Code of Good Research Practices

UNIVERSIDAD COMPLUTENSE MADRID

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COMPLUTENSE UNIVERSITY OF MADRID

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UCM CODE OF GOOD RESEARCH PRACTICES

1. GENERAL RESEARCH PRINCIPLES AT THE UCM

The UCM adheres to, and undertakes to carry out its research in accordance with the principles described by the Code of Conduct for Scientific Integrity (ALLEA- All European Academies) and the National Declaration of Scientific Integrity (COSCE-CRUE-CSIC). All people who carry out research at the UCM or on its behalf, whether they are teaching and research staff, administration and services staff, students or staff with honorary posts or positions and regardless of the sources of funding for their activity, must observe these principles. . To facilitate this effort, this document provides general guidelines on good research practice. This code is applicable to all of them, regardless of the phase of one's research career.

1.1. General principles

Purpose and objective of the research. All people involved in research at the UCM (hereinafter, "research staff"), in the pursuit of their scientific activity, must contribute to the advancement of knowledge for the benefit of humanity, respecting the dignity of human beings and the autonomy of their will, protecting personal rights, guaranteeing the welfare of animals and preserving the natural environment and cultural heritage.

Scientific integrity. Research staff must systematically pursue objective knowledge that can be assumed to be true, that is, based on verified and validated results in order to guarantee their credibility and soundness. They must use appropriate methods and procedures and base their conclusions on a critical and independent analysis of all the results they obtain, interpreting them completely and objectively, verifying the precision and consistency of their research results before making them public. They must recognize the contributions of third parties, comply with the applicable agreements, terms and regulations and favour the good governance and transparency of their activity.

Excellence. Research staff must observe the highest standards of integrity, honesty and professionalism, both in their own research activities and in their response to the research of others. This includes, but is not limited to: the design of studies and experiments; the generation, collection, recording, archiving, analysis and interpretation of data; the sharing of data and materials; the request for funding; the presentation and publication of results; the training of researchers, staff and students; and the evaluation of the work of third parties. Direct or indirect contributions from colleagues, collaborators and others should be recognized. Research staff must strive for excellence when conducting their research, and pursue the production and dissemination of work of the highest quality.

Ethics and legality. The research staff must comply with all the ethical and legal requirements of their field of study, declaring any conflict of interest. They must be aware of UCM policies and procedures and ensure that their research complies with these. They must also submit proposals, projects and activities to ethical reviews and prior or subsequent approvals that may be applicable. When collaborating with other countries, they must ensure compliance with Spanish regulations as well as with that of the countries in which the research is carried out.

Safety. Research staff must protect the dignity, rights, safety and well-being of all those involved in the research and avoid unreasonable risks or harm to the subjects under study, researchers and the social environment. In the event of any action that deviates from this principle, they have the obligation to inform about it.

1.2. Organization of research at the UCM

The main research governing bodies at the UCM are the Vice-Rectorate that is competent in the matter and the Research Commission (see). Research at the UCM is carried out within its own administrative structures or in other centres with which the university has agreements for this purpose. The main ones are summarized below:

Research groups[1]

A research group is a group of people who share scientific objectives and research activities, under the direction of one of them. Groups can be made up of people from one or more departments and faculties, and can include researchers from other institutions. Research staff of the UCM can also participate in research groups from other entities. Research groups recognized by the UCM must have an organizational structure in which responsibilities and modes of collaboration and communication are clearly defined, and meet a series of requirements (see). All members of a research group must commit themselves to collaboration and actively participate in the group's activities.

Research Institutes[2]

Research institutes are centres devoted to scientific and technical research or artistic creation. They can belong to two main categories: University Research Institutes, approved by the Community of Madrid, which can, among other activities, organize and develop postgraduate programmes and studies and provide technical advice in their field of competency. The second category is made up of the Complutense Research Institutes, which have not been recognized by the Community of Madrid, and cannot develop their own postgraduate programs. Research institutes may belong to the UCM itself or have been created with other research institutions, and their members may belong to the UCM or other entities. Their activities, in general, are complementary to those carried out by the departments (see list).

1 Art. 167 UCM Statutes

2 Art. 16 UCM Statutes

Health Research Institutes

Health Research Institutes are the result of the association of universities and other public and private research centres with teaching and research hospitals of the National Health System. The main purpose of Health Research Institutes is to carry out translational research, in order to transfer the results of basic, clinical, epidemiological, health services and public health research to the National Health System, the Spanish Science and Technology System, to the patient and to society in general. The ultimate goal of these alliances is that all knowledge generated from biomedical research of excellence should lead to improving the treatment and prevention of diseases and improving the health and quality of life of the population. Other structures directly related to research at the UCM are:

Analogous centres or structures (see).

Research Assistance Centres[3]

Research Assistance Centres are research infrastructures that offer services (frequently based on the use of high-level equipment whose cost is difficult to bear for a group, project or centre) to the scientific community (see list of RACs here).

Madrid Science Park UCM-UAM

The Science Park is an infrastructure of facilities designed to support entrepreneurs and research and development. It offers support to science-technology entrepreneurs, providing business incubation and acceleration services, as well as quality offices and laboratories. In addition, it offers scientific support services to research personnel in the areas of genomics, proteomics and microanalysis of materials.

University Knowledge Transfer Companies (UKTCs) or spin-offs

These are companies in the form of trading companies, which benefit from the promotion of permanent teaching or research UCM staff, who make use of the results of the research activity carried out at the UCM with public funding, the latter holding the ownership of these results, for the production of goods or the provision of services with a high added value. UKTCs sign the corresponding agreement with the University for the transfer of research. At least one of the inventors, authors or connoisseurs of the know-how on the part of the UCM must be a promoter of the company. The UCM may or may not hold capital stock of UKTCs. This code of good practices is of mandatory application for UKTCs.

3 Art. 168 UCM Statutes

2. CONFLICTS OF INTEREST

Research staff must know and comply with state and European Union legislation regarding incompatibilities and conflicts of interest, as well as the policy and institutional requirements in this regard, and the eventual requirements of the funding entities.

Research staff must identify and declare any real, potential or apparent financial, professional or personal conflict, as described in the applicable regulations, or any other situation that could unduly influence or compromise the adequate fulfilment of research activity, collaboration with other entities, staff training or evaluation tasks or the dissemination of results.

Conflicts of interest will be declared to the Research Ethics Council (REC) of the UCM. The Board will identify the type and severity of the conflict, and will take the appropriate measures in accordance with the applicable regulations. These may include preventing participation in decisions, activities or bodies in accordance with institutional regulations and guidelines, or even prohibiting the continuation of research when conflicts pose a risk that compromises the integrity of the work. Any conflict of interest must also be declared when the results of the research are reported or disseminated.

3. THE RESEARCH PROCESS

3.1. Research design and execution

Research design and planning

• Research must address issues relevant to society and be designed to add knowledge or develop new methodologies.

• Research design and process must be previously specified in a research plan or protocol. This plan will include, at least: antecedents, objectives, methodology to be used and procedures to be applied and work team. It should also include a schedule that establishes the phases of the research, the planning of the associated human resources, the assignment of tasks, the necessary material resources and a duly justified budget. All of which should be appropriate to resolve the issues raised and take into account potential biases.

• Research planning should foresee the dissemination of results and the criteria relating to authorship and the order of authorship.

• Where appropriate, statistical power[4] should be taken into account. This aspect is especially important in studies that involve the use of humans or animals in experimentation, in order to avoid unnecessary testing and ensure that the fewest possible number of specimens are used.

4 Statistical power is understood as the probability of research detecting a significant effect when it actually exists. If statistical power is high, the probability of concluding that there is no effect, when there really is an effect, decreases. In general, it is considered acceptable for statistical power to have a value equal to or greater than 80%

• Depending on the type of research, the specific legal and ethical aspects of each field must be taken into account. In research involving human beings, biological samples of human origin and/or personal data; biological agents and/or genetically modified organisms; and animals, the approval of the project will be obtained by the corresponding ethics committee, and its subsequent modifications must also be reviewed. See relationship and structure of the Research Council and the Committees it is composed of. In the case of protected assets, the pertinent authorizations will also be necessary.

• It is necessary to anticipate any type of risk of the results being misused or employed for illegal or harmful purposes; If such risks are identified, information should be provided and guidance sought.

Research procedures

• All procedures and methods used in research must be adequately referenced and documented to allow their subsequent review as accurately as possible. Both the final results and the methods and data used throughout the research must be kept for the time established by the corresponding regulations. The entire research team must be able to access the same versions of the documents and data.

• The methods used in research must originate from reliable sources (reference methods, scientific publication standards, etc.). In the event of the research consisting in the development of a new methodology, its approach, development and application must follow the same principles of rigour and reproducibility as any other research.

• The planning and procedures or protocols contemplated must be monitored in order for one

to verify that the activities being carried out are in accordance with what was planned and, if applicable, make the appropriate changes.

Infrastructures, availability and management of resources

• It is necessary to verify and ensure the availability of the resources needed for the research to be carried out, their suitability for the processes to be developed and their compliance with the applicable risk prevention and safety requirements. Those people who have to use research equipment must be suitably trained and have adequate instructions for its use. In the case of complex equipment, these instructions must be documented in as much detail as possible.

• If the development of the project requires the purchase or acquisition of new equipment, the corresponding institutional regulations must be met.

• All the facilities or places where the research is carried out must be adapted in such a way that the activities can be carried out, as regards both the safety and accessibility of the people who work in them and the quality of the results obtained.

Responsible use must be made of the means and resources available, allocating them for their purposes intended, administering and managing them according to criteria of economy, transparency and efficiency.

Research monitoring, control and auditing

• The terms and conditions of any research grant or contract will be complied with, which extends to the institutional rules regarding the use and management of the funds that finance research projects.

• Research staff must ensure that they comply with the monitoring, auditing and control requirements from the initial conception of the project.

• Research staff will collaborate with any financial monitoring or auditing and will inform the relevant persons of any concern or irregularity as soon as they become aware of them.

3.2. Management of data and material resulting from research

The plan for the collection, recording, conservation and custody of any type of data, material or sample generated during the research, as well as access to them, must be drawn up in the early stages of project design and be part of the research plan. Any inter-institutional collaboration agreement must contain provisions related to these points. Research material means everything used during the research process and from which data are obtained. Research materials include, for example, samples, physical and other objects, documents, databases, files, and ideas.

Research data means the facts, observations, or experiences on which the argument, theory, hypothesis or evidence is based. Data may be numerical, descriptive or visual, experimental or observational. One may distinguish three types of data: original primary data prior to research, raw data obtained during research and processed data.

Research materials and primary data

• The management of research material and primary data (collection, recording, use, storage

and custody) must be carried out in accordance with the regulations and corresponding conventions for the type of material or data in question and with maximum guarantees of accessibility for research staff. This must be done in such a way that it guarantees its integrity, traceability and conservation at all times.

• All primary materials or data involved in research activities or those derived from these activities must be clearly and durably identified together with the project or protocol from which they originate.

• Any exchange of primary materials or data with other institutions must be carried out with the corresponding signed transfer protocol.

Data generation and management

• Research data must be generated using rigorous techniques and processes.

• Information on the origin of the data should include the how, when, where and with what (for example, instruments). The software code used to generate, comment or analyse data may also be considered data.

• Primary research data must be kept in its original form and not be manipulated in any way.

• In any research that involves the use of personal data, there must be a guarantee that these have been obtained and stored in accordance with current legislation and the corresponding ethical practices. This will include informing all research participants about what will be done with their data, who will have access to them, and to whom, outside of the university, such data are to be conveyed (if applicable).

• Clear and accurate records must be kept of the procedures carried out and the permits obtained during the research process. Records of intermediate and final results, as well as preliminary, negative, unexpected, or discordant results must be included. The records should identify the person who obtained the data and the date. Any changes made must show the corrected data and identify the data of the correction and the person who carried it out.

Storage and custody

• All research data must be effectively managed and preserved throughout their life cycle to ensure their integrity, security and quality.

• Copies of the main programmes used to process the data obtained must be kept.

• Electronic files containing personal data must be encrypted or protected with a password and access to them must be limited to the fewest possible number of people.

• In the case of electronically stored data, backup copies must be generated periodically in a systematic way and, taking into account the established retention period, their recovery must be guaranteed, especially in cases in which the format or standards are modified.

• All data must be kept in such a way that it can be recovered and reproduced by third parties, always subject to the limitations imposed by legislation and the general principles of confidentiality.

• Research data retention periods will vary depending on the specific contractual conditions and the nature and sensitivity of the research. Whenever possible, they should be maintained indefinitely.

• All data destruction must be adequately justified and done in accordance with all legal, ethical, funding entity and institutional requirements, with particular attention paid to confidentiality and security.

• The storage and custody of the data is the joint responsibility of the main researcher, the members of the research team and the university.

Dissemination and confidentiality

• The data and materials resulting from research must be public and potentially available to third parties, except in such cases in which restrictions have been established for reasons of confidentiality or possible future commercialization.

• The guidelines provided by the funding bodies must be complied with, which extends to the University requirements established in this code, and the specifications of the UCM Policy on information security and research data protection.

• Steps must be taken to ensure that all means are available to prevent accidental dissemination of data as a result of error, lack of knowledge or the lack of protection mechanisms against external attacks.

Ownership and access

• All raw data, as well as the material obtained during research, are the property of the institution and/or shared with the participating institutions.

• All members of the research team must be able to access the research data obtained.

• Should there be a change of institution on the part of any member of the UCM team, the person in question may request a copy of all or part of the data generated by his or her research. If the change affects the principal researcher, this process must be carried out under the responsibility and supervision of a person designated by the institution.

• Before third parties are granted access to data and materials, it is necessary to know the use that will be made of them and follow a transfer protocol that includes an approval by the person responsible for the research, the institution and the corresponding ethics committee. The third party requesting the data and materials will accept responsibility for any production or procedure costs. The granting of access may be limited for reasons of availability, competition or confidentiality. All material or data originating from people must be shared in such a way that the subjects of the source cannot be identified; otherwise, specific permission must be obtained from the persons from whom they originate.

3.3. Leadership and collaboration

Research groups must have at least one principal researcher leading the group and representing it publicly. The responsibilities of such leadership encompass both academic and organizational aspects.

Principal researchers must exercise mentorship and leadership fairly, sensibly, and responsibly. They should promote and maintain an environment in which research is conducted in accordance with good practices and ensure that all those involved are aware of these guidelines and the applicable policies and requirements. They will promote a manner of working in which the members of the group can obtain experience and develop their capacities

and in which the exchange of ideas and knowledge is encouraged, along with the achievement of common research objectives. They will promote critical judgment, the exchange of views and teamwork and, inasmuch as this is possible, they will foster cooperation with other teams of researchers.

Principal researchers must direct and supervise all phases of the research process, including the establishment of hypotheses, preparing funding applications, designing experimental or research protocols, as well as data collection, data analysis and the interpretation and the dissemination of results.

The members of a research group must maintain frank, open and continuous communication in the interests of an adequate understanding and interpretation of the research carried out within the group.

When it comes to research conducted in collaboration with other entities, any issues that may arise as a result of collaborative work must be anticipated and the manner in which they will be addressed must be agreed upon in writing. Principal researchers must communicate any decisions to all members of the research team. In particular, they must agree on the role of the research staff involved in the project in relation to intellectual property, the publication and the attribution of authorship, knowing that such roles and contributions may change throughout the research.

In projects that include participants in different countries or in which the work is to be carried out in other countries, the appropriate legal and ethical requirements must be known and applied.

3.4. Research staff training

The training process for young research staff is one of the responsibilities of established research staff, in order to provide them with essential research skills. This process must include a systematic understanding of one's field of study and a mastery of research skills and methods related to that field; the ability to conceive and carry out substantial research processes, to carry out critical analyses and syntheses of new ideas, to communicate to the academic and scientific community and to society in general, and to promote the advancement of knowledge. It also includes developing personal skills to function in environments with little specific information, identifying key issues to solve complex problems, designing and undertaking innovative projects, working both as a team and autonomously in international and multidisciplinary environments, and integrating knowledge, dealing with complexity and making judgments with limited information.

Principal researchers are responsible for the training process, taking into account the objectives defined and the timetable for achieving them. Therefore, they must provide research staff in training with the best possible conditions to carry out their scientific work. More specifically, they must:

• Encourage internship staff access to discussion forums and scientific meetings and offer advice for their future, as well as encourage their participation in research projects, stays abroad, courses, etc.

• Ensure that research is carried out in safe conditions, informing the research staff in training about the safety regulations and risk prevention measures and insisting on their compliance.

• Ensure compliance with the code of good practices by research staff in training and promote self-criticism in their work.

• Carry out their own work in a way that serves as an example to research staff in training.

Research staff in training must actively collaborate in all tasks related to training and request the support and help of the principal researcher whenever necessary. Research staff must undergo the necessary training to carry out their duties and develop their knowledge and skills throughout their careers.

3.5. Ethical practices in research

All research carried out at the UCM must comply with the legal, regulatory, professional and ethical requirements and standards established by the competent authorities. The research staff must be informed about and know how to access these requirements. Should there be any doubts, or if conditions of risk or damage arise for the participants in the research (humans or animals), the research staff must inform those persons responsible for that, and if necessary the latter, in turn, must duly inform the corresponding ethics committee and/or the regulatory authority and follow the instructions received. Any improper use of human material or personal data must be communicated following the same channels. In the event of discrepancies regarding the measures to be adopted, the Research Ethics Council must be informed.

Research staff must ensure that all ethical issues affecting their projects are identified and addressed throughout the entire research cycle. One must ensure that all necessary permits or approvals are obtained prior to starting the research, and that they are updated in the event of the schedule changing.

Research involving human participants, human material or personal data

The dignity, rights, safety and well-being of potential participants should be the first consideration when undertaking a research project with humans. Research should only be initiated if the anticipated benefits outweigh the risks.

All research involving human participants or personal data carried out by UCM personnel or at UCM facilities must comply with the applicable legislation, as well as the university's ethical policy. In particular, it must comply with what is stipulated in Law 14/2007, of July 3, on Biomedical Research, and in Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights.

Research staff must present research projects to the relevant committees for evaluation and approval, and respect the results of these evaluations. It is necessary to guarantee that the projects have been approved by all the ethical, regulatory or other bodies involved.

In particular, special attention should be paid to:

• Ensuring that the participants or their legal representatives give their informed consent, by means of the provision of adequate and accurate information, ensuring that is has been fully understood.

• Guaranteeing the confidentiality and security of personal data, as well as the human material involved (biological samples, genetic analysis or others) and protecting the rights of the holders

of the samples in accordance with the law.

• Guaranteeing the traceability of the information throughout the entire experimentation and research process.

• Specifying any economic compensation that the subjects participating in the research will receive, which will be provided for the inconveniences or risks assumed and may not be used as an incentive to participate in the research.

• Carrying out genetic analyses under the criteria of relevance, quality, equity and accessibility.

• Complying, when appropriate, with the legally established requirements for the import and export of biological samples.

When the participation of UCM staff and students in a project is contemplated, guarantees must be made that it is free and voluntary, measures must be taken to avoid adverse consequences for those who decide not to take part or those who decide to leave the project, and all the aspects indicated in this document must be taken into account.

Research with animals

Research with animals will be conducted when there are no other viable alternatives.

All species used in research and teaching will be treated in an ethical, responsible and respectful manner. More specifically, all research with animals will be conducted in accordance with:

• The principles of replacement (the use of animals as the last alternative), reduction (the use of the fewest possible animals) and refinement (guaranteeing the maximum possible welfare for the animals).

• Royal Decree 53/2013, of February 1, which establishes the basic rules applicable to the protection of animals used in experimentation and other scientific purposes, including teaching. Correction of errors in BOE (Official State Bulletin) 04-26-2013.

• Law 32/2007, of November 7, and its modification by Law 6/2013, of June 11, for the care of animals, during their use, transportation, experimentation and sacrifice.

• Royal Decree 65/2006, of January 30, which establishes requirements for the import and export of biological samples.

• Order ECC / 566/2015, of March 20, which establishes the training requirements to be met by personnel who handle animals used, raised or supplied for experimentation and other scientific purposes, including teaching.

• The guidelines regarding transparency in animal research, promoted by the Confederation of Scientific Societies of Spain (COSCE), as well as the European Animal Research Association (EARA).

Research using animals requires the following procedures and approvals (through the relevant bodies):

• The people involved must have obtained recognition of the training to handle animals used, raised or supplied for experimentation purposes.

• The project must have obtained the corresponding reports and authorizations from the

Animal Experimentation Committee (CEA).

Research with biological agents and/or genetically modified organisms

In the field of biosafety, the adoption of measures and the application of regulations in order to preserve the safety of living beings and the environment against certain factors that could alter them, such as biological risk agents (bacteria , viruses, fungi, parasites, cell cultures, samples from treatment plants, ...) and genetically modified organisms.

Research that uses biological risk agents and/or genetically modified organisms must ensure that Good Scientific Practices (GSP) are carried out and promote the values of biosafety, information, precaution, prevention of personal and occupational risks, and environmental protection. It is necessary to verify that there is no alternative research method of comparable efficacy and that the risks of the research are not disproportionate in relation to its potential benefits.

Research that uses risky biological agents and/or genetically modified organisms must have gone through the following procedures and approvals (via the relevant bodies):

• The persons involved must have obtained recognition of the training to handle such samples for experimentation purposes.

• The facilities and activities must comply with the regulations established by the UCM Health and Safety Committee.

• The project need to have obtained the corresponding reports and authorizations from the Biosafety Committee on research with Biological Agents and/or Genetically Modified Organisms.

Misuse and dual-use research

Dual-use research is understood as that which can generate products, results and technology that may be used for both civil and military uses or nuclear uses. Research staff must consider any risk that their research may generate results that could be misused or harmful, both in the establishment of agreements and in the communication of results or in training. When such a risk exists, one must seek advice and take active steps to minimize it.

Research staff must comply with legal requirements regarding dual use, particularly export controls. Export controls apply to the transfer (by any means) of goods, technology, software or knowledge from Spain to an external destination, which may be used for military purposes or for the development of weapons of mass destruction. In particular, it must comply with European legislation on the control of exports, transfer, brokerage and transit of dual-use products, [5] as well as with Spanish legislation in this regard. [6]

Research involving natural, cultural and landscape heritage

Research activities carried out in natural spaces and in places declared (natural, historical, archaeological, etc.) heritage sites or using materials and assets that are protected or have been declared of cultural interest must respect current legislation and adapt the research to ensure the maintenance, conservation and sustainable development of those spaces, places and assets that make up the natural, tangible and intangible heritage, bequeathed to future generations.

Any type of research that involves archaeological, ethnographic heritage, movable or

immovable, documentary or bibliographic assets of cultural interest must be carried out in accordance with the national, regional and international legislation in force in each place, which in the Spanish case would be Law 16/1985, of June 25, on the Spanish Historical Heritage (BOE-A-1985-12534). At an international level, the Convention for the Protection of the World Cultural and Natural Heritage (UNESCO, 1972), and the Convention for the Safeguarding of Intangible Cultural Heritage (UNESCO, 2003), among others, must be respected.

5 COUNCIL REGULATION (EC) No. 428/2009, of May 5, 2009, establishing a Community regime for the control of exports and the transfer, brokerage and transit of dual-use products

6 LAW 53/2007, of December 28, on the control of foreign trade in defence and dual-use material. Royal Decree 679/2014, of August 1, approving the Regulation for the control of foreign trade in defence material, other material and dual-use products and technologies. ECC Order / 1493/2016, of September 19, updating the annexes to the Regulation for the control of foreign trade in defence material, other material and dual-use products and technologies, approved by RD 679/2014 , of August 1.

4. AUTHORSHIP, DISSEMINATION AND INTELLECTUAL PROPERTY

4.1. Authorship

Decisions on the publication and authorship of research papers, provided they are not individual, must be taken jointly and communicated to all the people who have participated in the research work.

Authorship should be restricted to those individuals who have made a significant intellectual or practical contribution to the work. No person who meets the requirements to be considered an author should be excluded. “Honorary” or “gifted” authorship is not considered good practice. The work of all the people who have collaborated and do not meet authorship criteria should be indicated in an acknowledgment section. Anyone listed as the author of a work assumes public responsibility for such work and guarantees its accuracy.

Regardless of the forum in which the research is presented, the authors must declare any current or potential conflicts of interest in relation to this research.

The research staff of the UCM must indicate their affiliation to the UCM in all the work they carry out within the framework of their research work at the university. The institution (Complutense University of Madrid), the faculty and department of the research staff, and additionally the research institute or some other UCM centre to which it is attached must be indicated.

When disseminating the results of a research undertaking, all the sources used in the research must be clearly indicated, and the financing entities and sponsors must be explicitly identified.

The university has adhered to the recommendations of the International Committee of Medical Journal Editors (ICMJE) and the Committee on Publication Ethics (COPE) regarding authorship. *See Annex on Authorship*.

In the event of bad practices being detected in relation to these guidelines, the Research Ethics Council should be informed.

4.2. Dissemination, publication and open access

The university urges its staff to disseminate the results of their research, once they have been verified and validated. This dissemination must be done in a transparent and honest manner, avoiding subjective or abusive interpretations of the results, as well as intentional omissions of information that may generate confusion or create false expectations. Likewise, the authors must consider the possible implications or consequences of the dissemination of research results in society. Decisions on the publication of research papers must be agreed upon with the funding entities. In any case, the research staff must comply with the conditions established by these entities.

When the eventual need arises to postpone the publication of results for reasons of intellectual property protection, the situation will be negotiated and agreed between the research staff and the funding entities.

Publications should not be submitted to more than one editor simultaneously except with the knowledge and agreement of the editors.

People under pressure to publish and disseminate their research or to present or interpret its results in a self-interested, biased, inappropriate or erroneous way must report this to the Research Ethics Council of the UCM.

The university is committed to the widest possible dissemination of research and to respecting academic freedom to choose the place and nature of the publication.

The university recommends avoiding publication in so-called "predatory journals", with dubious systems for selecting, evaluating and publishing manuscripts. It is advisable to consult *document N-AEI 18-01 Predatory magazines. Questionable and unreliable Open Access publications of the State Research Agency*.

The institutional policy of the UCM[7] determines that research production must be openly accessible by means of the relevant publication being cited in the "e-prints" repository. More specifically, this commitment involves:

• That the publications resulting from research and academic activity be deposited in the Complutense institutional repository.

• This deposit will take editorial policies into account, respect copyright and intellectual property rights, as well as the usual conditions of self-archiving in institutional repositories.

• The deposit of the documents published by the Complutense staff must be carried out within a period not exceeding 12 months after they are published.

• The version of the articles published in scientific journals allowed by the editor will be deposited. If the editor establishes an embargo period, open access to the content of the article in the institutional repository will be delayed for the time required.

• Complutense teaching and research staff may deposit their teaching materials or other unpublished materials in the institutional repository. The UCM recommends that the total transfer of copyright be avoided when publishing a work, so as to allow its deposit in open access repositories.

7 Open access institutional policy regarding the scientific and academic production of the UCM. 2014.

4.3. Intellectual property and exploitation of results

The research staff must respect the intellectual and industrial property policies of the UCM.

It is presumed that any intellectual property discovered or developed using public or charitable funds must be disseminated so that it may have a beneficial effect on society at large. This presumption can be refuted when there is an express restriction on its dissemination, such as projects in which private companies participate (for example, via article 83). Outside of these cases, research staff may freely decide on the dissemination of their research.

Research staff must ensure that all contracts or agreements related to their research include provisions on intellectual property and its use, such as ownership of property rights, the granting of licenses or the transfer of exploitation rights. They must comply with any additional conditions related to intellectual property established by funding entities, as well as anticipate any circumstance that may arise in relation to intellectual property, and jointly agree on how to address it, communicating any decision to all members of the research group.

The Office for the Transfer of Research Results (OTRI) is the body in charge of supplying information and providing advice on intellectual property and industrial exploitation.

5. EVALUATION, MONITORING AND CONTROL OF THIRD-PARTY RESEARCH

When the research staff of the UCM act as evaluators of projects, research works or publications by third parties, as well as in selective processes of all types, they will do so in accordance with criteria of confidentiality, impartiality, objectivity, independence and diligence. Participation in these activities will be declined if the information needed is not available or the appropriate skills are lacking. Any relevant conflict of interest must be declared and one must abstain from participating as an evaluator should there be any concurrence of the causes provided by current regulations or any other circumstances that compromises the independence of one's criteria or professional judgment.

Research staff must follow the guidelines of any entity for which they carry out this evaluation. They should not retain any copies or materials evaluated without the express written authorization of the organization that requested the evaluation. They must not make use of the designs or research results of an article under review without the express permission of the author(s) or allow others to do so.

If, during the evaluation process, the research staff discover any malpractice, such as plagiarism, fabrication or falsification, or have ethical doubts about the design or development of the research, they must confidentially report to a representative of the organization that requested the review, such as the editor of the journal, or the person who presides over the corresponding ethics committee or the awarding of the grants in question.

6. MALPRACTICE IN RESEARCH

Malpractice is understood to be any conduct that violates the principles described above, particularly the fictitious elaboration, falsification or misrepresentation of data; the manipulation of interests and of the authorship of the research; plagiarism; not following

accepted procedures or not proceeding with due diligence in the responsibilities related to avoiding risks or unreasonable harm to humans, animals used for experimentation, the environment or cultural heritage, or the proper handling of private information about the individuals collected during the research.

Research staff must know what conduct constitutes research malpractice and avoid it. Good research practice also includes reporting reasonable indications of malpractice to third parties and cooperating with any such research for which they are required.

7. REVIEW OF THIS CODE

This code must be reviewed every two years.

8. ANNEXES

Annex I: Main references

• The European Code of Conduct for Research Integrity, ALLEA, 2017.

• Recommendations of the Bioethics Committee of Spain in relation to the promotion and implementation of good scientific practices in Spain, 2010.

• Good Research Practice Guidelines, University of Cambridge, UK, 2018.

• Code of practice for research. Promoting good practice and preventing misconduct. UK Research Integrity Office, 2009.

• National Declaration on Scientific Integrity, CRUE-COSCE-CSIC, 2015. • Code of Good Practices of the CSIC, CSIC, 2011.

• Code of good practice in research, Autonomous University of Barcelona, 2013.21

Annex II: Regulations and recommendations[8]:

Research in humans

• Law 14/2007, of July 3, on Biomedical Research.

• Law 14/2007, of May 26, on assisted human reproduction techniques.

• Royal Decree 2132/2004, of October 29, which establishes the requirements and procedures to request the development of research projects with stem cells obtained from surplus pre-embryos.

• Royal Decree 1301/2006, of November 10, which establishes the quality and safety standards for the donation, obtaining, evaluation, processing, preservation, storage and distribution of human cells and tissues and approves the coordination and operation standards for their use in humans.

• Order SCO/393/2006, of February 8, which establishes the organization and operation of the National Bank of Cellular Lines.

• Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 regarding the protection of natural persons with regard to the processing of personal data and the free circulation of these data, whereby Directive 95/46/EC (General Data Protection Regulation) is repealed.

• Correction of errors in Regulation (EU) 2016/649 of the Parliament and of the Council, of April 27, 2016, regarding the protection of natural persons with regard to the processing of personal data and the free circulation of these data, whereby Directive 95/46/EC (General Data Protection Regulation) is repealed.

• Organic Law 3/2018, of December 5, on Protection of Personal Data and guarantee of digital rights.

• Royal Decree 1527/2010, of November 15, which regulates the Guarantee Commission for the Donation and Use of Human Cells and Tissues and the Registry of Research Projects.

• Royal Decree 1716/2011, of November 18, which establishes the basic requirements for the authorization and operation of biobanks for biomedical research purposes and the treatment of biological samples of human origin, and regulates the operation and organization of the National Registry of Biobanks for biomedical research.

• Law 33/2011, of October 4, General Public Health.

• Royal Decree 53/2013, of February 1, which establishes the basic rules applicable to the protection of animals used in experimentation and other scientific purposes, including teaching.

• Royal Decree 65/2006, of January 30, which establishes requirements for the import and export of biological samples.

• Royal Decree 120/2003, of January 31, which regulates the requirements for carrying out controlled experiments for reproductive purposes involving the fertilization of previously frozen oocytes or ovarian tissue, in relation to assisted human reproduction techniques.

• Law 41/2002, of November 14, basic law regulating the autonomy of the patient and the rights and obligations regarding information and clinical documentation.

• Law 30/1979, of October 27, on organ extraction and transplantation.

• Declaration of Helsinki of the World Medical Association –

8 The links refer to the consolidated version of the aforementioned regulations.

• Council of Europe Convention on human rights and biomedicine, ratified by Spain on July 23, 1999.

• UNESCO Universal Declaration on the Human Genome and Human Rights.

Research with animals

• Law 8/2003, of April 24, on animal health.

• Law 32/2007, of November 7, for the care of animals regarding their exploitation, transport, experimentation and sacrifice.

• Law 6/2013, of June 11, modifying Law 32/2007, of November 7, regarding the care of animals, their exploitation, transport, experimentation and sacrifice.

• Royal Decree 53/2013, of February 1, which establishes the basic rules applicable to the protection of animals used in experimentation and other scientific purposes, including teaching. Correction of errors in BOE 04-26-2013.

• Royal Decree 65/2006, of January 30, which establishes requirements for the import and export of biological samples.

• Transparency Agreement on the use of animals in scientific experimentation, Confederation of Scientific Societies of Spain (COSCE).

• European Animal Research Association (EARA).

Protection of the environment, natural and cultural heritage

• Law 42/2007, of December 13, on Natural Heritage and Biodiversity.

• Law 30/2006, of July 26, on seeds and nursery plants and on phytogenetic resources.

• Law 9/2003, of April 25, which establishes the legal regime for the confined use, voluntary release and commercialization of genetically modified organisms.

• Law 43/2002, of November 20, on plant health.

• Royal Decree 178/2004, of January 30, which approves the General Regulation for the development and execution of Law 9/2003, of April 25, which establishes the legal regime for the confined use, voluntary release and commercialization of genetically modified organisms.

• Royal Decree 58/2005, of January 21, which adopts protective measures against the introduction and spread within the national territory and the European Community of organisms that are harmful to plants or plant products, as well as for export and transit to third countries.

• Royal Decree 39/1998, of January 16, which modifies Royal Decree 401/1996, of March 1, establishing the conditions for the introduction into the national territory of certain harmful

organisms, plants, plant products and other objects, for testing or scientific purposes and for the activity of selection of varieties.

• Royal Decree 401/1996, of March 1, which establishes the conditions for the introduction into the national territory of certain harmful organisms, plants, plant products and other objects, for testing, scientific purposes and for the selection of varieties.

• Convention on Biological Diversity.

• Cartagena Protocol on Biosafety.

• International Treaty on Plant Genetic Resources for Food and Agriculture.

• Antarctic Treaty on environmental protection. (and Protocol to the Antarctic Treaty on Environmental Protection (Madrid Protocol, 1991)

• Law 16/1985, of June 25, on Spanish Historical Heritage (BOE-A-1985-12534)

• Royal Decree 111/1986 on the partial development of Law 16/1985, of June 25, on Spanish Historical Heritage (BOE of January 28, 1986)

• Law 1/2017, of April 18, on the restitution of cultural property that has been illegally taken out of the territory of Spain or another Member State of the European Union, incorporating Directive 2014/60/EU into Spanish law, of the European Parliament and of the Council of May 15, 2014.

• Functions of the European Union related to Cultural Heritage

• Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. For an integrated approach to European cultural heritage.

• Convention for the protection of the world cultural and natural heritage (UNESCO, United Nations Educational, Scientific and Cultural Organization, 1972).

• Convention for the Safeguarding of the Intangible Cultural Heritage (UNESCO United Nations Educational, Scientific and Cultural Organization, 2003).

• Information; Management bodies in the Ministry of Culture and Sports and in the Autonomous Communities; Lines of action in matters of Cultural Heritage.

Personal data protection

• Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016 regarding the protection of natural persons with regard to the processing of personal data and the free circulation of these data, whereby Directive 95/46/EC (General Data Protection Regulation) is repealed.

• Correction of errors of Regulation (EU) 2016/649 of the European Parliament and of the Council, of April 27, 2016, regarding the protection of natural persons with regard to the processing of personal data and the free circulation of these data, whereby Directive 95/46/CE (General Data Protection Regulation) is repealed.

• Organic Law 3/2018, of December 5, on the protection of personal data and guarantee of digital rights.

Dual-use research

• Council Regulation (EC) No 428/2009, of May 5, 2009, which establishes a Community regime for the control of exports, transfer, brokerage and transit of dual-use items.

• Law 53/2007, of December 28, on the control of foreign trade in defence material and dual use.

• Royal Decree 679/2014, of August 1, approving the Regulation for the control of foreign trade in defence material, other material and dual-use products and technologies.

• Order ECC/1493/2016, of September 19, which updates the annexes to the Regulation for the control of foreign trade in defence material, other material and dual-use products and technologies, approved by RD 679/2014, of August 1.

Protection of workers

• Royal Legislative Decree 5/2015, of October 30, approving the revised text of the Law of the Basic Statute of Public Employees.

• Law 54/2003, of December 12, reforming the regulatory framework for the prevention of occupational hazards.

• Law 22/2011, of July 28, on waste and contaminated soils.

• Law 31/1995, of November 8, on the prevention of Occupational Risks.

• Royal Decree 374/2001, of April 6, on the protection of the health and safety of workers against the risks related to chemical agents during work. BOE No. 104 05-01-2001 Royal Decree 665/1997, of May 12, on the protection of workers against the risks related to exposure to carcinogens at work. BOE No. 124 05-24-1997.

• Directive 2004/37 / EC of the European Parliament and of the Council of April 29, 2004 on the protection of workers against the risks related to exposure to carcinogens or mutagens at work (specific Sixth Directive as per section 1 of Article 16 of Council Directive 89/391/EEC)

• Royal Decree 773/1997, May 30, on minimum health and safety provisions relating to the use by workers of personal protective equipment. BOE No. 140 06-12-1997

Protection and exploitation of intellectual property

• Law 24/2015, of July 24, on Patents.

• Law 14/20144, of June 1, on Science, Technology and Innovation.

• Law 2/2011, of March 4, on Sustainable Economy (Title II-Competitiveness, Chapter V Science and Innovation). Royal Legislative Decree 1/1996, of April 12, approving the revised text of the Intellectual Property Law, regularizing, clarifying and harmonizing current legal provisions on the matter.

• Royal Decree 55/2002, of January 18, on the exploitation and transfer of inventions made in public research entities, in accordance with the provisions of article 20 of Law 11/1986, of March 20, on Patents.

• Directive (EU) 2019/790 of the European Parliament and of the Council, of April 17, 2019, on copyright and related rights in the digital single market and amending Directives 96/9/EC and

2001/29/EC.

Other regulations

• Law 14/2011, of June 1, on Science, Technology and Innovation.25

• Law 53/1984, of December 29, on Incompatibilities of Personnel at the Service of Public Administrations (last modification: October 31, 2015).

• Law 19/2013, of December 9, on Transparency, access to public information and good governance.

• Law 2/2011, of March 4, on Sustainable Economy (Title II-Competitiveness, Chapter V Science and Innovation).

• Law 7/2007, of April 12, on the Basic Statute of Public Employees.

• Law 30/1992, of November 26, on the Legal Regime of Public Administrations and the Common Administrative Procedure. • Royal Decree 99/2011, of January 28, which regulates official doctoral studies.

• Decree 32/2017, of March 21, of the Governing Council, which approves the Statutes of the Complutense University of Madrid.

Other recommendations

• Montreal Statement on Research Integrity in Cross-boundary Research Collaborations.

• Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals. Updated December 2018. International Committee of Medical Journal Editors.

• Responsible research publication: international standards for editors. Wager E & Kleinert S (2011) Responsible research publication: international standards for authors. A position statement developed at the 2nd World Conference on Research Integrity, Singapore, July 22-24, 2010.

• OECD Guidelines for managing conflicts of interest in the public service, OECD – Organization for Economic Cooperation and Development, 2003.

• Guidance note – Research involving dual-use items. European Commission, Directorate-General for migration and home affairs; Directorate-General for research and innovation; Directorate-General for trade,

• Commitments of the Universities to Open Science. CRUE, 2019. Working group coordinated by Francisco Mora Mas, member of the Standing Committee of Crue Spanish Universities and rector of the Polytechnic University of Valencia.

• Note from the State Research Agency *N-AEI 18-01 Predatory magazines. Questionable and unreliable Open Access publications of the State Research Agency.*

Annex III: Authorship: UCM adhesion to COPE and ICMJE recommendations

RESPONSIBLE RESEARCH PUBLICATION

ADHESION OF THE UCM TO THE INTERNATIONAL ICMJE AND COPE STANDARDS

1. Introduction

The publication of research and its results is often the final research phase and a responsibility of all research staff. Publications form **the basis for both new research and the application of results**, which affects not only the research community but society as a whole.

It is therefore the responsibility of researchers to ensure that their publications be **honest, respectful, accurate and complete** and to avoid being misleading, selective or ambiguous.

Publications are also important for **the reputation, promotion, and funding of research staff**, as well as for strengthening the prestige of institutions.

The authorship of the publications is the way of recognising the **merits** of the research staff, while also entailing the assumption of **responsibility** for the research and its results.

Authorship includes the original scientific production, images, artistic works, texts or other material generated by the researchers. It can refer to products in paper, electronic or other format, and be already published, or to be published, or be for local use. Authorship ranges from contributions that seek to disseminate scientific discoveries to reviews of previous publications and educational material.

The **authorship policy** is part of the legislation on intellectual property and the exploitation of results.

2. Adherence to international standards.

The UCM adheres to the **criteria defined by the International Committee for Medical Journal Editors (ICMJE)[9] for authorship and to the international standards for authors** developed at the ***2nd World Congress on Research Integrity[10]*.**

These standards are internationally recognized and have been adhered to by institutions and groups of scientific, academic and publishing institutions committed to publishing ethics from around the world.

3. Responsible scientific publication.

The UCM will ensure compliance with international standards applicable to authors, especially the following principles of these standards:

• The research reported must have been conducted in an **ethical and responsible** manner and must comply with all relevant legislation.

• Researchers must present their **results clearly, honestly and without fabrication, falsification or inappropriate manipulation** of data.

9 International Committee for Medical Journal Editors (Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals).

10 Wager & Kleinert s (2011) Responsible research publication: international standards for authors. A position statement developed at the 2nd World Conference on Research Integrity, Singapore, July 22-24, 2010. Chapter 50

in: Mayer T & Steneck N (eds) Promoting Research integrity in a Global Environment. Imperial College Press / World Scientific Publishing. Singapore (pp 309-16). (ISBN 978-981-4340-97-7).

• Researchers should strive to **describe their methods** clearly and unambiguously so that their findings can be confirmed by others.

• Researchers must meet the publication requirements that the submitted work **be original, not plagiarized, and not previously published** elsewhere.

• Authors must assume **collective responsibility** for the works presented and published.

• Authorship of research publications must accurately reflect each person's **contributions** to the work and to its publication.

• Sources of **funding and conflicts** of interest must be indicated.

4. Authorship in scientific publications.

Authorship will be applied to those people who:

a) Make substantial **contributions to research**:

- The conception and design of the work,

- The collection, analysis and interpretation of the data.

b) Contribute substantially to the **writing of the manuscript** (e.g. Article, book ...) and/or critically **review** its content in a substantial way.

c) Approve the **final version** of the work to be published.

d) **Agree to be responsible** for all aspects of the work, ensuring that questions regarding the accuracy or completeness of any part of its content are appropriately researched and resolved.

In addition to being responsible for the parts of the work he or she has created, the author must be able to identify which co-authors are responsible for other specific parts of the work. Also, authors should have strong confidence in the integrity of their co-authors' contributions.

Additional guidance:

• All persons who comply with **the contents of section 4.a)** should have the **opportunity to participate in the review, writing and final approval** of the manuscript. In this sense, guaranteeing funding, providing space, equipment, samples or materials, collecting some data for research, or managing or supervising the researchers involved in the project do not in themselves justify authorship.

• Issues related to publication and authorship, especially the roles of authorship and contribution, should be taken into account at an **early stage in the design of the research project**, making appropriate modifications as the research progresses.

• Decisions on publication and authorship must be agreed upon and communicated to **all members of the research team** involved.

• No person who meets the authorship criteria **may be excluded** as an author.

• The **list of authors**, and any modifications made to that, must be approved by all authors, **in writing**.

• The work of all the people who have contributed to the research, but do not meet the authorship criteria must be **properly recognized** in the publications. This includes advisers, scientific societies, funding entities, sponsors or others.

• The authors of the publication must necessarily cite all the **sources and references** used, so that the work of other researchers receives due recognition.

• Authors must comply with the conditions established by the **funding entities or other organizations** in relation to the publication of their research.

• Regardless of the forum in which the research is presented, the authors must declare any current or potential **conflict of interest** in relation to this research.

• The same work must not be sent to more than one **potential publication simultaneously**, nor should the results be disseminated in more than one publication without properly declaring and acknowledging any previous dissemination, unless there has been an agreement known to all parties in this regard.

• In the event of researchers being dissuaded from publishing and disseminating their research or findings or being influenced to publish their results in an inappropriate way, the researchers in question must report this to the competent body.

• When authorship is shared and the order of appearance of the authors does not respond to the importance or relevance of their contributions, the **ordering criterion** that has been followed must be explicitly indicated (alphabetical, etc.)

• Authors must reach an **agreement on the order of authorship** that will appear in the publication and, when necessary, must be able to explain the reasons for this.

Disputes over authorship

Disagreements often stem from the lack of adequate communication between the participants from the start. Disputes are minimized when authorship is agreed upon at the beginning of the works, and, where appropriate, they are reviewed and agreed throughout the process.

In the event of persistent disagreement, it is advisable to refer to:

- Council of Ethics in Research of the UCM

- Inspection of services.

Annex IV: Biosafety level of the laboratory

It is compulsory to determine the biosafety level of the laboratory in accordance with current legislation (Royal Decree 664/1997, "BOE" no. 124, 01 January 1970. (https://www.boe.es/buscar/pdf/1997/BOE-A-1997-11144-consolidado.pdf).

The biosafety level of a laboratory categorizes the degree to which biological agents can be handled safely in the laboratory. Article 3 of the aforementioned RD establishes the classification of biological agents according to the risk of infection in four groups: "*a) Group 1 biological agent: one that is unlikely to cause illness in humans. b) Group 2 biological agent: one that can cause illness in humans and may pose a danger to workers but is unlikely to spread to the community and there is generally effective prophylaxis or treatment. c) Group 3 biological agent: a biological agent which may cause serious disease in humans and presents a serious hazard to workers, with a risk of spreading to the community, and where effective prophylaxis or treatment is generally available. d) Group 4 biological agent: a biological agent which causes serious disease in humans and presents a serious hazard* to workers, with a high probability of spreading to the community, and where effective *prophylaxis or treatment is generally not available. 2". "Annex II of this Royal Decree contains a list of biological agents, classified in groups 2, 3 or 4, following the criteria set out in the previous section. For certain agents, additional useful preventive information is also provided". Based on the above, four possible levels of biosafety in a laboratory can be distinguished according to the biological agent used, as well as the combination of techniques and practices carried out in the laboratory.*

In general, UCM centers and facilities may only work with biological agents classified in groups 1 and 2, provided that the conditions necessary for their safe use are met. At present, only the VISAVET center has facilities and work practices for working with biological agents classified in group 3. At UCM there are no plans to work with group 4 agents.

Any research activity involving the use of biological agents included in RD 664/1997 must be notified to the competent authority as established in the RD itself.

The laboratory director, main researcher or department head, is responsible for requesting the biosafety level that corresponds to his/her laboratory, for the constant assessment of the risks associated with the research carried out, for the appropriate application of the recommended biosafety levels, for carrying out and requesting periodic evaluation, and for notifying any modification of the activities carried out in the laboratory that involve a change in the biosafety level.

At UCM, the Occupational Risk Prevention Unit (*Unidad de Prevención de Riesgos Laborales, UPRL*) has elaborated the Operating Instructions of "*Instrucción operativa: trabajo seguro con agentes biológicos. Notificación*" (https://www.ucm.es/file/io-17-trabajo-seguro-con-agentes-biologicos.-notificacion); as well as the Operating Instructions of "*Medidas preventivas laboratorio nivel de bioseguridad P1*" (https://www.ucm.es/file/io-018-medidas-prev-bioseguridad-p1); "*Medidas preventivas laboratorio nivel de bioseguridad P2*" (https://www.ucm.es/file/io-019-medidas-prev-bioseguridad-p2); and "*Medidas preventivas laboratorio nivel de bioseguridad P3*" (https://www.ucm.es/file/io-020-medidas-prev-bioseguridad-p3). In the UCM Research web page (https://www.ucm.es/hrs4r_es/bioseguridad-laboratorios-p2) you can find these Operating Instructions, as well as a form that allows you to verify if your laboratory complies with the requirements related to preventive and containment measures, both for work practices and facilities, as well as other necessary additional information.

The laboratory director, main researcher or department head, will fill out the form and, once all the necessary prevention, protection and containment measures have been taken; will notify the Vice-Deanship with research competences of his/her center, as well as the Vice-Rectorate with research competences (sec.investytrans@ucm.es). The Vice-Rector will inform the UPRL, as well as the external evaluator, who will carry out an inspection of the laboratory to verify compliance with the regulations.

The first use of Group 2 or 3 biological agents, once the laboratory has the appropriate biosafety level, must be notified to the labor authority prior to the start of the work (minimum of thirty days before the start of any activity). Work with group 1 biological agents does not require notification. Notification will be made by the laboratory director, main researcher or department head. "*Instrucción operativa: trabajo seguro con agentes biológicos. Notificación*" includes in article 3 the notification of first use to the labor authority, which is mandatory, and details the documents required (https://www.ucm.es/file/io-17-trabajo-seguro-con-agentes-biologicos.-notificacion). In the Community of Madrid, the notification procedure is carried out through registration in the "Registro de empresas que manipulan Agentes Biológicos de Grupos 2, 3 y 4 de la Comunidad de Madrid".

The contained use of biological agents (Genetically Modified Organisms, GMOs) requires, in addition to the above notification of first use, notification to the National Biosafety Commission (https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-

/notificaciones-y-autorizaciones/uso_confinado.aspx). According to Law 9/2003, article 5, is it is considered as contained use any activity by which the genetic material of an organism is modified or by which it, thus modified, is cultivated, stored, used, transported, destroyed or discarded, whenever that in carrying out such activities, confinement measures are used to limit its contact with the population and the environment. The legal framework for the contained use of genetically modified organisms is established in Chapter I of Title II of Law 9/2003, and in Chapter I of Title II of Royal Decree 178/2004. The National Biosafety Commission has prepared a practical guide for the submission of applications for registration of facilities and for carrying out contained use activities with genetically modified organisms. (https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/guiadeutilizacionconfinadanoviembre2021_tcm30-533924.pdf)