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Code of conduct

for Research Integrity

"Carol Davila" University of Medicine and Pharmacy in Bucharest

Content

Terms and abbreviations

1. **UMFCD:** "Carol Davila" University of Medicine and Pharmacy of Bucharest
2. **The university community of UMFCD:** consists of students, doctoral students, trainees, teaching and research staff, auxiliary teaching and research staff and administrative staff. The university community also includes persons who have been granted membership of the university community, by decision of the University Senate. Those graduates (alumni) who are pursuing a form of postgraduate training within the university, teaching staff and researchers who have worked in UMFCD, but without thereby having decision-making or electoral prerogatives and powers in the University, are considered members of the university community. Romanian and foreign personalities who hold honorary titles granted by the University, but who, in turn, do not have decision-making or electoral prerogatives and powers are also considered to belong to the university community.
3. **R&D** : research-development-innovation
4. **AI** : artificial intelligence.
5. **Automated tools** : software used in content writing.

Documents that formed the basis for the development of this code

- European Charter for Researchers and Code of Conduct for the Recruitment of Researchers (Recommendation 2005/251/EC);
- Charter of Fundamental Rights of the European Union (2010);
- European Code of Conduct for Research Integrity (2023);
- Government Decision No. 305/2024 for the approval of the Framework Code of University Ethics and Deontology
- Charter of the "Carol Davila" University of Medicine and Pharmacy in Bucharest, 7th edition, (2023);
- Helsinki Declaration (2013);
- Guide to integrity in scientific research (CNECSDTI, 2020);
- Law No. 8/1996 on copyright and related rights - republished, with subsequent amendments and supplements;
- Law No. 129/1992 on the protection of designs, republished;
- Law No. 190/2018 on implementing measures for Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation);
- Higher Education Law No. 199/2023, with subsequent amendments and supplements;
- Law No. 43/2014, on the protection of animals used for scientific purposes, as subsequently amended and supplemented;
- Law No. 64/1991 on patents, republished, with subsequent amendments;
- Law No. 95/2006 on the reform in the field of health, republished, with subsequent amendments and supplements;
- Law No. 206/2004 on good conduct in scientific research, technological development and innovation, ~~updated~~ ;
- Law No. 319/2003 on the Status of Research and Development Personnel, with subsequent amendments and supplements;
- Law No. 183 of June 10, 2024 on the status of research, development and innovation personnel, in force from 12.07.2024

- Order of the Ministry of Education and Research No. 5229/2020 for the approval of methodologies relating to the granting of the habilitation certificate, the granting of the doctoral title, as well as the resolution of complaints regarding non-compliance with quality standards or professional ethics, including regarding the existence of plagiarism, within a doctoral thesis;
- Order of the Ministry of Public Health No. 903/2006 for the approval of the Principles and detailed guidelines on good clinical practice in clinical trials for investigational medicinal products for human use, as well as the requirements for the manufacture and import of these medicinal products;
- Order of the Ministry of Public Health No. 904/2006 for the approval of the Norms regarding the implementation of good practice rules in the conduct of clinical trials conducted with medicinal products for human use;
- Order of the Ministry of Public Health No. 905/2006 on the approval of the Principles and guidelines of good manufacturing practice for medicinal products for human use, including those for clinical investigation.

Preamble

UMFCD, through its assumed mission, as a university of advanced education and research, aims to generate and transfer knowledge to society, to respond to the ongoing challenges in the biomedical field and to support the principles of sustainable development within society. UMFCD promotes in all its activities the principles of ethics and integrity in scientific research.
This code was developed by consulting national and European legislation covering good practice and ethics in RDI activities, in order to guide members of the UMFCD community in assimilating and applying the fundamental principles of research integrity:

- **Reliability** in ensuring the quality of research, translated into design, methodology, analysis and use of resources.
- **Honesty** in developing, conducting, reviewing, reporting and communicating research conducted in a transparent, fair, complete and impartial manner.
- **Respect** for colleagues, research participants, research subjects, society, ecosystems, cultural heritage and the environment.
- **Responsibility** for research from idea to publication, for its management and organization, for training, supervision and guidance, to ensure a superior impact at the societal level.

This code aims to strengthen good research conduct at the institutional level, by implementing good research practices and aligning them with European values, through an integrative approach to the professional, legal, social, ethical and moral responsibilities of all participants involved in the research process, with a decision-making or executive role.

By adopting the code, members of the UMFCD university community commit to adopting and applying the principles set forth at the highest quality standards and respecting institutional values.

The principles underlying the drafting of this Code are in accordance with the European Code of Conduct for Research Integrity and the Code of University Ethics and Deontology.

General framework:

Research is a fundamental element in the evolution of society, which involves obtaining a gain in knowledge, through processes of systematic study, experimentation, observation, thinking and critical analysis. Biomedical research is oriented with a predilection towards understanding phenomena with an impact on health and identifying solutions that contribute to increasing the quality of life, for a healthy and sustainable society. The credibility and impact of the results obtained are supported by R&D activities that respect ethics, principles and standards of good practice. These guide participants involved in the research process, in their work, as well as in addressing practical, ethical and intellectual challenges.

The principles underlying this code are:

1. *Transparency and Openness* : Researchers should be transparent about their methodologies, data collection processes, and analysis techniques. Openness in research promotes accountability and reproducibility of the findings.

2. *Honesty and Integrity* : Researchers must conduct their work with honesty and integrity, avoiding fabrication, falsification of data, and plagiarism. Researchers will accurately report their findings, even when they conflict with expectations or formulated hypotheses.

3. *Objectivity* : Researchers must pursue objectivity in the analysis and interpretation of data, minimizing bias and subjective influence. Objectivity ensures the reliability and validity of research results.

4. *Respect for Participants* : Researchers are required to respect the rights, dignity, and confidentiality of research participants. Informed consent must be obtained before subjects are included in the study, and any potential risks to participants must be minimized and, where appropriate, managed appropriately.

6. *Respect for the welfare of animals used for scientific purposes* : Researchers are required to develop study protocols following the "3R" principle (Replacement, Reduction and Refinement) and to ensure the welfare of the animals used in this regard.

7. *Data Management and Sharing* : Researchers should establish clear protocols for managing, storing, and sharing data. Data should be stored securely and available for review by other researchers whenever possible, promoting transparency and collaboration.

8. *Quality Assurance and Control* : Researchers must implement quality assurance and control measures for the results obtained to ensure their accuracy, reliability and validity, through specific procedures and regular checks or peer reviews.

9. *Compliance with Ethical Standards and Regulations* : Researchers are required to comply with relevant ethical guidelines, institutional, national and international regulations and policies governing the conduct of research. This includes obtaining appropriate approvals from ethics committees and ensuring compliance with legal provisions regarding R&D activities involving human subjects, laboratory animals and sensitive data.

10. *Disclosure of Conflict of Interest* : Researchers must disclose any potential conflicts of interest that could influence the research or interpretation of results. Transparency regarding financial, professional, or personal interests is necessary to maintain trust and credibility in research results.

11. *Responsibility and Accountability* : Researchers are responsible for the accuracy and integrity of their research. They undertake to take responsibility for addressing any errors or discrepancies identified in their research and for correcting the scientific record when necessary.

12. *Continuous Learning and Improvement* : Researchers should engage in continuous professional development and seek opportunities to improve their research skills and awareness of ethical standards in research. Continuous learning promotes excellence in the conduct of research and supports a culture of integrity within the research community.

These principles form the basis of good research practices and guide researchers in maintaining the highest standards of quality, integrity and ethical conduct in their work. The principles are applied within the "Carol Davila" University of Medicine and Pharmacy of Bucharest, contributing to the promotion of a culture of high-quality research and academic integrity within the institution.

Good practice in RDI activities carried out within UMFCD

The norms of good practice in RDI activities in the biomedical sector aim at a series of principles that guide the university community of UMFCD towards carrying out ethical research, at high quality standards, principles that refer to:

- Research environment,
- Conflict of interest,
- Training, supervision and guidance,
- Research procedures,
- Protective measures,
- Data practices and management,
- Working in collaboration,
- Publication, dissemination and authorship,
- Evaluation and review.

Research environment

At the institutional level (faculties, departments, clinics, research centers, IOSUD, administrative structures), UMFCD promotes awareness and stimulation of an organizational culture of research integrity among the university community, through a series of concrete measures.

In UMFCD, an environment of mutual respect between members of the university community is continuously supported and developed, regardless of their role and position, and the policy of equal opportunities is promoted, based on criteria of competence without discrimination on the basis of gender, age, ethnicity, religion or group affiliation.

UMFCD maintains an environment that facilitates independent and teamwork, stimulates creativity, does not exert undue pressure on researchers, and supports the implementation of ethical norms in all activities undertaken.

UMFCD operates clear policies and procedures that support the implementation of good research practices, as well as the transparent and appropriate management of potential deviations from the

ethics and integrity of R&D activities. UMFCD protects individuals who report potential abuses and offers support to any member of the university community who receives threats .

UMFCD offers mentoring/tutoring opportunities for young researchers, who are most frequently exposed to these situations. UMFCD prohibits requests, acceptances or collections of sums of money or gifts or the provision of certain services in order to obtain preferential treatment or other advantages.

UMFCD supports the continuous development of research infrastructure, so that members of the university community have equitable access to a material base that meets current challenges, providing conditions for the generation, management and protection of research data and materials in all their necessary forms, for reproducibility, traceability and accountability.

Conflict of interest

At the institutional level, in accordance with the legal provisions specific to the field of research, development and innovation , the following are considered to be a conflict of interest:

- EMPLOYMENT concurrent functions by the people who are in spousal relationship , in-laws and relatives up to the third degree inclusive , thus that each to find out towards the other in a position direct leadership , control , authority or ASSESSMENT institutional at any level in same research organization ;
- contribution in membership in doctoral committees , evaluation committees or competition committees , in the situation in which the decision AFFECTING spouses , relatives or affinity up to and including the third degree ;
- contribution in THE the same committees , established according to the law , of persons who have the status of husband / wife , relative or bilberry up to and including the third degree ;
- contribution of a person who has the status of member in commission or MCID councils , when analyzing of a situations related to the research organization of which he/she is a member of the research community ;
- other situations specific ESTABLISHED in applicable regulations SOME evaluation procedures , including in information packages of some project competitions , respecting Rulemaking link in vigor .

A person cannot participate directly, as an evaluator expert, or indirectly, by making nominal decisions for the direct selection or exclusion of evaluator experts responsible for the evaluation of a research organization , a project, a tender or a candidate, if that person is part of the staff list of the research organization , the project or tender evaluated or of other projects or tenders submitted for financing under the same funding line , tenders or requests for tenders or if they are in the following relationship with the candidate or with the persons on the staff list of the projects, tenders or research organizations evaluated: they are spouses , in-laws or relatives up to the second degree inclusive.

The staff list of a project or a tender is made up of the persons nominated in the project proposal or tender subject to evaluation, including the project director, and , in the case of projects carried out in partnership between several research organizations , the project managers.

Training, Supervision and Guidance

Within UMFCD, members of the university community who carry out RDI activities will benefit from training in the fields of study design, methodology, analysis, dissemination and communication.

UMFCD will ensure access to members of the university community to training sessions/programs on ethics and integrity in research, as well as in biomedical research, to ensure that all those involved are informed about the relevant codes and regulations, are aware of their importance, and develop the necessary skills to apply them in research.

Senior researchers, research team leaders, and mentors/tutors lead team members and young researchers by example, guiding and coaching them, so that they can develop and structure their research activities correctly.

Members of the university community involved in R&D activities, throughout their careers, are required to attend training courses in research ethics and integrity.

Research Procedures

Members of the university community, who carry out RDI activities, will analyze the current state of knowledge and will carry out RDI activities in a careful and transparent manner, both in terms of study design and conduct, and for recording, analyzing, and interpreting data.

Members of the university community carrying out R&D activities will develop study protocols that will take into account, whenever appropriate, the relevant differences between research participants: age, gender, sex, culture, religion, worldview, ethnicity, geographic location, and social class.

Members of the university community involved in RDI activities will appropriately use the funds allocated for research, strictly respecting the legislative provisions and institutional procedures regarding this aspect.

Members of the university community who carry out R&D activities will communicate the results obtained in an open, honest and accurate manner, and will respect the confidentiality of data or discoveries in accordance with legal regulations.

Members of the academic community carrying out R&D activities will report their results and methods, including the use of external services or AI and automated tools, in a manner compatible with accepted norms and that facilitates verification or replication, where appropriate.

Protective measures

UMFCD and members of the university community who carry out R&D activities are committed to complying with the relevant codes, guidelines and regulations for conducting research.

Members of the university community involved in R&D activities will treat study participants, laboratory animals used for scientific purposes, the socio-cultural environment with respect, and will manage recorded data in accordance with legal provisions and ethical principles.

Members of the university community will take into account the health and safety of collaborators and other persons directly or indirectly involved in research activity.

Members of the academic community will assess the possible harms and risks related to their own research activity and will try to minimize any potential negative impact thereof.

Data practices and management

UMFCD and members of the university community involved in R&D activities will take steps in accordance with the legal regulations in force for the access, management and adequate preservation,

for a clearly defined period of time, of data, metadata, protocols, codes, software and other relevant materials related to the research process.

UMFCD and members of the university community involved in R&D activities will ensure that access to data is as open as possible and restricted only to the extent necessary *(as open as possible, as closed as necessary) , and will respect the FAIR (Findable, Accessible, Interoperable* and *Reusable)* principles for data management, when applicable.

Members of the university community involved in R&D activities inform research participants about how their data will be used, reused, accessed, stored and deleted, in accordance with GDPR rules.

UMFCD and members of the university community involved in R&D activities recognize data, metadata, protocols, codes, *software* , as well as other relevant materials related to the research process as legitimate and citable research products.

UMFCD and members of the university community involved in R&D activities ensure that any contracts or agreements relating to research results include fair and equitable provisions for the management of use, ownership and protection under intellectual property rights.

Working in collaboration

All partners involved in collaborative RDI activities assume responsibility for the integrity of the research and its results.

All partners involved in collaborative RDI activities formally express their agreement on monitoring and adapting, as appropriate, the research objectives, and establish the means of communicating the RDI activities undertaken and the results obtained, as transparently and openly as possible.

All partners involved in collaborative RDI activities will formally agree, monitor and adapt, as appropriate, expectations and standards regarding research integrity, regulations that will apply, protection of collaborators' intellectual property, procedures for managing conflicts and possible cases of misconduct.

All partners involved in collaborative RDI activities are consulted and formally agree on the scientific papers prepared for the publication of research results and other forms of dissemination or exploitation of results.

Publication, dissemination and authorship

Authors are required to agree on the order of authors within publications, recognizing that the position occupied by each author is based on: (1) a significant contribution to the design of the research, the collection of relevant data, its analysis and/or interpretation; (2) the drafting and/or critical revision of the publication; (3) the approval of the final form of the publication; (4) the acceptance of responsibility for the content of the publication; unless otherwise specified in the publication.

Authors are required to include an “Author Contribution Statement” in the final publication, where possible, to describe the responsibilities and contributions of each author.

Authors are required to acknowledge the important work and contributions of those who do not meet the criteria for authorship, including collaborators and funders who enabled the research.

Authors are required to disclose any financial and non-financial conflicts of interest, as well as sources of support for research or publication.

Authors and editors will make corrections or withdraw publications, when appropriate, following a clear process.

Authors, editors, funders, and the research community recognize that negative results can be as relevant as positive findings for publication and dissemination.

In communicating with colleagues, decision-makers, and society at large, authors are obligated to be accurate and honest.

Authors are required to be transparent about the assumptions and values that influence their research, the robustness of the evidence, and any uncertainties or knowledge gaps.

Authors are required to comply with the criteria in the previous paragraph, regardless of whether they publish in a subscription journal, an open access journal, or any other form of publication, including preprint servers.

Members of the academic community are required to write correct and real information in grant or funding applications, in application files for habilitation, and in application files for teaching or research positions.

Evaluation and review

Members of the university community involved in R&D activities must demonstrate seriousness and fairness in their commitment and responsibility towards the research community, including by participating in peer review, review and evaluation activities , *activities* recognized and respected within the UMFCD.

Members of the university community involved in R&D activities review and evaluate documents submitted for publication, promotion or awards in a transparent and justified manner.

Members of the university community involved in RDI activities use AI and automated tools in a transparent manner.

Reviewers, evaluators, and editors are required to declare any real or potential conflict of interest, and when the situation requires it, they withdraw from the *peer-review process* , granting funding, promotion, or any form of reward.

Evaluators will maintain confidentiality unless there is prior approval for disclosure.

Reviewers and editors are required to respect the rights of authors as well as applicants and to ask for permission to use the ideas, data, or interpretations with which they have come into contact.

UMFCD and members of the university community involved in R&D activities adopt evaluation practices that are based on the principles of quality, knowledge advancement and impact, which go beyond quantitative indicators, and take into account diversity, inclusion, openness and collaboration where appropriate.

Deviations from Research Integrity

This code aims to ensure that all members of the UMFCD community involved in R&D activities are aware of the correct methodologies and ethical practices associated with biomedical research. Failure to comply with the norms of good practice in specific research is in contradiction with the academic and professional responsibilities of members of the university community, being likely to lead to a deterioration of R&D activities in the biomedical field, as well as to the alteration of the results obtained, to undermine the trust and credibility of biomedical research and to waste allocated resources, potentially exposing end users (patients, society) or the environment to unnecessary risks and damages.

Intellectual Theft and Other Unacceptable Practices

Intellectual theft is defined as falsification, fabrication, or plagiarism in the proposal, conduct, review of research, or reporting of research results:

Fabrication of results or data - reporting fictitious results or data, which are not the real result of a research and development activity;

Falsification of results or data - selective reporting or rejection of data or unwanted results, manipulation of representations or illustrations, alteration of experimental or numerical apparatus to obtain desired data, without reporting the alterations made, for the purpose of distorting scientific truth;

Plagiarism - the presentation as a supposedly personal creation or scientific contribution in a written work, including in electronic format, of texts, ideas, demonstrations, data, theories, results or scientific methods taken from written works, including in electronic format, of other authors, without mentioning this and without referring to the original sources;

Self-plagiarism - republishing substantial parts of one's own previous publications, including translations, without properly indicating or citing the original.

In the current context, other violations of good research practices have been identified, which distort the records of R&D activities or affect the integrity of the research process or researchers. In correlation with the European Code of Conduct for Research Integrity, a number of other unacceptable practices have also been defined, such as:

a) Compromising the independence of the research or reporting process by sponsors/funders so as to introduce distortions of the conclusions;
b) Misuse of seniority/position or academic position to encourage research integrity violations or to advance one's career;
c) Delaying or obstructing the work of other researchers;
d) Misuse of statistics to inappropriately suggest a certain meaning of the data obtained;
e) Hiding the use of AI or automated tools in content creation or publication editing;
f) Withdrawing data or research results without justification;

g) Dividing research results with the specific aim of increasing the number of research publications (*“salami” publications);*
h) Selective or inaccurate citation;
i) Unjustified expansion of the bibliography of a study to gratify editors, reviewers, or colleagues, or to manipulate bibliographic data;
j) Manipulating authorship or denigrating the role of other researchers in publications.
k) Establishing, supporting or deliberately using journals, publishers, events or services that undermine the quality of research (*predatory journals or conferences* and article mills);
l) Participation in cartels of reviewers and authors who collaborate to review each other's publications;
m) Misrepresentation of research achievements, data, involvement or interests;
n) Accusing, in bad faith, a researcher of irregularities or other misconduct;
o) Ignoring potential deviations from the integrity and ethics of members of the university community, covering up inadequate responses to proven irregularities;
p) Intimidation of members of the university community involved in RDI activities in the production, interpretation and dissemination of results.

UMFCD, through this code, strengthens the efforts made at the institutional level to prevent, discourage and stop these issues, through training, supervision and guidance, as well as by supporting a positive and supportive research environment.

Addressing allegations of misconduct

At the institutional level, the reporting and management mechanisms for situations involving deviations from the norms of conduct for the integrity of research are in line with national legal provisions, and the reporting and resolution procedures are transparent. The investigations undertaken are fair, comprehensive and carried out expeditiously, without compromising accuracy, objectivity or exhaustiveness. UMFCD ensures the successful completion of the investigations, which will be carried out confidentially, in order to protect the persons involved.

Any person accused of violating the rules of research integrity shall be presumed innocent until final judgment. Any person accused of violating the rules of research integrity shall be given full details of the charges and shall be afforded a fair opportunity to respond to the charges and present evidence.

The parties involved in the investigation declare any conflict of interest that may arise during the investigation.

Whistleblowers' rights are protected during investigations to ensure that their career prospects are not jeopardized.

The general procedures for addressing violations of good research practices are public and accessible to ensure their transparency and uniformity.

Investigations into violations of research integrity codes of conduct consider both the individual and institutional roles in ensuring good research practice.

Sanctions against persons for whom the allegations have been confirmed must be proportionate to the seriousness of the violations and will be applied in accordance with the legislative provisions in force. The procedures for investigating and sanctioning violations of the norms of this Code are the responsibility of the University Ethics Committee.
The provisions of this Code are complemented by the provisions of the UMFCD Code of Ethics.
In accordance with Higher Education Law No. 199/2023.