UNIVERSITAS Miguel Hernández

CODE OF GOOD SCIENTIFIC PRACTICE

2ND EDITION

COMMITTEE ON ETHICS AND INTEGRITY IN RESEARCH
VICE-RECTORATE FOR RESEARCH

CONTENTS

1. PRESENTATION

The Code of Good Scientific Practice (hereinafter, CGSP) of the Miguel Hernández University of Elche (UMH) encompasses a set of indications on practising scientific activity, whose goal is to favour the quality of the research conducted as well as to prevent integrity-related issues in the behaviour of scientists, the research staff in training and students who take part in research activities. Its content supplements existing legal regulation and has been updated by the **Committee on Ethics and Integrity in Research (CEII)** of the UMH, formerly known as the Project Assessment Body, for its use starting with school year 2020/21. The first edition of the CGSP was published in April 2011.

The goal of this second edition is to adapt the CGSP to the new ethical and legal requirements, as well as to align it with the concept of responsible research and innovation that the European Commission establishes in its Horizon 2020 programme, and with the principles and values of the 2030 Agenda and the Sustainable Development Goals of the United Nations. Furthermore, in an era where even scientific production is called into question, it is important to look into the concepts whose purpose is to maximise the scientific integrity of researchers and students in training. Two documents of reference on scientific integrity have been taken into account in this revision to do so: The ***European Code of Conduct for Research Integrity***, published by ALLEA (All European Academies) and ***The Concordat to Support Research Integrity***, an agreement whose signees include universities, which seeks to provide a national framework (in the United Kingdom) to guarantee good practice in research.

The CEII is an independent body at the service of the scientific community whose tasks include encouraging better internal knowledge of the CGSP, ensuring that the provisions included in said code are followed and complied with, and updating its contents. Furthermore, it must remain attentive and receptive to new issues related to scientific integrity, answer enquiries or mediate in possible conflicts linked to said integrity, and to assess the suitability of all research proposals from an ethical and legal point of view.

2. RESPONSIBLE RESEARCH AND INNOVATION

Responsible research and innovation (RRI) is an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of inclusive and sustainable research and innovation.

RRI entails that societal actors (researchers, citizens, policy makers, business, third sector organisations, etc.) work together during the whole research and innovation process in order to better align both the process and its outcomes with the values, needs and expectations of society.

In practice, RRI is implemented as a package that includes multi-actor and public engagement in research and innovation, enabling easier access to scientific results, the inclusion of gender and ethics in the research and innovation content and process, as well as formal and informal science education.

The European Commission describes RRI as a framework that consists of six keys that the UMH adopts in this code:

- **Public commitment and citizen engagement:** Public commitment to RRI consists of creating a future in a joint way with citizens and organisations of civil society, as well as involving the greatest diversity possible of social actors who do not usually interact with each other, on issues of science and technology. It can be summarised as: science by and for the people.
- **Open access:** Open access makes it possible to improve the reproducibility of science and to decrease inequality in the access to knowledge and innovation. Responsibility in research and innovation moves in this direction, and therefore, researchers must publish in open-access format whenever possible. This concept is also linked to transparency.
- **Gender equality:** Gender is a transversal issue that is integrated in each of the different parts of the work programme, from creating the teams to studying sex/gender as a variable, which guarantees a more integrated approach to research and innovation. At the UMH we expand this concept and include the concepts of equality, diversity and inclusion in order to guarantee there is no discrimination of any type, in line with the equality and inclusion policies that the university has in effect.

- **Ethics and integrity:** Ethics is a vital part of research from beginning to end, and ethical compliance is considered essential to achieve excellence in research. It also includes avoiding any violation of research integrity, which means, in particular, to avoid fabrication, falsification, plagiarism or any other research misconduct. There is no high-quality research without scientific integrity.
- **Science education:** Developing skills and innovative ways of connecting science with society must be a priority. This will help make science more appealing to the youth, increase society's appetite for innovation and produce more research and innovation activities. The objective is to encourage formal and informal scientific education so that it reaches the greatest number of people possible.
- **Governance:** All the above is encouraged through integrated actions that promote institutional change, to foster the implementation of the RRI approach by all parties.

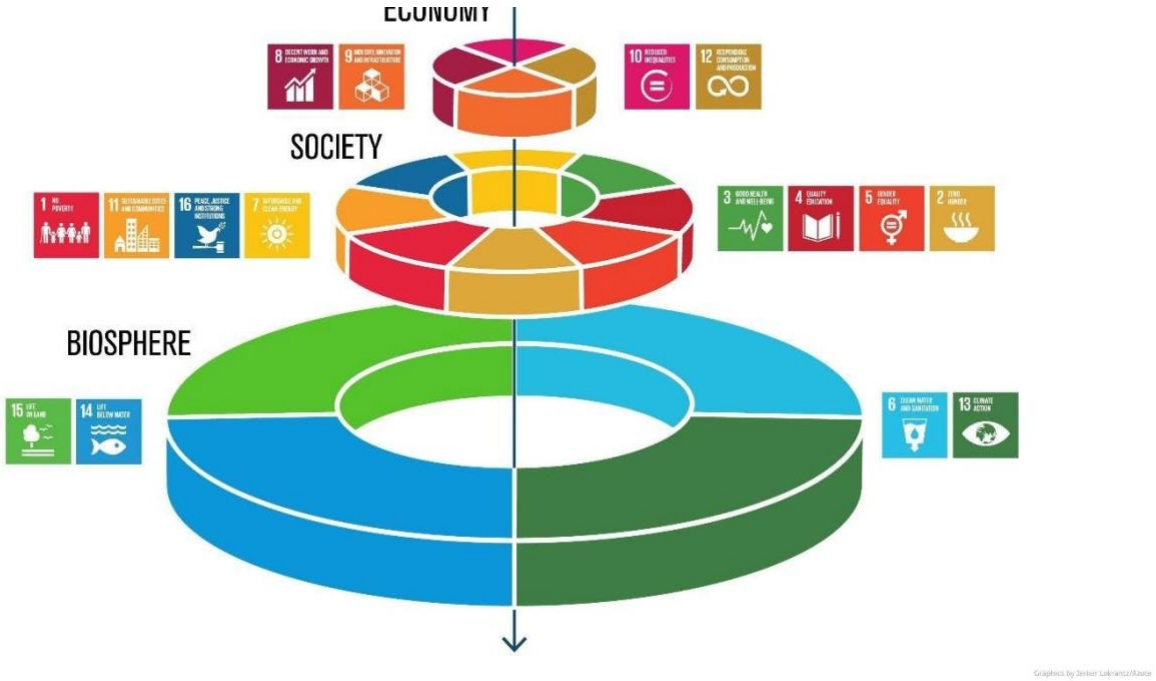
UMH researchers must have these six keys in mind so that they are fostered and implemented within the realm of their powers and possibilities in their daily academic activity, especially regarding any research or research training activities they perform.

Moreover, it is worth highlighting in this section one of the most important values at the UMH: social responsibility and economic, environmental and social sustainability. This value is directly related to the **Sustainable Development Goals (SDG)** of the United Nations, included in the 2030 Agenda.

The 17 SDG are seamlessly integrated in the six mentioned keys:

- Public commitment and citizen engagement to improve people's lives.
- Open access and gender equality to decrease inequality.
- Ethics and integrity to respect other people, the university, society and ourselves.
- Scientific education so that scientific knowledge spreads, creates new scientific vocations and it all leads to an improvement to society.
- Good governance to establish suitable policies and procedures that promote and facilitate responsible research.

Research conducted at the UMH, given that it must be based on public commitment and citizen engagement, must align, where possible, with one or several SDGs in the three mentioned pillars of sustainability: economy, society and the biosphere.



Source: Adapted from the **presentation of J. Rockström and P. Sukhdev at the EAT speech**

The vice-rectorates with competences in responsible research and innovation commit to:

- Design indicators that make it possible to measure the responsibility of research activity in an objective way.
- Promote an improvement of said indicators with specific programmes and actions that stimulate progressive change towards more responsible research and innovation at the UMH.

3. COMMITMENT TO DISSEMINATION AND IMPLEMENTATION

A basic responsibility of the research community is to develop research principles, define the criteria for suitable research behaviour, maximise the quality and robustness of research, and to respond in an appropriate way to threats or breaches of research integrity.

The governing bodies of the UMH must:

- Promote awareness and guarantee a prevailing culture of research integrity.
- Exercise their leadership in the development of clear policies and procedures relative to good practice in research as well as the transparent and appropriate management of breaches.
- Back a suitable infrastructure for the management and protection of data and research material in all its forms, which is necessary for reproducibility, traceability and accountability.
- Promote transparent and reproducible practices in the hiring and promoting of researchers considering the following European seal of quality: Human Resources Strategy for Researchers (HRS4R), http://hrs4r.edu.umh.es/

The UMH will publish the contents of the current CGSP on its website, so that it is available and may be freely viewed. Furthermore, it will make all the resources needed for its suitable dissemination and implementation available.

One of the duties of the CEII, as established in its regulation, is to encourage better internal knowledge of the CGSP, as well as to guarantee that the provisions included in it are followed and complied with. For this reason, the CEII, through the Office for Responsible Research (OIR), will conduct specific actions of dissemination and training on the concepts included in the CGSP.

Furthermore, the directors of the departments, institutes and research centres shall be responsible for providing all necessary information on the CGSP to all their current staff, as well as to any new staff upon being hired. Meanwhile, the directors of master's degrees, the people responsible for doctorate programmes and deans of the UMH, shall be responsible for notifying the students who are receiving training on research: students conducting their Bachelor's Degree Thesis (TFG in Spain) or Master's Degree Thesis (TFM in Spain) and doctoral candidates.

Researchers and students receiving training on research must know the CGSP and implement it in their scientific activity.

4. PRINCIPLES OF RESEARCH INTEGRITY

Good research practice is based on fundamental research integrity principles:

- **Reliability** in ensuring the quality of research, reflected in the design, methodology, analysis and use of resources.
- **Honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.
- **Respect** for colleagues, people in training, research participants, society, animals, ecosystems, cultural heritage and the environment.
- **Accountability** for research since the idea is published, for its management and organisation, for training, supervision and mentoring, and for its wider impacts.

5. RESPONSIBILITY OF THE INSTITUTION REGARDING RESEARCH TRAINING

The UMH must ensure that the researchers in training receive thorough training as regards research design, methodology and analysis.

Furthermore, it must develop relevant, suitable and continuous training regarding research ethics and integrity, to ensure that all interested parties are aware of the codes and regulations that affect them.

Researchers must take part in training activities in the field of research ethics and integrity throughout their entire professional career.

Expert researchers must advise the members of their teams and provide them with specific guidance and training to suitably develop, design and structure their research activities and to promote a culture of research integrity.

At the same time, researchers of all levels must proactively take part in their training in all aspects of research, without disregarding ethics and scientific integrity. This must be done proactively because science progresses rapidly, and in order to be up to date it is often necessary to conduct self-learning activities based on reading, as well as a subsequent deeper analysis of specialised news items, scientific articles, new cases of research integrity issues, new regulation or ethical or behavioural codes, etc.

6. SUPERVISION OF RESEARCHERS IN TRAINING

6.1 SUPERVISOR ASSIGNMENT

Anyone who becomes connected to the UMH in order to receive training on research will have a supervisor assigned to them. This includes the training of scientists or research support technicians: TFG students, TFM students, graduates and pre-doctoral graduates, among others.

The term supervisor corresponds to mentor or director of the thesis, work or project, or any other analogous figure.

The concept of researcher in training includes staff undergoing research training (with a contract or grant) and students who are undergoing a training process.

6.1 RESPONSIBILITIES OF THE SUPERVISOR

The supervisor sets the goals and will take responsibility for the educational process of the research staff in training. They will advise and guide the latter to meet the training expectations according to the initial purposes and in the planned timeframe. The supervisor must provide the best possible conditions for their future scientific outlook.

Meanwhile, the supervisor of the bachelor's or master's degree students who are involved in research in the framework of a TFG/TFM must advise and guide the students so that they acquire the knowledge that allows them to appropriately conduct said activity.

6.2 LIMITS TO THE NUMBER OF PEOPLE A SUPERVISOR IS IN CHARGE OF

The total number of researchers in training that a supervisor is in charge of must be appropriate and compatible with the scope of the supervisor's obligations and commitments.

6.3 OBLIGATIONS OF THE RESEARCHERS IN TRAINING

Researchers in training have different obligations to all other people who are contractually connected to the institution.

These obligations are:

- To become fully integrated in the project assigned for their training.
- To follow the advice and recommendations of the supervisor and notify the latter of any possible initiatives and the progress of the results. If a trainee encounters difficulties while developing their work, they must communicate it as soon as possible.
- To learn and follow the safety rules and procedures, as well as to respect the Code of Good Scientific Practice.
- If they have had access to personal data, the researcher in training must comply with the relevant legal, technical and organisational measures on the issue of data protection.
- To take part in scientific activities, discussion forums, seminars, etc. related to the development of their work when possible, and with a level of involvement suited to the type of activity.
- To recognise the contribution of their supervisor to the oral or written dissemination of their results.
- To respect and value the management, administration and any other tasks linked to their research activity, as well as to make proper use of the material means and facilities available to them.

6.4 OBLIGATIONS OF THE SUPERVISOR

The specific obligations of the supervisor are:

- To personally interact regularly with the researchers in training that they are in charge of, supervising the assigned tasks and ensuring they are fulfilled.
- To encourage the regular holding, within the availability of the supervisor, of meetings with the researchers in training, to talk about the progress of the assigned tasks and thus ensure the suitable execution of said tasks.
- The supervisor must be especially diligent with the researchers in training, keeping them from becoming involved in tasks outside their training. They should not take part in projects that have commercial restrictions in the dissemination of results due to their time limitations, and a suitable, clear and consensual confidentiality commitment must be produced regarding the data they have had access to, where appropriate.
- To guarantee that researchers in training know about the CGSP.
- To guarantee that researchers in training are appropriately prepared on the issue of occupational hazard prevention, at least regarding compliance with the occupational hazard prevention measures of the activities they are to conduct during the training process.
- To ensure suitable preparation on the issue of environmental protection of the researchers in training, at least regarding the appropriate management of dangerous waste generated and other environmental aspects derived from the activity which may entail a risk for the environment during their training.
- To guarantee the suitable preparation of the students they supervise regarding existing ethical and legal requirements that affect scientific practice, at least as it pertains to the activities they are to conduct during their training.
- When personal data is processed in the research, to guarantee compliance with the relevant legal, organisational and technical measures on this issue, at least regarding the activities to be carried out during the training process.
- To guarantee the working conditions of the research staff in training linked to the UMH with a contract or grant, taking into account the commitment of the university to the HRS4R seal, as well as promoting their participation in seminars and scientific conferences, and to advise them on the development of their professional career: publications, participation in projects, international mobility, etc.
- To recognise the individual work of the research staff in training and to be very rigorous and fair with the authorship of publications and any other dissemination of the research activity.

7. PREPARATION OF RESEARCH PROJECTS

7.1 PREPARATION OF RESEARCH PROJECTS

Before beginning, all research activity must be previously drafted in a written research project.

Researchers must take into account the most recent situation of the issue when developing research ideas, as well as designing, carrying out, analysing and documenting all research in a thorough and well-thought-out way.

Researchers must handle their human subjects and objects of research, whether animal, cultural, biological, environmental or physical, with respect and care, and in accordance with ethical and legal provisions.

Research protocols must take into account and be sensitive to the relevant differences in age, gender, culture, religion, ethnic origin and social class.

Researchers must identify and manage any possible damage and risks related to their research.

Researchers must make a suitable, conscientious and responsible use of the funds allocated to the research.

7.2 WRITTEN PROJECT SUBJECT TO THE SCRUTINY OF THIRD PARTIES

Before beginning any research activity, the information on said activity must be sent to the OIR following the procedure in effect at that time, which will be detailed on their website: https://oir.umh.es.

The ethical, legal, safety and health requirements of the activity will be considered when planning the research activity.

If the protocol involves people, their data and samples, or animals, the activity shall be subsequently assessed by the CEIl of the UMH and/or by an external ethics committee.

7.3 PREREGISTRATION OF CLINICAL STUDIES

Due to legal requirements, clinical trials with medicinal products for human use and post-authorisation observational studies authorised by the Spanish agency for medicinal products (AEMPS) must be included in the register of clinical trials with medicinal products for human use (REec) of the AEMPS.

If we have doubts on whether any given study must be preregistered or not, this query must be submitted to the AEMPS.

Even if it is not a clinical trial, when one of our research projects has human participants (either interventional or observational) and the purpose is to increase medical knowledge, the journal where we intend to publish it may require said preregistration. In these cases, we must preregister our study on the ClinicalTrials.gov platform of the NIH. At the UMH, this register is managed by the OIR.

7.3 NO TO SECRET RESEARCH

Under no circumstance will the secrecy of the entirety or part of a research project be acceptable.

The CEII will assess the alignment of the research project with the ethical-legal requirements, while always observing the necessary confidentiality.

7.4 EXPANSION OR MODIFICATION OF THE RESEARCH PROTOCOL

When it becomes necessary to expand or modify the research protocol, a corresponding supplementary protocol must be written and subjected to the assessment of the CEII before being implemented.

7.4 EXCEPTIONALLY URGENT RESEARCH

When security or public health circumstances require research to begin immediately, especially when it involves test people or animals, the beginning of the activities must also be backed by an action protocol. An urgent assessment may be requested to the CEII under these circumstances.

7.5 USE OF EXTERNAL FACILITIES AND EQUIPMENT

Any research protocol that entails the use of external facilities or equipment will require the prior approval of the person in charge of the institution, centre, facility or equipment that is to be used.

7.6 COLLABORATION PROJECTS

Researchers, research institutions and organisations must ensure that all contracts or agreements concerning research results include, in a fair and equitable way,

managing their use, their ownership and/or their protection by virtue of intellectual property rights.

All partners must reach a formal agreement at the beginning of their collaboration on their expectations and rules concerning integrity in research, applicable legal and regulatory provisions, the protection of the intellectual property of the collaborators, and the procedures to manage conflicts and possible cases of misconduct. These agreements must be in writing and must have the explicit approval (signature) of all participants.

When processing personal data in facilities or entities that are external to the UMH, the relevant agreement must be signed with them depending on the type of collaboration.

Regulations on the coordination of corporate activities as it pertains to occupational hazard prevention must be observed when there are researchers from different institutions or companies.

8. RECORDING, DOCUMENTATION, STORING, CUSTODY AND SHARING OF DATA AND BIOLOGICAL OR CHEMICAL MATERIAL ARISING FROM RESEARCH

8.1 PLAN FOR THE GATHERING AND PRESERVATION OF DATA

Any research protocol must include the system to gather the data, records and biological or chemical material arising from research, as well as a plan for their custody and preservation.

Any research protocol that entails the use and/or acquisition of identifying or identifiable personal data must be subjected to the assessment of the CEII and follow the "Procedure for the use of personal data in research" that can be found at the following link: https://oir.umh.es/datos-personales.

8.2 RECORDING DATA AND RECTIFICATIONS

All data arising from experiments or observations during research must be recorded, without exception. This information must be permanently recorded on databases, laboratory notebooks or any other relevant format, and in a way that allows them to be examined by third parties. The records will also include the changes, errors and negative, unexpected or dissenting results, as well as the person who conducts or observes them.

8.3 CUSTODY AND PRESERVATION OF GATHERED DATA

The person responsible for the research will be the person in charge of the custody and preservation of all the documentation and arising biological or chemical material in safe conditions. When the data is recorded in electronic format, a specific backup copy and physical location plan will be added.

The university will ensure that the researcher has access to all the means and infrastructure required to do so.

8.4 ACCESS TO GATHERED DATA

Any person who is part of the research team must be able to access the information on the data obtained and to interpret it, except for personal data, which must be limited to the people with access to it, as well as to include ways to access the data in a pseudonymised way (with the guarantees established by law, the independent team who performs said action, the confidentiality of the research team, the commitment to not re-identify the data, etc.).

The person responsible for the research will have an exclusive record of the different tools to gather data (notebooks, databases, etc.) and to custody samples. Access to it must be able to be made available to university officials or third parties when adequately justified.

8.5 OWNERSHIP OF THE DATA AND SAMPLES

All primary documentation (data gathering notebooks, databases, etc.) and the biological or chemical material obtained during research is owned by the UMH and the institutions who took part in the research, as previously agreed.

Its recording, storing and custody is at the discretion and responsibility of the person in charge of the project. If there is a change of institution, and only when necessary, the person in charge of the project may provide to the new institution a photocopy of part or the entirety of the record books, a copy of existing electronic information, a photocopy of the data gathering notebooks or aliquot portions of the available biological or chemical material. When the change affects the person in charge of the research, this process will be done under the responsibility and supervision of the institution's management.

8.6 SHARING DATA AND SAMPLES WITH THIRD PARTIES

The data and materials arising from research – except for personal data and cases where restrictions derived from their possible future commercialisation have been

established – must be made public and in condition to be shared with third parties once published, as established in section 8.1.

The transfer will require prior knowledge of the use that the petitioner wishes to make, knowledge of the request by the research team, a transfer protocol with the approval of the person in charge of the research, and the willingness of the petitioner to bear any possible generation and shipping costs. The transfer may be limited due to availability, competitiveness or confidentiality reasons. Any personal material or data must be shared without making it possible to identify the source individuals (prior anonymisation). Otherwise, it will require specific and express consent of transfer by the grantor or a clear legitimate basis in the GDPR that allows said transfer.

8.7 DATA AND SAMPLE PRESERVATION TIME

All primary and original information, as well as the biological or chemical material stored as a result of any research project, must be preserved in safe conditions for at least 10 years after the first publication of the results, except in those cases where the law allows for shorter periods of time or requires longer periods. If the centre allows it, the primary information and material may be stored for longer periods of time and its transfer will always require the approval of the person in charge of the research.

In the specific case of personal data, the preservation time will be the minimum necessary to carry out the research activity for which it was gathered.

9. MANAGEMENT OF ECONOMIC RESOURCES AND INTELLECTUAL AND INDUSTRIAL PROPERTY

Material and economic resources must be used efficiently and effectively, and handled with correctness and responsibility, so that they enable or facilitate achieving the planned goals and thus generate the highest degree of confidence possible in society. This is especially important considering that economic and material resources are limited.

The Research Results Transfer Office of the Research Management Service (SGI-OTRI) is tasked with the technical and administrative management of the funded research actions that are conducted at the university. It is also in charge of managing the industrial and intellectual property rights derived from the research activity of the university, the confidentiality commitments and contracts on data protection, and the transfer of research results by way of licences or agreements with spin-off companies. Researchers must collaborate with this service and address its requests within their capabilities. More information: https://otri.umh.es/

9.1 INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS DERIVED FROM RESEARCH RESULTS

The UMH is the owner of the intellectual and industrial property rights from research activities, as well as innovations and developments carried out by research staff as a result of tasks that belong to them and which are within the scope of their teaching and research duties.

Moral rights derived from research results belong to the researchers of the UMH.

Students have ownership and rights of exploitation of the inventions they conduct within the framework of their academic activity. In the case of academic projects, they may transfer their author's rights to the UMH and/or authorise their dissemination in the institutional repository of the university.

In the case of inventions conducted by the students together with research and teaching staff, the ownership and rights of exploitation of the invention will be shared, corresponding to the students and the UMH in the proportion agreed by the students and research and teaching staff. It is highly recommended for said co-ownership regime to be specified in a co-ownership agreement signed by the university and the students.

9.2 PROTECTION OF RESULTS WITH POSSIBLE COMMERCIAL INTEREST

If the person in charge of the research project deems that the results obtained through research can lead to inventions or uses that are potentially susceptible of being protected due to their commercial interest, the person in charge of the research project must notify the delegated committee on industrial and intellectual property of the UMH and handle the publishing of results in scientific journals taking this possibility into account.

9.3 RESEARCH PROJECTS FINANCED BY INDUSTRY OR OTHER FOR-PROFIT ENTITIES

9.3.1 TRANSPARENCY AND PRIMACY OF INTERESTS

Public interest must always prevail in the exchange or transfer of knowledge and technology with private entities, meaning that agreements must be completed with full transparency. Furthermore, the institution's management will establish the

necessary limits to protect the intellectual freedom of its researchers and prevent the disproportionate compromising of confidentiality or unjustified restrictions in the publishing of results obtained.

9.3.2 INDUSTRIAL PROPERTY RIGHTS

When research staff that takes part in a project backed by industry has key contributions to its design and execution, the necessary agreements will be established with the backing entity to share the corresponding industrial and intellectual property.

9.3.3 INTELLECTUAL PROPERTY RIGHTS

When the research group offers a technical service or the research staff exclusively takes part in the gathering of data from a protocol developed by third parties, the conditions for the communication and publication of obtained results will be established by mutual agreement with the backing entity, always taking into account the provisions established in section 10.1.

9.3.4 PROTOCOL FOR ECONOMIC COMPENSATION

All agreements reached by the financing entity and the institution that the person or persons in charge of the research work for, will be included in the corresponding contract (or contracts). The contract must also include all aspects related to economic compensations directly or indirectly linked to the research. These agreements will be available to the entities, committees and people with responsibilities on the agreed issue.

10. PUBLISHING AND DISSEMINATION PRACTICE

10.1 PEER REVIEW OF RESULTS

The results of scientific research must always be scrutinised by peers. In this sense, the publication of results in journals or other peer-reviewed media is an indispensable part of the research protocol.

10.2 IMPROVING THE QUALITY, TRANSPARENCY AND REPRODUCIBILITY OF PUBLICATIONS

10.2.1 UNEQUIVOCAL IDENTIFICATION OF THE AUTHORS AND INSTITUTION:

RESEARCHER PROFILE

Researchers must create a digital profile on the main identification platforms linked to their field of knowledge, use the same author's name on said platforms and always use that author's name in publications. This makes it possible to standardise the name and affiliation, to facilitate the recovery and dissemination of publications, increase visibility and obtain statistics on scientific production.

The institution must always be cited in publications the following way: Universidad Miguel Hernández. No other forms or abbreviations should be used.

10.2.2 USE OF INTERNATIONAL PUBLISHING GUIDES

Whenever there are recognised international publishing guides for a field of knowledge, researchers must publish following said guides. Examples of these guides are: STROBE for observational studies; PRISMA for systematic reviews; ARRIVE for animal research; SAMPL for statistics.

10.2.3 DISSEMINATION OPTIMISATION: OPEN ACCESS AND OTHERS

The UMH is committed to transparency and to give the greatest amount of dissemination to research results, and encourages the principles of open access among its researchers and teaching staff in accordance with current regulation, as well as with the requirements of competitive calls and their corresponding clauses. However, open access publishing is not always possible, mainly due to economic reasons, which is why researchers also have the right to freely choose the journal or publishing house through which to make their achievements and results known.

Furthermore, it is very important for the scientific publication to be easy to find by other researchers, which will also help achieve a higher number of citations. To do so, it is advisable to optimise the writing of the article for a suitable positioning in search engines, as well as its promotion, after being published, on social media.

10.2.4 VOLUNTARY REGISTRATION

Section 7.3 talks about the mandatory preregistration of clinical studies. There is also the possibility of conducting a voluntary registration for other types of projects. It consists of a publishing format used by over 200 journals that emphasises the importance of the research question and the quality of methodology by conducting a peer review **prior to the start** of the project, where it is accepted for publication if it meets all the journal's requirements, and another peer review before being published.

Source: Center for Open Science (CC BY-ND 4.0)

This format removes a variety of questionable research practices, including low statistical power, selective result reports and publishing biases, while allowing full flexibility to report chance discoveries. This is why voluntary registration is considered good scientific practice.

For more information, visit: https://oir.umh.es/calidad/

10.4 UNPUBLISHED RESULTS

The non-publication of research results or their unreasonable voluntary delay can represent gross misconduct due to the misuse of resources. Publishing results from clinical studies that included people or animals represents an ethical imperative.

10.5 NEGATIVE RESULTS

In clinical studies and certain epidemiological studies, it is required to also publish results that are negative or different from those expected in the research project. In any case, it is considered good practice to publish all types of results from the study, as it decreases publishing bias and prevents the duplication of unnecessary studies, which is especially important when working with people or animals.

10.6 DUPLICATE PUBLICATION

Duplicate or redundant publication (self-plagiarism) is considered an unacceptable practice. Secondary publication is only justified in the terms

established in the Vancouver Group guidelines[1].

1 "Acceptable secondary publication" in Uniform Requirements for Manuscripts Submitted to Biomedical Journals:

Writing and Editing for Biomedical Publication Updated February 2006 International Committee of Medical Journal Editors,
http://www.icmje.org/

10.7 BIBLIOGRAPHIC REFERENCES TO THIRD PARTIES

A reference to all studies directly related to the research must be included both in publications and in the records of patents or utility models, while avoiding unjustified or honorary references. References to third-party studies must sufficiently recognise their merit.

10.8 CORRECTION OF ERRORS AND RETRACTION

If an error is found that alters the value of the published results, the authors will publish a correction in the same journal or outlet. If the errors detected are major, it is mandatory to publish a retraction as soon as possible.

10.9 ACKNOWLEDGEMENTS

The "acknowledgements" section of a publication must be rigorous. Mentioned people or institutions have the right to decline being named. Some journals require a written authorisation by the people who are to be acknowledged. The same practice is applicable to mentions referred to as "personal communications".

10.10 INSTITUTIONAL CREDITS AND AIDS

The following must be explicitly declared both in communications to conferences or any other type of prior presentations as well as in the definitive publishing of results:

- The institutions that the authors work or worked for and where the research was carried out, as described in section 10.2.1.
- The independent ethical committees that favourably evaluated the research protocol, as well as the specific permits obtained, where applicable. The approval code awarded by the respective committee must always be included.
- A breakdown of the subsidies, aids or economic sponsorships received.
- Any conflict of interests that may exist.

Furthermore, being one of the goals of science dissemination and transfer to society, as good practice it is advisable to identify and communicate the link and/or contribution of the obtained findings or results to the Sustainable Development Goals and the 2030 Agenda of the United Nations.

10.11 PRESENTATION IN MASS MEDIA OUTLETS

The presentation of results in the media must always include an informative explanation or a part of the presentation adapted to the lay public. In this type of public presentations, the name of the authors must always be associated to their institutions, and any subsidies or aids received must be mentioned when possible.

In order to improve transparency with the use of test animals, the utilisation of animals to obtain these results must be mentioned.

10.12 PREMATURE PRESENTATION IN THE MEDIA

It is not acceptable to communicate and disseminate research results in the media before they have been accepted for publication or presented in certain types of conferences.

10.13 URGENT PRESENTATION

The prior or premature dissemination or publishing of results will only be justified as an exception for public health reasons. In these cases, authors must ensure that the results will be reviewed in parallel and urgently by a scientific publishing house. Likewise, editors of the journals where the results are to be definitively published must be informed regarding the scope of the prior communication.

10.14 USE OF PUBLICATIONS FOR THE PURPOSE OF EVALUATION

Regarding evaluations of people or groups of people who will analyse scientific publications, for the purposes of promotions or any other type of reward, the evaluation will always be based on the quality and potential relevance of the scientific production, and not just the amount.

11. AUTHORSHIP OF SCIENTIFIC WORKS, PUBLICATIONS AND PATENTS

11.1 WHO CAN BE AN AUTHOR

The status of author does not depend on belonging to a certain profession or hierarchical position, nor on the nature of the working relationship, but on the type of contribution made to the research. Therefore, only someone who takes part in a clear and active way in any aspect related to the research can be considered an author.

11.2 WHO MUST BE AN AUTHOR

These four conditions must be met to fully obtain the status of author of a publication or patent:

1) To have contributed in a substantial way to the creative process, to its conception and design and/or to the acquisition, analysis and interpreting of data.
2) To have contributed to preparing the resulting communications, reports or publications and/or to have critically reviewed them.
3) To be able to make a detailed presentation of the personal contribution to the research and be responsible for all aspects of said research, in order to guarantee that all doubts regarding the accuracy or integrity of any part of the study are appropriately investigated and solved.
4) Authors must produce a written acceptance of the final draft of the original manuscripts processed to be registered or published.

11.3 PROVISION OF DATA, OPINIONS OR TEST SUBJECTS

Mere participation in obtaining resources or in gathering data does not necessarily justify author status, even when recognised in the acknowledgements section. In research where samples, analyses or opinions produced by third parties are to be used, it is advisable to previously establish a communication and authorship plan that takes into account the potential intellectual contribution to the project and any other aspect related to author's rights.

11.4 PARTIALLY RESPONSIBLE AUTHORS

When a publication has an author who cannot take responsibility for the entirety of the content, their specific contribution shall be identified separately, except in cases where this issue is regulated by editorial standards.

11.5 HONORARY AND GHOST AUTHORS

Any person linked to the research group who, due to their hierarchical position or working relationship, asks to be listed as an ex officio author, is breaching academic freedom and committing an act of injustice, or even an abuse of authority. Inversely, omitting the name of any person who has made proven contributions according to the criteria detailed in section 11.2 represents an act of misappropriation by the other authors.

11.6 INDICATION OF AUTHORSHIP IN REPORTS

Producing reports, working papers, technical reports or any other document aimed at third parties must include the relationship between the authors of the research or investigation, the institution they work for, and the subsidies received in the same terms as if it were a scientific publication or patent.

11.7 AUTHORSHIP ORDER

As a general rule, the order in which authors sign scientific publications will be as follows:

- The first author is the person who has put forth the most notable effort during the research and who prepared the first draft of the article.
- The last author is the senior researcher who manages and/or has ultimate responsibility in the research protocol.
- All other authors can appear by order of importance or, in some cases, in alphabetical order.

In any case, it is worth considering the criteria of the National Agency for Quality Assessment and Accreditation of Spain (ANECA) for each field of knowledge and, of course, of the scientific journal where the article is to be published.

The author who takes responsibility for the correspondence has the main responsibility throughout the editorial process, as well as in future interactions that arise from the work being published.

11.8 SHARED PRINCIPAL AUTHORSHIP

In scientific publications there is the right to justify the signing order of the authors. Some journals already request it as a condition for publishing. When two or more authors have dedicated the same amount of effort and shared the main task of preparing the manuscript for an article, they will have the same consideration as first authors. Said circumstance shall be explicitly mentioned when the original copy is published. This same criterion can be applied in the case of intermediary and senior authors.

11.9 SIGNING THE CURRICULUM

When producing a personal curriculum, the author is responsible for the truthfulness of its contents. In this sense, they must sign (manually or electronically) the curricular document provided. If it is a group curriculum, it only needs to be signed by the person responsible for the request.

12. PEER REVIEW PRACTICE

12.1 THE PEER REVIEW CONCEPT

This concept includes any personal commission received for having the status of, or similar to, an expert, which involves carrying out a certain assessment, examination or critique as it pertains to a document sent for its eventual publication, a report that is hoping to achieve an individual or group subsidy, a clinical or experimental protocol being examined by an ethical committee, or a report resulting from an in-person visit to a laboratory or centre.

12.2 CONFLICTS OF INTEREST

Reviews must be objective. In other words, based on scientific criteria, and not on criteria based on opinions or personal ideas. A review must be rejected if there are conflicts of interest (for example, when there is a direct link with the authors when competing directly or indirectly with them) or when the reviewer is not considered sufficiently prepared to conduct the review

12.3 USE AND DESTINATION OF THE DOCUMENTATION FOR THE ASSESSMENT

Reports and texts being reviewed are always confidential and privileged information. As a result, this documentation:

- Cannot be used for the benefit of the person conducting the review until the information has been published.
- Cannot be shared with any other colleague except for specific reasons or without the explicit consent of the editor or the research agency.
- Cannot be withheld or copied unless this is allowed by the people responsible for the editorial process or the agency. It is common for the material to be destroyed or returned once the process comes to an end. If the publishing house allows its preservation, it must be custodied with suitable security measures.

13. MISCONDUCT AND UNDESIRABLE PRACTICE IN RESEARCH

13.1 BEHAVIOUR AND PRACTICE THAT SHOULD NOT TAKE PLACE

A. Very serious:

The following behaviours/practices are considered very serious offences in the field of research:

1) **Fabrication:** Fabricating results and registering them as if they were real.
2) **Falsification:** Manipulating research materials, equipment or processes or changing, leaving out or withdrawing data or results without a reason to do so.
3) **Plagiarism:** Using the work and ideas of others without appropriately citing the original source, thus breaching the rights of the original author(s) regarding their intellectual production.
4) **Not retracting an article:** Not publishing a retraction when serious errors are found in a published article.
5) **Breach of legal obligations:** For example:
   - Not complying with the legal requirements regarding participants used in research, whether humans, animals or human organs or tissues, or regarding the protection of the environment. This includes beginning a research project without a favourable report by the CEIl when one is legally required, and without the necessary additional administrative authorisations.
   - Breaching the duty of caring for humans and/or animals involved in research, including not obtaining the appropriate informed consent or the misuse of personal data (including the inappropriate dissemination

     of the identity of research participants and other breaches of

confidentiality).

B. Serious:

The following behaviours/practices are considered serious offences:

1) **Peer review**: Inappropriate conduct when reviewing research proposals, results or manuscripts sent for publication. This includes not revealing existing conflicts of interest, the inappropriate communication of clearly limited competence, misappropriation of the contents of the documents, breaches of confidentiality or the misuse of material provided in a confidential way to be peer reviewed.
2) **Correction of errors**: Not warning the journal of minor errors detected.
3) **Misrepresentation** in any of the following aspects:
   - Data: Including the withdrawal of relevant results and/or data or knowingly conducting a flawed interpretation of the data, in a reckless way or causing gross negligence. This includes the misrepresentation of the research achievements and exaggerating the importance and practical relevance of the results, as well as any intentional manipulation of the data in order to obtain statistically significant results or any other improvement that would otherwise not have been attained.
   - Participation: Including honorary or ghost authors.
   - Interests: Not declaring the existence of conflicts of interest, if there are any.
   - Qualifications, experience and/or credentials.
   - Publishing history: The non-disseminated duplication of the publication (**self-plagiarism**), including the non-disseminated duplicated presentation of manuscripts for publication, or using fragmented publishing (the fragmented publication of the report of a research project is unacceptable).
   - Companies: Allowing collaborating companies to endanger independence, both in the research process or when presenting results, in order to insert biases.
4) **Misbehaviour:**
   - Accusing a researcher of misconduct or other offences in a malicious way.
   - Inappropriately delaying or hindering the work of other researchers.
   - Using one's own professional experience to encourage a breach of research integrity.
5) **Improper handling of misconduct accusations:** Not addressing possible breaches, such as attempts to cover up misconduct and retaliation against those who report wrongdoing, or not appropriately complying with the agreed research procedures regarding misconduct during research.

Inappropriately handling complaints of misconduct includes the inappropriate censorship of any of the parties using legal instruments, such as confidentiality agreements.

C. Moderate:

The following behaviours/practices are considered moderate offences:

1) Establishing publications or providing support to publications that do not meet the research quality control standards in the peer review process (abusive or predatory publications).
2) Ignoring supposed breaches of research integrity committed by third parties or covering up inappropriate reactions to misconduct or other types of breaches.
3) Citing selectively in order to improve one's own results or to satisfy editors, reviewers or colleagues.
4) Unnecessarily expanding the bibliography of a study.

This classification includes a list of behaviours and practices that should not take place, but should not be considered an exhaustive list. Any issue regarding scientific integrity that is not included in this list must be reviewed within the context in which it took place.

Misconduct and undesirable practices may be punishable, but all possible efforts must be made to prevent, discourage and avoid them before reaching this extent through training, supervision, mentoring and developing a positive and collaborative research environment.

13.2 HOW TO ADDRESS BREACHES AND MISCONDUCT

A consistent and transparent processing of breaches always leads to benefits for society and the research community.

Principles that must be considered when an accusation of misconduct is being investigated:

- Investigations must be impartial, complete and be conducted expeditiously, without harming accuracy, objectivity or rigour.
- The parties that intervene in the procedure must notify any conflict of interest that may arise during the investigation.
- Measures must be adopted to ensure that investigations are carried out until reaching a conclusion.
- Procedures must be conducted in a confidential manner in order to protect those who take part in the investigation.
- Institutions must protect the rights of the complainants during the investigations and ensure that their professional career is not put at risk.
- The general procedures to address breaches of good research practice must

be available to the public to ensure their transparency and consistency.

- Investigations must be conducted in accordance with the appropriate procedures and in a way that is impartial for all parties.
- During the investigation, those accused of misconduct must have access to all the details of the accusation(s), and a fair process must be guaranteed to respond to the accusations and submit evidence.
- Actions must be taken against people who are proven to have committed misconduct, and these actions must be proportional to the severity of the breach.
- If the researchers are acquitted from an accusation of misconduct, the appropriate compensation measures must be conducted.
- During the investigation, anyone accused of misconduct must be considered innocent until proven guilty.

You can find more information on the complaint procedure at the following link: https://oir.umh.es/integridad.

14. MAIN REGULATORY REQUIREMENTS FOR SCIENTIFIC PRACTICE

14.1 RESPONSIBILITIES

14.1.1 OF THE UNIVERSITY

The university, through its governing bodies and committees established to this effect, is responsible for:

- Ensuring that the facilities and infrastructures meet the requirements and that the relevant authorisations are available in order to carry out any scientific practice subjected to specific regulations.
- Ensuring that research is conducted in accordance with the appropriate frameworks, obligations and ethical, legal and professional standards. Specifically:
    - Ensuring respect and the ethical treatment of people and animals participating in any study.
    - Ensuring the safety and health of the staff, students and people participating in any study.
    - Minimising the environmental impact generated while conducting research activities.
- Maintaining a research environment that fosters good research practice and includes a culture of integrating research, including training on ethics and

integrity, and support for researchers who act according to the expected standards, values and behaviours.
- Having transparent, solid and fair procedures to investigate alleged research misconduct.

14.1.2 OF THE PRINCIPAL INVESTIGATOR

The Principal Investigator must have freedom in their academic choices and must also accept responsibility for the decisions taken. Therefore, they are responsible for:

- Ensuring that they act in accordance with the principles of integrity and responsibility in all aspects of their research work.
- Conducting research in accordance with the appropriate frameworks, obligations and ethical, legal and professional standards, as defined in the previous section.

14.2 HUMAN RESEARCH

Any research protocol that directly involves the participation of people, their data or their biological samples, must always have, at least, the approval of the CEIl of the UMH. An additional ethical authorisation from another ethics committee may be required in the case of studies with people who are ill, or when the CEIl of the UMH establishes this condition.

In the case of research with people who are ill, the members of the research team who are not in charge of the clinical treatment of the participants must collaborate and not interfere in any issue established by the medical staff in charge.

It is important to be especially diligent with everything regarding the information on the purpose, inconveniences and possible risks and benefits of the research, securing the express and specific consent of participating people, as well as the confidentiality of the data, samples and obtained results. Furthermore, as in clinical research the data obtaining process is complex and cannot always be repeated, the research team will pay special attention to the quality of the gathering process and the data custody procedure.

14.2.1 RESEARCH WITH GENETIC PURPOSES

Any research protocol that entails obtaining, processing and/or preserving biological samples for genetic analysis shall adjust to that which is specifically laid out in existing regulation. In particular, it must guarantee the privacy and the right

to informational self-determination of the source individuals.

The consent of source individuals may include the use of the sample for research

projects other than the one initially proposed but connected to it. This consent must be renewed if the biological samples are to be used for purposes other than the ones planned when the donation was made.

14.2.2 RESEARCH WITH HUMAN EMBRYONIC MATERIAL

Any research protocol that entails obtaining, processing and/or preserving biological material of human embryonic origin must previously have the corresponding authorisation of the Ministry of Health, with an ethical authorisation and the approval of the Committee for the Guarantees on the Donation and Use of Human Cells and Tissues. The consent of source individuals may include using the sample for other research projects related to the one initially proposed. This consent must be renewed if the biological samples are to be used for purposes other than the ones planned when the donation was made.

14.2.3 PERSONAL DATA PROTECTION

Any research protocol that entails the use or acquisition of identifying or identifiable personal data must be subjected to the assessment of the CEIl and follow the "Procedure for the use of personal data in research" that can be found at the following link: https://oir.umh.es/datos-personales.

14.3 ANIMAL RESEARCH

Any research project that entails the use of animals must always have the approval of the CEIl and the express authorisation of the competent authority, where necessary.

Any researcher who uses animals for experimental and other scientific purposes must comply with the training requirements stipulated in current legislation.

14.4 RESEARCH ON HEALTH OR ENVIRONMENTAL SAFETY

Non-clinical studies aimed at health or environmental safety whose results must be submitted before the relevant regulatory authorities shall be performed following the principles of good laboratory practice.

14.5 PREVENTION ON THE ISSUE OF HEALTH AND SAFETY

UMH researchers are beholden to the Occupational Hazard Prevention Plan (PPRL) of

the university, to integrating the PPRL in their research activity and to comply with valid general procedures on the issue of prevention approved by the university's Committee

for Health and Safety (CSS). Said procedures will be published on the website of the Department of Occupational Hazard Prevention, and its use will always have the guidance and support of the mentioned department: https://prevencion.umh.es/.

In particular, in the research activity, the principal investigator must account for the nature, degree and duration of the exposure of female research staff who are in a situation of pregnancy or recent delivery, to agents, procedures of working conditions that could negatively affect the health of the workers, the foetus or any activity susceptible of representing a specific risk, acting in accordance with the current procedure.

Research projects will also be subjected to an assessment on behalf of the CEII of the risks related to health and safety and, in the specific case of the use of biological agents and genetically modified organisms, it may be necessary to obtain additional external authorisations.

14.6 ENVIRONMENTAL RISK MANAGEMENT

Research activity often represents an environmental risk that the principal investigator must know and duly manage. There may be significant environmental risk in the following cases:

- Due to the generation of waste with risk of biological infection or contamination.
- Due to the use of species that represent a risk to change or threaten biological diversity (invasive exotic species, genetically modified organisms, etc.).
- Due to the generation of test animal cadavers.
- Due to the use of cadavers or dissected human remains.
- Due to the generation of carcinogenic or mutagenic waste.
- Due to the generation of other dangerous chemical waste (toxic, oxidising, flammable, explosive, inhalation hazard, dangerous for the aquatic environment or for the ozone layer, etc.).
- Due to the generation of waste from electric or electronic devices.

In all these cases, the waste management procedure detailed on the website of the Environmental Office of the UMH must be followed: https://www.umhsostenible.com/

15. THE COMMITTEE ON ETHICS AND INTEGRITY IN RESEARCH AND THE OFFICE FOR RESPONSIBLE RESEARCH

15.1 DEFINITION AND DUTIES

The CEII of the UMH is a multidisciplinary body presided by the Vice-Rector for Research and is comprised by different scientific and technical profiles that guarantee a transversal assessment of the ethics and integrity of the research activities conducted at the UMH. Furthermore, the CEII, by way of the Office for Responsible Research, has its own budget to develop all the administrative activities that its duties generate, as well as recruiting external scientific consultants when required by the complex nature of its activities.

It is the CEII's duty:

- To assess the ethical aspects that arise in the design and development of conducted research projects.
- To guarantee compliance with the precepts included in the CGSP.
- To remain attentive and responsive to new issues related to research integrity, as well as to update the contents of the CGSP.
- To act as an arbitration body before the uncertainties or conflicts that may arise in relation to research integrity.
- To inform and raise awareness among the scientific community of the UMH on the events, needs and guidelines relative to ethical and deontological aspects of research conducted at the university.

It is the OIR's duty:

- To provide advice on ethics, integrity and regulatory aspects for research projects that involve human beings or animals.
- To guarantee that research conducted at the university is done in an ethical and upright manner.
- To guarantee compliance with applicable regulation in the fields of health and safety, the protection of the environment and human and animal research.
- To provide a response to the growing social concern on the protection of test animals, ensuring strict compliance with current regulation and transparency.
- To appropriately manage the assessment and monitoring of research projects and contracts, maintaining a close collaboration with the SGI-OTRI, with the Department of Occupational Hazard Prevention, with the Environmental Office and the Data Protection officer.
- To design an educational offering aligned with the legal and ethical requirements of today's society.

15.2 THE NATURE OF THE CEII'S ACTIVITY

Regarding the aforementioned duties, the CEII will ensure at all times the diligence of its management, the independence of its activity, the anonymity and confidentiality when processing personal data, the soundness of the information generated, the impartiality of its deliberation and the fairness of its resolutions, as well as the possibility to appeal against them.

15.3 CONTACT US

You can contact the CEII and the OIR at the following email address: oir@umh.es