal data, vulnerable groups (ethnic minorities, people with disabilities, infants, migrants, women, LGBT+ community, etc.), protection and biological security, including the prevention of occupational risks, and issues that affect the balance between economic development, the welfare of society and the environment.

3. The CEIPSA must include the following individuals:

Three people from the URV's full-time teaching and research staff with demonstrated experience in the areas of research into the protection of personal data, vulnerable groups (ethnic minorities, people with disabilities, infants, migrants, women, LGBT+ community, etc.), protection and biological security, including the prevention of occupational risks, and issues that affect the balance between economic development, the welfare of society and the environment.

A member of the URV's full-time teaching and research staff with proven experience in research methodologies.

An individual who carries out technical support duties for the Committee and who acts as the technical secretary of the CEIPSA, but without the right to vote.

4. The CEIPSA must also have a jurist, a personal data protection officer, an officer from the Occupational Risk Prevention Office, a member of the URV's full-time teaching and research staff with demonstrated experience in research areas that have no relation to the areas that fall under the competence of this committee.

5. The CEIPSA must create a bank of evaluators taken from the URV's full-time teaching and research staff who will be called upon to attend meetings according to the nature of the R+D+I activity.

3. Functions.

With regard to R+D+I activities that affect the protection of personal data, protection and biological security, including occupational risk prevention, or that affect the balance between economic development, the welfare of society and the environment, the CEIPSA has the following functions:

a) To evaluate these activities correctly and with equanimity, respect and efficiency. Prior to any activities, the CEIPSA must issue a favourable preceptive report, notwithstanding any other reports that have to be emitted. Any significant subsequent modification after the publication of the CEIPSA's favourable report must also include a favourable report from the Committee.

b) To monitor the R+D+I activities related to the favourable reports in the initial evaluation. The CEIPSA must establish the procedures and guidelines for carrying them out in accordance with the current legislation and the scientific community.

c) To propose recommendations, good practice guides and training activities in ethical matters that facilitate the work of members of the teaching and research staff and the administrative and services staff regarding R+D+I activities involving personal data protection, protection and biological security, including occupational risk prevention, or that affect the balance between economic development, the welfare of society and the environment.

d) All those functions that are specified in the current regulations and that the governing bodies of the URV consider necessary and opportune.

CHAPTER 4. ETHICS COMMISSION FOR INTEGRITY IN R+D+I

ARTICLE 16. ETHICS COMMISSION FOR INTEGRITY IN R+D+I (CEIR)

1. Definition and aims

1. The Ethics Commission for Integrity in R+D+I (CEIR) is responsible for promoting the awareness and internal adoption of the Code of Good Scientific Practices, for attending to queries and for mediating in conflicts. It acts independently and serves the scientific community, the teaching and research staff and the administration and services staff of the URV with the aim of providing support to ensure the quality and integrity of R+D+I activities.

2. This commission must ensure compliance with the current regulations regarding R+D+I.

2. Composition

1. The CEIR must have at least five members. They are chosen from among the full-time URV teaching and research staff and administrative and services staff who are put forward. They are appointed by the rector at the proposal of the vice-rector competent in the matter, whilst respecting at all times the criteria of parity as far as possible.

2. The CEIR has an interdisciplinary composition and its members are elected on the basis of their competence, professional experience and demonstrated interest in working to ensure integrity in R+D+I activities.

3. The CEIR must have the following members:

a) Three members from the URV's full-time teaching and research staff with demonstrated experience in R+D+I activities.

b) One member from the URV's full-time teaching and research staff with training in ethics.

c) One member who provides technical support for the Commission and acts as technical secretary to the CEIR, but without a vote.

4. The CEIR must also have a jurist and/or an officer from the Legal Bureau.

3. Functions.

1. The functions of the CEIR are:

a) To ensure compliance with the precepts of the Code of Good Scientific Practice.

b) To ensure that the Code of Good Scientific Practice is updated as relevant new regulations come into effect.

c) To provide mediation and advice regarding any uncertainties and conflicts that may arise in relation to the integrity of R+D+I activities, at the request of interested parties or at the indication of the Executive Council of the URV. The CEIR's conclusions are intended for consultation by the parties involved in conflicts that are reported on by the CEIR.

d) To inform and raise awareness among the scientific community of the URV regarding events, needs and orientations relating to ethical and deontological aspects of R+D+I activities. The CEIR will ask the PDI Commission, delegated by the Governing Council, for the resources and measures that enable it to carry out this task.

e) To be receptive to new problems related to integrity in R+D+I activities, to discuss them in the appropriate forums and to propose updates to the Code of Good Scientific Practice to the URV's Executive Council.

f) All those functions that are specified in the current regulations and that the governing bodies of the URV consider necessary and opportune.

2. Regarding the previous functions, at all times the CEIR commits to manage diligently, act with independence, ensure anonymity and confidentiality in its handling of personal data, generate reliable information, deliberate with impartiality and be fair in its conclusions.

FIRST ADDITIONAL PROVISION. DELEGATED OFFICE OF THE VICE-RECTOR

The rector may approve a resolution to change the Office of the Vice-Rector that is charged with ensuring the good functioning of the bodies responsible for ethics in research and innovation at the URV.

SECOND ADDITIONAL PROVISION. ORGANISATION

The Ethics Commission for Research and Innovation may:

a) Take on new functions related to its ambit of application that are not specified in the present regulations or it may assign them to the existing evaluation and monitoring committees or to the Ethics Commission for Integrity in R+D+I.

b) Create new evaluation and monitoring committees according to the requirements at a given moment.

TEMPORARY PROVISION

Within 6 months of the entry into force of the present regulations, the Commission, the three evaluation and monitoring committees and the Ethics Commission for Integrity in R+D+I must each create their own specific regulations that define and specify their respective scope, their members and their basic functions in accordance with criteria of confidentiality and representativeness, and that ensure the impartiality of their decisions. This document will be published as an annex to the present regulations.

Until the specific regulations have been created, the Commission, the three evaluation and monitoring committees and the Ethics Commission for Integrity in R+D+I will be governed by the present regulations.

OVERRIDE PROVISION

The entry into force of the present regulations explicitly repeals the Regulations on good practices in works of transfer and the provision of services of the URV, of 10 July 2003, and the Regulations on transfer in ambits of special public sensitivity, of 24 April 2008, regarding those issues relating to research and innovation ethics bodies.

FINAL PROVISIONS

One. Accreditation of Evaluation Committees

For those evaluation and monitoring committees that are required by the legislation to obtain accreditation from the competent authorities, the vice-rector competent in this matter, or the designated individual, will be responsible for applying for the accreditation, in the event that the committee has yet to receive such accreditation.

Two. Entry into force

These regulations will enter into force the day after they are published in the Official Bulletin of the URV.