ΠΑΝΕΠΙΣΤΗΜΙΟ
ΔΥΤΙΚΗΣ ΜΑΚΕΔΟΝΙΑΣ

CODE OF RESEARCH ETHICS

ETHICS and INTEGRITY COMMITTEE

OF

THE UNIVERSITY OF WESTERN MACEDONIA

Kozani 2018

Article 1

Research Ethics and Integrity Committee (REIC)

1. By decision of the Research Committee, the University of Western Macedonia (UoWM) has established the Research Ethics and Integrity Committee (REIC), comprised of 5 members and their deputies.
2. Members must be research, ethics/bioethics, and research ethics experts. At least one (1) member must be an ethics/bioethics expert.
1. At least two (2) REIC members should be Doctoral degree holders (in absence of Doctoral degree holders, Master's degree holders may be eligible), given that they a) hold a UoWM discipline-related degree, b) provide evidence-based research experience, and c) engage in professional activities compliant with UoWM disciplines.
2. Up to three (3) REIC members are academic staff members (teaching and research staff) and Emeriti Professors at the University of Western Macedonia.
3. Selection processes for REIC membership takes place upon invitation for expression of interest, posted by the Research Committee on UoWM's website. The Research Committee considers nominations and decides on REIC composition.
4. The Research Ethics and Integrity Committee is established upon the University REICtor's decision, who also decides on the Committee Chair and Vice-Chair.
5. The term of office for REIC members is 3 years and may be renewed only once.

Article 2

Scope

The Research Ethics and Integrity Committee (REIC) aims at ensuring reliability of research in terms of ethics and integrity at the University of Western Macedonia (UoWM). REIC controls respect for human dignity, participants' independence, privacy, and personal data, as well as respect for the natural and cultural environment for the research projects carried out. REIC also oversees compliance with common accepted principles of research integrity and the criteria for good scientific practice.

Article 3

Competencies

1. The Research Ethics and Integrity Committee engages in determining that a prospective research project at the University of Western Macedonia is not contrary to the legislation in force and adheres to common accepted research ethics, both in terms of content and conduct. The Committee shall assess research proposals and:

   i. Approve them, or
   ii. Recommend revision should ethics and integrity issues are raised.

2. Recommendations and proposals must be specifically reasoned. REIC may request that research supervisors provide further information or explanations, where appropriate, and oversee progress of approved research.
3. Funded research which, as stated by supervisors, involve research on humans, human-derived samples (such as genetic material, cells, tissues, and personal data), animals, or the environment (natural and cultural), shall be submitted for mandatory approval by REIC. Non-approval of research projects implies that they cannot begin at the University of Western Macedonia.
4. In addition to research as described in the previous paragraph, REIC may examine, upon an individual's request or complaint, other research projects and provide expert opinion on ethical issues related to research studies to be published in scientific journals, or dissertations and doctoral theses in progress.
5. REIC's decisions are binding upon the University of Western Macedonia.
6. Where legislation provides approval or project licensing by other competent public services, administrative bodies, or independent administrative authorities, REIC's decision does not replace required approval or licensing.

7. REIC decision-making takes place within a reasonable timeframe, not exceeding fifteen (15) days from the application date and submission of all required supporting documents. Unless a decision is not issued within the specific period, applications are considered approved.
8. In the event of complaints, REIC decides no later than fifteen (15) days upon complaint submission. Unless no decision is issued within the specific period, complaints are considered rejected.
9. Requests for reconsidering REIC's recommendations may be submitted by interested parties within ten (10) days from the decision-making process, providing new evidence. To examine reconsideration requests, REIC applies to the National Bioethics Commission, which must formulate opinion within fifteen (15) days. Unless the National Bioethics Commission does not provide an opinion within the aforementioned deadline, REIC proceeds with examining reconsideration requests without the opinion of the National Bioethics Commission.

Article 4

Scope of Implementation

1. The present Code includes ethical regulations to be implemented to all research activities conducted under the responsibility or participation of the University academic and research staff, within or outside its premises, with or without funding.
2. Research ethics also applies to specialist research service activities, training programmes, or other scientific applications overseen by the Finance and Administrative Support Unit (FASU) of the Special Account for Research Funds (SARF, ELKE in Greek) of the University of Western Macedonia.
3. Separate discipline-specific 'Codes of Research Ethics' may be formulated by University Schools or Departments.
4. The present Code is enforced in conjunction with current legislation and the Internal Regulations of the University of Western Macedonia.

Article 5

Fundamental Principles of Research Activities

1. 'Research' is defined as creative work systematically undertaken to augment existing knowledge. Research may imply non-anticipated (basic research) or anticipated (applied research) use of knowledge resources for devising new applications.
2. 'Development' implies systematic work which relies on existing knowledge with a view to: a) creating new materials, products, or equipment, and b) introducing new or improved processes, systems, or services.
3. Research aims to advance scientific knowledge, in accordance with globally acknowledged scientific theories or the formulation of new theories which gain recognition of the international scientific community. The research must adhere to the principles of scientific truth, academic freedom, and must respect life, nature, and the environment, and uphold the biological and intellectual integrity of humans, human dignity, intellectual property, and personal data. Throughout the research process, any discriminatory practices against individuals based on factors such as ethnicity, race, national origin, language, gender, religion, private life, physical ability, genetic orientation, or socio-economic status must be avoided.
4. Research autonomy is a public good. It is, thus, imperative that the state and competent authorities establish a framework to facilitate unrestricted progress of research initiatives, guided by fundamental ethical principles and specific ethical rules derived from discipline-specific research frameworks.

Article 6

Researchers' Responsibilities

1. Researchers enjoy the constitutionally guaranteed freedom of research, which they must safeguard against political, ideological, or other pressures or interventions from third parties.
2. Researchers commit to adhering to overarching principles regarding safeguarding human rights, equality, public health, the protection of children and socially sensitive groups, as well as the preservation of biodiversity and the environment. They are dedicated to protecting research

contributors' personal data and ensuring fair, unbiased, and scientifically ethical selection processes of research participants.
3. Researchers are committed to mutual respect, confidentiality, and the right to equal treatment.
4. Throughout the research process, researchers must be informed and adhere to the provisions of the relevant legislation, ethical principles, and ethics of a specific research project, as well as the ethical principles of their profession.
5. Researchers adhere to research schedules to minimise risks for individuals involved in research projects. A robust research design ensures that research procedures do not unduly expose participants to risks, and whenever feasible, the procedures are integrated into the participants' diagnosis or treatment methods.
6. Upon undertaking, conducting, and publishing research findings, researchers must ensure that:
a) Necessary and required permissions for research implementation have been obtained from competent authorities.
b) No conflict of interest occurs or will arise during research, to prevent or hinder research objectivity and integrity.
c) Adherence to any special statutory regulations pertinent to specific types of research (e.g., for social research involving sensitive social groups, clinical research on animals in biology, etc.) is maintained.
d) Under no circumstances, protection of intellectual property and personal data of third parties is infringed upon.
7. In any of the four (4) aforementioned instances, researchers are required to address SARF's or the University competent legal service to request guidance and support and, accordingly, relevant legal advice. In such instances, academic staff are obligated to keep copies of mail files to avoid potential complications.
8. Researchers should not replicate previous research conducted by others, unless scientifically reasoned. In addition, they are obligated to conduct research in compliance with current statutory provisions for protection of intellectual property and patent.
9. Research design and conduct must adhere to the principles of scientific documentation practice. Fabrication or falsification of research findings is absolutely forbidden and incurs disciplinary and criminal sanctions.
10. Plagiarism, appropriation, or falsification is strictly forbidden and is subject to sanction, in accordance with the relevant provisions outlined in the Internal Regulation of the University of Western Macedonia.
11. Researchers are required to disclose research funding source/s. No conditions shall be included in the agreement regarding research funding, which evidently compromise freedom in designing and conducting research.
12. Researchers must keep a complete record of the progress and outcomes of research projects, ensuring control over, and, in each instance, acknowledging intellectual property rights relating to the research subject, according to the degree of their researchers' contributions.
13. Researchers are required to submit proposals to the University Research Committee for legal participation in funded research projects not conducted in the University of Western Macedonia.
14. The University of Western Macedonia does not implement research projects for Military Organisations, except for those of the Greek Armed Forces and International Organisations, in which Greece participates serving National Security.
15. Research conducted on UoWM premises should not disrupt other educational processes and functions.
16. Other categories of University staff apart from academic staff members, such as staff seconded to University services and external collaborators, are also eligible to engage in research.
17. The use of administrative job titles held by academic staff members in collective bodies to request external funding requires the consent of the specific collective body.
18. Researchers are primarily responsible for ensuring the protection of research participants and the environment. They are personally accountable for their actions in compliance with current legislation and international declarations on bioethics and human rights.
19. Researchers must ensure the protection of personal data of research participants and safeguard fair, unbiased, and compliant participants' selection processes with relevant codes of ethics.
20. Research design should ensure environmental protection.

21. Research findings are available to participants in a comprehensible format.
22. Research findings are recommended to be published in prestigious scientific journals or other relevant means.
23. Having regard to the assent of the Research Ethics and Integrity Committee, researchers and research sponsors are enabled to adjust protocols or temporarily or permanently suspend research to promptly take measures aimed at the protection and well-being of participants or enhance research proposals.

Article 7

Scientific Coordinators' responsibilities

1. Throughout the research process, Scientific Coordinators are required to adhere to and monitor collaborators' compliance under general and specific provisions of current legislation, fundamental ethical and moral principles, and the guidelines outlined in the present code.
2. Research Scientific Coordinators are required to inform, in a concise yet honest manner, citizens-participants about research objectives. When obtaining the required participants' consent, they provide comprehensible information. In addition, Scientific Coordinators are obligated to inform citizens who are not participating in the research but are directly impacted by its implementation.
3. Scientific Coordinators engaged in collaborative research should not exploit research projects solely for personal promotion, or present research findings as personal accomplishments. Respect for unique individual contribution of researchers and upholding transparency and mutual communication are commitments for all research participants.
4. Research outsourcing of research parts or research assistantship assigned to third parties falls within the Scientific Coordinators' responsibilities and supervisory duties.
5. In funded projects, for which Scientific Coordinators are appointed by a University collective body, collaborators are required to be recruited by Coordinators following the procedures specified by the Funding Body, provided that there is a relevant provision addressing this requirement.
6. A substantial breach of the regulations outlined in this article by research Scientific Coordinators may be grounds for terminating a research project. The decision to terminate is made by the Research Committee, following a recommendation of the Research Ethics and Integrity Committee, issued upon receiving a relevant written and signed complaint. Prior to any recommendation of the Research Ethics and Integrity Committee, both the complainant and the research Scientific Coordinator are summoned before the committee to present their views on the complaint, either orally or in writing.

Article 8

Collaborators' responsibilities

1. Research collaborators have the privilege of freedom of thinking and expression of opinion; however, they should abide by the limitations on the freedom imposed by an organisation and follow the guidelines provided by the Scientific Coordinator supervising research.
2. Research collaborators are required to: a) conduct research aiming at advancing scientific knowledge and contributing to societal welfare, and b) adhere to statutory provisions related to research topics, observe professional ethical standards, and abide by UoWM's present Code.
3. Serious infringement of the provisions outlined in the present document by research collaborators or non-compliance with the directives of the competent parties in cases involving ethical rule violations, could entail their replacement.

Article 9

Relationships between Researchers

1. Researchers are committed to mutual respect, confidentiality, and the right to equal treatment. Experienced researchers bear the responsibility of introducing new researchers to research methodology and ethics to foster advancement of research activities. New researchers' personal integrity and fair assessment of their knowledge and skills should be duly acknowledged. Similarly, new researchers are obligated to respect and recognise expertise of more experienced

researchers.
2. Researchers' individual contribution to collaborative research should be duly acknowledged and explicitly stated, whether in public or scientific presentations. Explicit statement of this contribution, whether in public research presentations or in scientific publications, is a researcher's own right. The specific responsibility is shared by all members of the scientific team, and more specifically, research scientific coordinators.

Article 10

Compliance with Safety Regulations

1. Throughout the implementation of research activities, researchers are required to implement safety measures and, overall, adhere to safety regulations as stipulated by the overarching and specific provisions of the current legislation.
2. Researchers are obligated to undertake all necessary measures to safeguard the health of those involved in research projects, preventing accidents, and minimising potential research-related adverse effects.
3. In the event that inadequate adherence to safety regulations is induced by deficient infrastructure or insufficient equipment, research Scientific Coordinators should bring the matter to the University competent authorities.

Article 11

Promotion of Research

1. Promotion of research should be undertaken with a view to and by means of fulfilling requirements for information provision to the scientific community and the general public, instead of promoting oneself or one's profession unfairly. Promotion practices should acknowledge and cite researchers' individual contribution to research.
2. When publishing part or all research findings in print or electronic format, it is crucial to include the name of the institution where the specific research project was carried out.
3. Acknowledgment of prospective funding sources should be explicitly stated to avoid confusion about research entities, avoid promoting a specific product and convey a sense of permanent connection between sponsors and UoWM.

Article 12

Participant Selection Procedure

1. Researchers shall ensure that all research participants are protected against unintended risks, that their decision to participate is voluntary and are fully informed and, where possible, that participants and/or society stand to benefit from the knowledge acquired through the specific research. No coercive methods are used during the participants' selection process, no promises are unfulfilled, and participants' personal data are protected.
2. Research information documents shall not: a) imply a guaranteed positive outcome resulting from participation, b) promote any intervention or product as safe, effective, or superior to existing alternatives, and c) assert that participants will receive free treatment when, in effect, participation primarily serves experiment objectives rather than addressing their needs.

Article 13

Participants' Information and Consent

1. Researchers should ensure informed and voluntary consent of participants in research.
2. Informed consent entails ensuring that individuals participating in research are fully informed about various issues, such as research objectives, anticipated duration of participation, description of the procedures to be followed, potential adverse effects, the possibility of declining participation or withdrawing at any time without any consequences, post-research retention of data, and other pertinent details. Information provided to participants should be presented in a manner easy to remember, such as via interviews, video presentations, etc. In addition, informed consent should encompass a clear description of potential risks or inconveniences, as well as the anticipated benefits associated with participating in the research.
3. Informed consent should include a written participants' statement endorsing commitment to

confidentiality and privacy. It should also state that participation is voluntary, and that declining participation does not incur penalties or loss of benefits. In addition, informed consent should describe any anticipated risks or discomforts, as well as the benefits gained from participating in the research.

4. The content of the consent form should:

i. be comprehensibly stated to prospective participants.

ii. use the official spoken language of the country of origin of the prospective participants.

iii. clearly explain medical vocabulary, if any.

The consent form should include information on:

i. Research declaration
ii. Research purpose
iii. Duration of participation in research
iv. Procedures to be followed
v. Procedures under research or during experimental stages
vi. Potential risks, if any
vii. Expected benefits
viii. Alternative treatments available to the specific individual (relevant in clinical research)
ix. Personal data protection or potential disclosure
x. Adverse effects or potential harm, if risks exceed minimal, including possibility for compensation and medical treatment in the event of harm
xi. Researchers' contact details (to be used for study-related information)
xii. Certification that participation is voluntary, that refusal to participate implies no possible consequences, and participants can withdraw at any time without any repercussions.

5. Consent must be obtained from individuals capable of comprehending questions and agree. When "informed consent" is not possible, non-written consent should be endorsed with documented and witnessed evidence. "Vulnerable" individuals (prisoners, individuals with intellectual disabilities, or serious illnesses, very young children, etc.) can participate only when appropriate protective legal framework is in place (legal, medical representatives). In addition, the financial details of the research should be disclosed since financial transparency fosters ethical behaviour. Participants should not derive financial benefits from research participation.

Article 14

Data Security Measures

Researchers are required to keep a complete record of research progress and outcomes, ensuring oversight while safeguarding intellectual property rights. In clinical research, researchers are bound by the guidelines of the National Organisation for Medicines (EOF, in Greek) regarding oversight, monitoring, and control of safety-related data and incidents (e.g., reporting serious adverse events).

Article 15

Protection of Personal Data

1. Personal data processing shall imply any operation or set of operations performed upon personal data, whether by automated means or not, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise, correlation or combination, blocking, erasure, or destruction.

2. Researchers are obligated to ensure full protection of participants' personal data during processes, such as obtaining informed consent, data collection and analysis; they should also uphold confidentiality with regard to participants' personal data. During the research protocol design, researchers are required to assess the extent to which personal data disclosure may inflict on participants' social or family standing, employment prospects, insurance coverage, or even their personal legal status.

3.Participants shall be able to decide how and when their personal data will be used or disclosed. For post-research retention, the consent form should provide justification for the extended

retention period.
4. In all instances, personal data collection is subject to relevant legislation. Researchers are required to adhere to ensuring confidentiality of participants' data (e.g., encoding, secure data storage, monitoring access to the data, and the elimination of identifiers during analysis or disclosure of research outcomes).
5. When exclusively disclosing anonymous data, it is vital that robust security measures evidence be demonstrated in terms of data management and storage.

Article 16

Clinical Research

1. Researchers should adhere to the principles of clinical studies, as detailed in the relevant statutory provisions and codes of ethics. General principles of particular concern involve those related to informed consent, the protection of children and vulnerable groups as well as protection of personal data collected and are subject to processing.

Article 17

Research on Vulnerable Groups

1. In research involving vulnerable group individuals (e.g., children, pregnant women, prisoners, individuals with mental health problems, and other disabilities), particular measures are implemented to protect their rights, and under no circumstances are they forced to participate in research. In instances of legal incapacity, written consent is provided by legal representatives, and, in parallel, verbal consent is obtained from participants.

Article 18

Submission of Proposals

1. Proposals (applications and attached documents) are submitted online by the research Scientific Supervisor on the University website. Following submission, applications and attached documents may be submitted to the University Research Committee to be forwarded to the National Ethics Committee for approval. Proposals are submitted by research Supervisors to the National Ethics Committee for approval upon receiving positive funding response from funding agencies.
2. Upon submission for approval to the National Ethics Committee, research project proposals should include a questionnaire and brief report assessing appropriateness of and compliance with current legislation. The specific reports, written by Scientific Supervisors specify whether research purpose and methodology are compliant with ethical principles and legal requirements.
3. The Research Ethics and Integrity Committee approves the purpose and methodology (protocol, execution process, and data collection) of research projects submitted for publication, upon request of those interested. The primary criterion for approval is the degree of compatibility with ethical principles and the stipulations of national and international legislation.
4. The Research Ethics and Integrity Committee (REIC) may oversee and control compliance with the code of research ethics after the start and upon completion or termination of the research. It establishes and updates the website of the University of Macedonia to inform university members about the fundamental principles and rules of research ethics. The committee is also responsible for creating and regularly updating UoWM's website to communicate fundamental principles and regulations of research ethics to university members.
5. Applications and attached documents may be submitted online by the research Scientific Supervisor on UoWM's website. The specific applications and attached documents may be submitted to the University Research Committee to be forwarded to REIC.
6. REIC Chair appoints a rapporteur for each submitted application, preferably a REIC member, depending on the topic of research projects. In cases when REIC members lack expertise in the specific subject, an external expert is appointed to provide an opinion.

Article 19

Research Ethics and Integrity Committee Operation

1. REIC holds regular meetings once (1) a month and whenever requested by REIC's or UoWM's Research Committee Chair, who may also convene extra sessions.
2. REIC may hold meetings by teleconferencing.

3. REIC's Chair is engaged in ensuring smooth operation of the Committee and is responsible for convening and overseeing meetings.
4. REIC meetings shall be quorate when at least three (3) members are present, including the Chair or Deputy Chair, and one member not affiliated with the University of Western Macedonia; decisions are made by a majority vote among attendees.
5. Members' participation in REIC meetings does not entail compensation or any other remuneration.

Article 20

Incompatibilities – Conflict of Interest

1. Holding a membership in REIC is incompatible for:

A) Rectors, Vice Rectors, Deans, as well as University Research Committee members or Department Heads.

B) Chairs and members of the Board of the Research and Technology Centre or Institute and the Greek Statistical Institute, Law 4310/2014, Article 13a.

2. REIC members are disqualified from participating in meetings in any case where a conflict of interest may arise. A conflict of interest arises when a member's personal interest could influence or appear to influence impartial and disinterested performance of duties. Such is considered any possible advantage in favour of oneself, one's spouse, or first-degree relatives. In case of declaring such a disqualification related to a specific proposal under evaluation, members declaring disqualification are replaced by deputies.
3. REIC members, rapporteurs, and any member carrying out support duties are required to uphold confidentiality of information and details provided to the Committee about the research proposals under evaluation.

Article 21

Transitional (Overarching) Provisions

1. REIC is established by research entities upon Rector or Board Chair's decision, within six (6) months after the entry into force of Law 4521/2018. If a Research Ethics and Integrity Committee, bioethics committee or similar research collaborative body have already been established, they shall, within the specific time frame, amend the respective decisions, in accordance with the provisions of Law 4521/2018.
2. The Regulation on REIC's principles and operation is drawn up in accordance with the funding directive of Law 4485/2017, Article 68. The specific regulation provides details of the documents submitted by Scientific Coordinators, such as application, questionnaire, suitability report, and submission procedures, REIC's operation methodology and decision-making processes, and other pertinent issues related to REIC's functions.