

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ Εδνικόν και Καποδιστριακόν Πανεπιστήμιον Αδηνών

— ΙΔΡΥΘΕΝ ΤΟ 1837 –



Appendix A15

Code of Ethics for Research of the Master's Program

"MSc in Women's Health"

REGULATIONS FOR THE PRINCIPLES AND OPERATION OF THE ETHICS AND DEONTOLOGY COMMITTEE OF RESEARCH OF EKPA Law 4521/2018 (Articles 21-27), as replaced by Law 4957/2022 (Articles 277-282)





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ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ Εдνικόν και Καποδιστριακόν Πανεπιστήμιον Αδηνών - IAPYOEN TO 1837

CHAPTER A ESTABLISHMENT - ADMINISTRATIVE BODIES OF THE RESEARCH ETHICS COMMITTEE (R.E.C.) Article 1 Establishment – Purpose

The Research Ethics Committee (R.E.C.) of the National and Kapodistrian University of Athens (N.K.U.A.) is established and operates in accordance with the provisions of Articles 21 to 28 of Law 4521/2018, which were replaced by Articles 277-282 of Law 4957/2022.

The mission of the R.E.C. is to provide an ethical and deontological guarantee of the reliability of research projects conducted at the National and Kapodistrian University of Athens. The R.E.C. ensures that a research project, beyond scientific adequacy, is carried out with respect for the value of human beings, health, the autonomy of the individuals involved, their privacy, and personal data, adherence to principles of equality and non-discrimination, the protection of intellectual property, and care for the natural and cultural environment.

The Committee also checks adherence to generally accepted principles of research integrity and criteria of good scientific practice. The review of the ethics and deontology of research is an essential guarantee of reliability and quality, contributing to excellence and is a prerequisite for enhancing public trust and acceptance of research conducted at N.K.U.A. The R.E.C. is distinct from the Ethics Committee of the National and Kapodistrian University of Athens, as established in Article 47 of Law 4485/2017 "Organization and operation of higher education, regulations for research, and other provisions."

Members of N.K.U.A. and external collaborators are required to comply with the law, this Research Ethics and Deontology Regulation when conducting research. N.K.U.A. members are also bound by the University's Internal Regulations, Code of Ethics and Good Practice, especially concerning the rules of the School or Department to which they belong.

Article 2

Composition - Term of Office

1. The R.E.C. of N.K.U.A. consists of seven (7) regular members and their alternates. The members must be scientists specialized in research, ethics/bioethics, and research deontology, covering, as much as possible, one or more of N.K.U.A.'s scientific fields.

Five (5) of the members – and their alternates – should be faculty members of N.K.U.A., preferably Professors or Associate Professors, as well as Emeritus Professors of N.K.U.A.

Two (2) of the members – and their alternates – should be individuals outside N.K.U.A. For these external members, candidates may include Emeritus Professors from other Greek or foreign universities and researchers from Research Centers, preferably at the A' or B' level.

At least one (1) of the seven members – and their alternate – must specialize in ethics/bioethics.

2. The members of the R.E.C. are selected as follows:

a. The Research and Management Committee of the Special Research Fund publishes a call for interest to fill the positions no later than three (3) months before the end of the term of each member. The call specifies the exact number of R.E.C. members and the qualifications required. Candidates and necessary documents are submitted electronically.

b. The Research and Management Committee evaluates the applications and decides on the composition of the R.E.C. The following factors are considered:

- The experience of candidates in implementing and managing projects as Scientific Supervisors.
- Participation in collective bodies at the national and international level with the purpose of decision-making or providing advisory opinions on ethics, bioethics, and research deontology.
- Scholarly work related to ethics, bioethics, or research deontology and relevant teaching.
- Representation of the disciplines of the nine Schools of the Institution in the composition of the R.E.C.
- Formation of the final composition of the R.E.C. ensuring an interdisciplinary approach and thorough examination of the ethical, deontological, and legal issues arising in research, and representation of both genders and various age groups.
- 3. The R.E.C. is constituted by the decision of the Rector of N.K.U.A. The decision designates the Chairperson and Vice-Chairperson of the Committee, as well as the alternate member for each regular member.
- 4. Each member of the R.E.C. must be familiar with Greek legislation, the N.K.U.A. regulations, the principles of research ethics and deontology, and the principles of scientific integrity defined by the European Union, international regulatory texts, and must not have been convicted of violating the rights of participants or any infringement of scientific integrity principles (e.g., plagiarism, data falsification), nor for any violation of laboratory animal welfare.
- 5. The term of office of R.E.C. members is three years and can be renewed only once.
- 6. If a member of the R.E.C. resigns or their term ends for any other reason, they are replaced by their alternate for the remainder of their term.

Article 3

Incompatibilities - Conflict of Interest

- 1. The position of R.E.C. member is incompatible with the positions of Rector, Vice-Rector, Dean, and member of the Research and Management Committee or Department Chair of N.K.U.A.
- 2. A member of the R.E.C. is prohibited from participating in any meeting if there is a potential conflict of interest. A conflict of interest arises when a member has an interest (financial, personal, or otherwise) that could affect or appear to affect their impartial and objective performance of their duties. This includes any potential advantage for the member, their spouse, or a first or second-degree relative by blood or marriage. In case of such a conflict regarding a specific proposal under review, the member immediately informs the Chairperson, who arranges for their replacement by an alternate. The member must leave the meeting before the discussion begins. All statements or other issues affecting the impartiality of the member are recorded in the meeting minutes.

Article 4

Confidentiality Obligation

- 1. The members of the R.E.C. are required to maintain strict confidentiality regarding any information obtained during the performance of their duties. This obligation also applies to any external expert or advisor invited to provide opinions or recommendations on a specific research protocol.
- 2. The confidentiality obligation extends to the Committee's Secretary and any involved member performing supportive tasks. The disclosure of confidential information or personal data accessible to these individuals due to their duties is prohibited.
- 3. The confidentiality obligation also applies to the content of discussions between R.E.C. members, which are necessary for evaluating protocols and making final decisions.



CHAPTER B RESPONSIBILITIES – EVALUATION & APPROVAL PROCEDURES

Article 5: Responsibilities

1. The responsibility of the E.H.D.E. (Ethics and Research Committee) is to verify if a specific research project to be carried out at the National and Kapodistrian University of Athens (E.K.P.A.) complies with the applicable legislation and aligns with widely accepted research ethics and integrity standards in terms of its content and methodology. Specifically, the responsibilities of the E.H.D.E. include:

a) Examining funded research projects, which, as declared by the scientific supervisor, involve research on humans, human-derived materials such as genetic material, cells, tissues, and personal data, research on animals, or on the natural and cultural environment, which must be submitted for approval to the E.H.D.E. before implementation. The project cannot begin at E.K.P.A. without prior approval from the Committee.

b) Examining, beyond the research projects mentioned in paragraph a, any other research project following a request from an interested party or a complaint.

c) Providing an opinion on ethics and deontology for articles intended for publication in scientific journals or for ongoing thesis or doctoral dissertations.

d) Monitoring proposed changes to already approved and ongoing research.

e) Ensuring the protection of individuals when processing their personal data arising from relevant research, in collaboration with the designated DPO (Data Protection Officer).

2. The E.H.D.E. verifies the receipt of approvals from the competent authorities, if required, checks compliance with ethical, deontological, and legal frameworks, and has the authority to conduct inspections even after approval, throughout the progression of the research until its completion, providing recommendations for ethically and deontologically sound execution.

- 3. The E.H.D.E. may, before approving the protocol, provide feedback on ethical and deontological matters and request the resubmission of the protocol. It may also recommend to the Research and Management Committee of E.L.K.E. the suspension of an ongoing research project if there is a violation of the law or this Regulation.
- 4. The E.H.D.E. may offer scientific opinions or recommendations to the Research Committee of E.L.K.E., if requested.
- 5. If the legislation requires approval or licensing of a research project by another competent public service, administrative body, or independent administrative authority, the relevant decision of the E.H.D.E. does not replace such approval or licensing.
- 6. The E.H.D.E. seeks to inform and raise awareness among the scientific and administrative staff and students of the National and Kapodistrian University of Athens on ethical and deontological issues in research through lectures, seminars, and the publication of informational materials and any other suitable means.
- 7. The E.H.D.E. collaborates with the National Bioethics Committee and corresponding committees in Greece and abroad, representing E.K.P.A. in these organizations.
- 8. The E.H.D.E. provides opinions on any research conducted at E.K.P.A., if no other competent authority exists.
- 9. The E.H.D.E. submits an annual report to the Research and Management Committee of E.L.K.E.
- 10. The decisions of the E.H.D.E. are binding for E.K.P.A.

Article 6: Scope of E.H.D.E. Review

The E.H.D.E.'s review primarily concerns issues related to:
a) Compliance with the ethical, deontological, and legal research frameworks as specifically defined in the law and the

E.K.P.A. Code of Ethics and Deontology of Research.

b) Ensuring that no pressure or undue influence, including financial, is applied to research participants to encourage participation. The E.H.D.E. pays particular attention to research involving vulnerable or dependent individuals or groups.

c) Verifying that the written information provided to potential research participants (or their legal representatives) is clear and understandable, and assessing the process for obtaining their consent, or the consent of legal representatives for those incapable of consenting. This includes justifying the involvement of children, minors, or legally incapable individuals in research.

d) Ensuring free and voluntary consent of participants or their legal representatives. The Committee approves the consent form, ensuring it includes required elements according to the Code of Ethics and Deontology of Research, based on the type of proposed research. If new information arises during the research, the consent form must be appropriately modified and resubmitted for approval.

e) Ensuring respect for the physical and mental integrity of participants, their right to privacy, protection of personal data, and confidentiality.

f) Verifying the voluntary nature of participation and the methods of participant selection and inclusion.

g) Assessing the individual and social impacts of the research.

h) Ensuring compliance with animal protection and ethical treatment principles in animal-based research.

i) Ensuring adherence to rules regarding the protection of cultural and natural environments, as well as waste management.

- 2. The Committee evaluates whether the risks to the individual or group participating in the research, and the resulting harm or discomfort, are proportionate to the potential benefit of the research. Risks, harm, or discomfort may include physical, psychological, or social factors. If the research offers no immediate benefit to participants, the E.H.D.E. ensures that risks and harm are minimized.
- The E.H.D.E. examines the impact of the proposed research on the local community, particularly on the communities from which participants are drawn. It assesses whether participation or the dissemination of research results might create or exacerbate vulnerability, social marginalization, stigmatization, prejudice, or other negative social distinctions.
- 4. The E.H.D.E. examines how the results will be communicated to the relevant community and participants. In cases where risks to participants are identified, the Committee evaluates the measures proposed by the researcher to minimize the negative consequences of participation and the dissemination of results.
- 5. The E.H.D.E. considers and suggests improvements, when necessary, on aspects related to: (a) The characteristics of the participant population, including gender, age, education, economic status, nationality, and cultural background,
 - (b) How participants are approached,
 - (c) How participants are informed,
 - (d) The criteria for participant inclusion and exclusion,
 - (e) The methods for disseminating and communicating research results.

Article 7: Submission and Receipt of Applications

- 1. Applications and supporting documents must be submitted electronically by the Scientific Supervisor (S.S.) of the project to the address: resethic@uoa.gr, through the E.K.P.A. website. In the case of theses or doctoral dissertations, the application must be signed by the supervising professor.
- 2. The Secretary of the E.H.D.E. confirms receipt of the application, after verifying the completeness of the submitted documents and registering them.

- 3. The members of the E.H.D.E. (Ethics and Deontology Committee), upon receiving the application, must inform the President and the Secretary if there is any conflict of interest that prevents their participation in the evaluation.
- 4. The President of the E.H.D.E. designates a rapporteur for each application submitted, preferably a member of the E.H.D.E., depending on the scientific subject of the research project. If the scientific field of the project cannot be covered by the members of the E.H.D.E., an external expert is appointed, who reports to the E.H.D.E. in writing.

General Procedure for Approval of Research Protocol

For the approval of a research project, each submitted application must include the following documents:

 The completed application form to the E.H.D.E. for the approval of the research protocol, which must include a reference table/questionnaire and a summary report regarding the suitability and compatibility of the research project with the applicable legislation. In this report, the scientific supervisor specifies whether the purpose and methodology of the research project comply with the principles of scientific integrity, research ethics and deontology, and the law. The application must also include a statement from the researcher acknowledging the Research Ethics Code of the University of Athens and committing to adhere to it (Supporting Form 1).

II. A summary (maximum three lines) of the research content and the name of the responsible person. III. The research protocol.

IV. A sample informed consent form for the participants in the study, which includes their prior information and consent (if required).

V. Any other document or supporting material related to the study.

2. Research funding by private entities related to the commercial exploitation of research results (such as pharmaceutical companies or companies producing or marketing mechanical or other types of equipment) is allowed, provided that a written acceptance of the Research Ethics Code of the National and Kapodistrian University of Athens by the company is also submitted to the E.H.D.E., which governs the research activities.

Article 9

Approval Process for Research Protocol in Human Studies

Specifically, for the approval of a research protocol related to a study involving humans, the following process is followed, subject to the provision of Article 100 of Law 4692/2020.

Research involving humans must be conducted with absolute respect for bioethics, and their physical and mental integrity. Researchers are committed, in addition to the law, to the generally recognized principles of human dignity, protection of fundamental rights, freedom and equality, public health protection, protection of children and vulnerable groups, and personal data protection.

A. For all research activities involving human participants (e.g., healthy subjects from the general population, students, patient groups outside hospitals) conducted under the responsibility of scientific staff at the National and Kapodistrian University of Athens, the following are required:

I. Application to the E.H.D.E. for the approval of the research protocol, with all the necessary accompanying forms (see Article 8.I - Supporting Form 1).

II. The research protocol.

III. A sample informed consent form for participants in the research, which includes their prior detailed, complete, and clear information and consent (Consent Form).

B. For research involving human embryos:

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I. Application to the E.H.D.E. for the approval of the research protocol, with all necessary accompanying forms (see Article 5.1.I - Supporting Form 1).

II. The research protocol.

III. A sample informed consent form for the donors, which includes their prior information and consent.

IV. A declaration from the researcher regarding previous similar research on animal models, unless this is not scientifically feasible.

V. Approval from the E.H.D.E.

VI. Authorization from the National Bioethics Committee.

C. The consent form for research involving the processing of personal data of participating subjects requires complete written information, which must include the following:

(I)

- The details of the data controller and the data protection officer.
- The purposes of the data processing.
- Explicit mention that the participant's data will only be processed for the aforementioned purposes.
- The types of data that are strictly necessary for the purposes of the processing. If special categories of personal data (health data, genetic or biometric data, data related to religion, political or trade union beliefs, etc.) are to be collected, this must be specifically stated.
- A description of the precise use of the data. If a profile is to be created, this should be specifically mentioned.
- A clear commitment that no other recipients will receive the participant's data (or, if any, who they are).
- A reference to the duration for which personal data will be retained (specified clearly and noting that it will be deleted afterward, or that if this is not the case, the subject's consent will be requested again, and if not given, the data will be deleted immediately).
- That the participant can refuse their consent or withdraw it at any time.
- That the participant has the right to exercise their rights to access, deletion, or correction of the data, and the right to lodge a complaint with the Personal Data Protection Authority.

(II)

The consent of the participant in research must be in writing or meet the conditions set by law and this Code of Ethics and Deontology of Research. The consent form must explicitly state that the participant, or their legal representative in the case of minors or individuals lacking legal capacity, may withdraw their consent at any time without consequence. The participant must be able to withdraw their consent at any time.

D. Other

For conducting a research protocol on a corpse, consent from the next of kin is required.

For potential research involving prisoners, researchers must comply with the special provisions of the Penal Code, while also considering the guidelines of the Forensic Code of Ethics. The Committee checks whether the proposed research aims to find interrogation methods that could endanger the physical or mental health of the prisoners or diminish their moral integrity and human dignity, in which case the research is excluded.

Article 10





Special Cases

Special research, which must be conducted according to Greek and European legislation following international and European treaties, includes, in particular, the following:

A. Environmental Health and Safety, Environmental Protection, and Biodiversity

Research must take into account and minimize potential environmental risks. Specifically, based on the constitutionally guaranteed principle of sustainability, compliance with laws enacted for environmental protection, including waste management, must be ensured. Additionally, compliance with laws protecting biodiversity and endangered species must be ensured. Researchers must include in the research protocol information on potential environmental risks and plans for minimizing them.



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Research on Genetically Modified Organisms (GMOs) and Genetically Modified Products (GMPs) is conducted in specially designed laboratories/facilities that meet the appropriate specifications. The research protocol must contain information regarding the potential harm to the environment and humans, as well as the measures taken to address or mitigate such risks.

Research on genetically modified organisms and microorganisms must be conducted in accordance with the applicable legislation [by way of example and not limited to, the provisions of Community Directive 2001/18, as incorporated into Greek legislation by Ministerial Decision 38639/2017, and those of Community Directive 1998/81, concerning the limited use of genetically modified microorganisms, as incorporated into Greek legislation by Ministerial Decision HΠ/11648/1943/2002].

For the use, movement, and disposal of radioactive substances, special permission from the Hellenic Atomic Energy Commission (EEAE) is required, in accordance with the relevant applicable provisions (by way of example and not limited to: Laws 1733/1987, 2480/1997, Decree 854/1971, Presidential Decree 22/1997).

In the case of using ionizing or non-ionizing radiation, specific protective measures must be taken for both researchers and the general population, in accordance with the applicable legislation.

No research justifies harm to the environment in violation of laws established for its protection, as well as for waste management.

B. Protection of Intangible and Tangible Cultural Heritage

No research activity justifies harm to intangible or tangible cultural heritage in violation of the provisions of the applicable legislation.

C. Dual-Use Research (Civilian, Military)

In cases of research proposals with potential dual-use, whether civilian or military, or proposals submitted to military organizations, a clear reference must be made to non-civilian uses. The need for conducting such research must be adequately documented, as well as the appropriate special handling for the publication of sensitive research results or the need for complete concealment.

Article 11 **Approval Process for Research Protocols in Animal Studies**

For projects involving experiments using animals or animal models, approval from the relevant School or Department is required. The E.H.D.E. will accept the documented recommendation from the relevant School or Department.

Research involving animals is governed by the rules described in national legislation, incorporating Directive 2010/63/EU, and supplemented by the interpretative circular 2215/117550/2013 from the General Directorate of Veterinary Affairs of the Ministry of Rural Development on the protection of animals used for scientific purposes.

• In the case where the research involves administering drugs to animals (preclinical studies), researchers must apply the Good Laboratory Practice (GLP) guidelines (Directives 2004/9/EC & 2004/10/EC, OECD Principles of GLP), where applicable. Medical studies and studies on experimental animals are carried out according to the existing regulations (according to the Internal Operating Regulations of the University of Athens). The decision of the E.H.D.E. does not replace the licensing required by Decree 56/2013.

Chapter C Operations and Decisions of the E.H.D.E. Article 12 Operation of the E.H.D.E.

1. The E.H.D.E. of the University of Athens meets regularly once a month and exceptionally whenever requested by its President or the President of the Research and Management Committee of the ELKE. It may, following a decision, meet in subcommittees in accordance with paragraph 3 of this article.

2. The President of the E.H.D.E. is responsible for the smooth operation of the Committee and convenes and leads its meetings. In case of obstruction, the Vice-President substitutes for the President in all duties and may also perform any additional tasks assigned by the President.

3. The E.H.D.E. is quorate when at least four (4) members are present, including the President or Vice-President, and one member not belonging to the University of Athens.

4. In case of an obstacle to the participation of a regular member of the Committee, the Secretariat must notify the alternate member.

5. The meetings of the E.H.D.E. may be held remotely through electronic means.

6. E.H.D.E. members are not entitled to any payment or compensation for their participation in the meetings.

7. For the facilitation of its work, the E.H.D.E. may cooperate with the National Bioethics Committee and any other competent authority on issues related to its responsibilities.

Article 13

Consultation and Decision-Making

1. The President may appoint one of the Committee members as the rapporteur for a specific research proposal. The rapporteur must submit their recommendation electronically within seven (7) days of receiving the proposal.

2. If the Committee deems it necessary, it may invite the responsible researcher to present the research protocol or provide clarifications.

3. The E.H.D.E. may invite external experts to give their opinion on the reviewed protocol. When relevant, specialized scientists may be invited to provide expert opinions on the subject matter.

4. The E.H.D.E. makes its decision within a reasonable timeframe, not exceeding fifteen (15) working days from the submission of the application and the collection of all required documents. If the deadline of fifteen (15) working days is exceeded, the application is considered approved. The decision is made in the absence of invited individuals and

only if the researcher has submitted all necessary documentation. The recommendations and decisions must be substantiated.

- 5. In the case of a complaint, the E.H.D.E. makes a decision within a maximum of fifteen (15) working days from the submission of the complaint and notifies the Research and Management Committee of the ELKE. If a decision is not made within this period, the complaint is considered rejected.
- 6. The decisions of the E.H.D.E. are made by the majority of the present members after an attempt to reach consensus. In case of a tie, the President's vote prevails.
- 7. Voting is open, except for decisions concerning the disqualification of Committee members, which are confidential.

Article 14 Discussion and Evaluation of E.H.D.E. Working Methods

- 1. The President may periodically schedule a meeting dedicated to discussing and evaluating the work and methods of the Committee. During this, members are encouraged to express concerns and suggest ways to improve the Committee's work.
- 2. Meetings may also be held upon request from the E.H.D.E. members.
- 3. External experts or members of other Ethics and Research Ethics Committees of the country, or other specialized scientists, may participate in the meetings.

Notification of decisions

- 1. The interested party is notified in writing about the decision within three (3) working days from the meeting, and a copy of the decision is sent to them.
- 2. The decision includes:

a) the name and title of the responsible researcher,

b) the exact title of the protocol that was examined,

c) the exact version of the protocol or any potential modifications upon which the decision was based,

- d) the accompanying documents that were examined (e.g., informational material, consent form),
- e) the date of the decision,

f) in the case of a conditional decision, all requested modifications and the procedure for re-examining the protocol,

g) in the case of a positive decision, a list of possible obligations of the researcher, e.g., submission of periodic or one-time reports, need for informing the Committee about possible future necessary protocol modifications, reporting of serious or adverse or unexpected events during the research,

h) in the case of a response for revision or modification, a full justification,

i) the date and signature of the President or, in their absence, the Vice-President of the Ethics Committee (E.H.D.E.).

Article 16

Submission of appeal application

Any interested party may submit an appeal to the Ethics Committee (E.H.D.E.) within ten (10) days from the issuance of the decision, by providing new evidence. For the review of the appeal application, the E.H.D.E. requests the opinion of the National Bioethics Committee, which must be provided within fifteen (15) days. If the National Bioethics Committee does not provide an opinion within the specified period, the E.H.D.E. proceeds with the examination of the appeal without the opinion of the National Bioethics Committee.

Article 17

Monitoring of the research protocol

 During the research and depending on its subject, the Committee has the discretion to request from the responsible researcher periodic or one-time reports on issues related to compliance with ethical and deontological frameworks, as well as the following data:

a) the number of participants,

b) any unforeseen problems that arose, including information on any accidents and how they were handled, c) the departure of participants.

- If the E.H.D.E. determines that a specific research, either due to its content or its conduct, violates the law, generally accepted ethical and deontological principles, or the provisions of the Code of Ethics and Deontology of Research of the University of Athens (E.K.P.A.), it will make observations and recommendations to the researcher for compliance.
- 3. If the responsible researcher does not submit the above information to the Committee, the Committee informs them about the possible decision to suspend the research, notifying the Research Committee and the Management of the National and Kapodistrian University of Athens.

Suspension of the research protocol

- In the course of examining the research protocols or later, the E.H.D.E. may propose changes to the protocol, even if the research is ongoing, or suspend the research if there is a reason related to the ethics and deontology of the research.
- 2. The E.H.D.E. may recommend to the Research Committee the suspension of the research if it finds, following a written and signed complaint, that the research deviates from the E.H.D.E.'s guidelines or has resulted in unforeseen serious consequences for the participants or laboratory animals. The decision to suspend the research is made by the Research Committee, is fully justified, and is communicated to the responsible researcher and the Faculty and Department conducting the research.
- 3. Before making any recommendation, both the complainant and the responsible researcher are invited to present their views orally or in writing concerning the complaint.

Chapter D

Miscellaneous Provisions

Article 19

Recordkeeping - Secretariat

- 1. The E.H.D.E. is required to maintain an electronic file with the following documents:
 - a) Protocol of incoming and outgoing correspondence,
 - b) The curriculum vitae of the Committee members,
 - c) Minutes of meetings and agendas, managed by the E.H.D.E. secretary,
 - d) Applications submitted for approval and the corresponding justified decisions,
 - e) Approved research protocols and the accompanying documents,

f) Copies of correspondence between the E.H.D.E. and the responsible researchers, including any recommendations to the researcher and any documents related to the suspension of approved research.

- The collection, processing, and maintenance of personal data are carried out in accordance with the applicable personal data protection laws, with emphasis on the security principles of processing and storage systems.
- 3. The Secretariat maintains a separate electronic protocol and the E.H.D.E. file, which is secured in accordance with the provisions for the security of the electronic records of the University of Athens. The files are maintained electronically in a secure manner for at least three years after the completion of the research program unless specified otherwise by the funder. The storage conditions must ensure the protection of confidentiality.
- 4. The Secretariat must treat and handle as confidential all information and documents related to the requests referred to it and must not disclose the information or documents to third parties.
- The E.H.D.E. is provided with appropriate space and modern computing equipment by the University of Athens for managing all information produced by the Committee. The related expenses are covered by the University's budget.

Article 20

Destruction of records

1. After the expiration of the period defined above in Article 19, and following a decision by the Committee, the following documents will be destroyed:

- Applications submitted for approval
- Approved research protocols and accompanying documents
- Copies of correspondence between the Committee and responsible researchers, including any recommendations to the researcher and any documents related to the suspension or termination of approved research.
- 2. The destruction of digital records is governed by the provisions of Presidential Decree 25/2014 (Government Gazette 44/A/25.02.2014) "Electronic Archive and Digitization of Documents," Article 11 "Clearing and Destruction of Printed and Electronic Documents."
- 3. The following will not be destroyed and will be kept:
 - Minutes of meetings and approval decisions of the E.H.D.E.
 - The curriculum vitae of the Committee members.

4. Finally, a destruction protocol is maintained, and for this reason, the E.H.D.E. (Ethics and Deontology Committee) recommends the destruction of records.

CHAPTER E RELATIONS BETWEEN RESEARCHERS AND THE UNIVERSITY OF ATHENS (E.K.P.A.)

Article 21

They must maintain complete records for the progress and results of a program, ensuring that control is possible while simultaneously safeguarding intellectual property rights in all cases.

Researchers conducting research at E.K.P.A., who manage research programs, must take all necessary and mandatory scientific measures to protect the health of workers in the programs from accidents or other side effects that may arise under the special conditions of the research.

They must adhere to the general and specific safety rules of E.K.P.A. in research areas.

All researchers at E.K.P.A. are personally responsible for actions or omissions related to the compliance with this Regulation, the applicable national, European, and international legislation, and international declarations and conventions. Specifically, researchers must:

a. Obtain written consent from all individuals participating in the research or from their legal representatives, after fully and clearly informing them of the content and objectives of the research. This consent cannot be the result of coercion or deception and can be withdrawn at any stage of the research. Exceptionally, when prior full or absolutely clear information about the objectives of the research may affect its validity, written consent may follow the completion of the research and refer to the use of the research data. In cases where written consent is not required, such as in research with anonymous questionnaires, only the information sheet and other related materials are provided to the participants. The obligation to inform also includes individuals not directly involved in the research but affected by its conduct.

b. Ensure the protection of the personal data of participants in the research according to the applicable legislation, applying commonly accepted anonymization-pseudonymization practices.

c. Maintain complete records of the progress and results of their research activities for a period of ten (10) years.

d. Ensure, according to current practices, the selection of research participants in a manner consistent with the principles of equal treatment and impartiality, in conjunction with the sampling criteria dictated by the research objectives.

e. Adhere to the principle of impartiality.

f. Not conceal or alter the results of their research (duty of scientific truth).

g. Participate and cooperate in every quality control and assurance process conducted by E.K.P.A. or other public authorities.

h. Follow general and specific safety and hygiene rules in all E.K.P.A. facilities or any other research or project location where their research is conducted.

i. Adhere to principles of sound, transparent, and effective financial management.

j. Not accept terms during the conclusion of funding agreements that compromise their freedom and integrity, or the credibility and interests of E.K.P.A. regarding the design, conduct, and publication of their research.

k. Respect the specific ethical principles and the code of conduct in each field of the sciences (both positive and humanistic).

I. Continuously update themselves on developments regarding ethical principles and codes of conduct that govern the scientific field in which they specialize.

m. Report any conflicts of personal, professional, or financial interest that preexist the commencement of the research or arise during its execution.

n. Adhere to ethical and deontological commitments concerning their fields [this applies to specific categories of researchers (doctors, lawyers, psychologists, etc.)].

In any case of violation of the above, researchers will be subject to scrutiny according to the applicable national and European legislation and the provisions of the Internal Regulations of E.K.P.A.

Regarding the relations between researchers, the following apply:

a. Researchers must respect each other, and the contribution of each person to the final result should be duly recognized according to intellectual property law. Specifically, for publications, the order of co-authors is determined by agreement among the participants, considering that the participation and position in the authorship group is based on significant contribution to the research design, data acquisition, or analysis and interpretation of results.

b. The project leaders of research projects must be fully consistent with their obligations to the Research and Management Committee of E.L.K.E. and other involved entities, ensuring that members of their research team comply with this Regulation.

c. The project leaders may replace researchers who participate in the project if they violate this Regulation or fail to adequately execute their tasks.

d. In case of violation of the above principles, all those involved in the research process must immediately contact the competent university authorities, as specified in the Internal Regulations of E.K.P.A., reporting the violations.

Signs, websites, announcements, and general means of promoting research programs should be designed and used in a way that serves to inform the scientific community and any interested parties, without creating false expectations regarding the use of their results or providing misleading information of any kind about them. The mention of potential sponsors in activities, websites, or printed materials of the research teams should be done with care, so that there is no confusion about the agency conducting the research, no perception of advertising specific products, and no impression of a permanent connection between the sponsor and E.K.P.A.

Signs, websites, and all types of promotional materials for the programs must mention all contributors to the research.

In any publication of the research results, presentation at conferences, or any form of public disclosure, the connection of the researchers with E.K.P.A. should be noted, and its official seals and logos should be used.



Revision and Amendment of Regulation Articles

This Regulation on the Ethics and Deontology of Research of the Special Research Fund of E.K.P.A. is subject to modification based on a proposal from the E.H.D.E. The proposed changes are approved, following a recommendation from the E.H.D.E., by the Research Committee of E.L.K.E., provided that they have the support of 2/3 of its members, and are then sent to the Senate for approval.

Article 23

Clarification

It is not within the duties of the Ethics and Deontology Committee of Research to examine issues of ethics between the members of the academic staff or students of E.K.P.A.

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