

**REGULATION OF PRINCIPLES AND OPERATION OF THE
RESEARCH ETHICS COMMITTEE OF THE NATIONAL AND
KAPODISTRIAN UNIVERSITY OF ATHENS**

LAW 4521/2018 (articles 21-27)

CONTENTS

CHAPTER A	4
ESTABLISHMENT - GOVERNING BODIES OF THE E.I.D.E.	4
Article 1 Recommendation – purpose.....	4
Article 2 Composition - Tenure.....	4
Article 3 Incompatibilities - Conflict of interest	5
Article 4 Obligation of confidentiality	6
CHAPTER B	6
RESPONSIBILITIES – EVALUATION & APPROVAL PROCEDURES	6
Article 5 Responsibilities	6
Article 6 Object of control of the E.I.D.E	7
Article 7 Submission and receipt of applications	8
Article 8 General procedure for the adoption of a research protocol	9
Article 9 Procedure for approval of research protocol in human studies	9
Article 10 Special cases	11
Article 11 Procedure for the adoption of a research protocol in animal studies	12
CHAPTER C	13
OPERATION AND DECISIONS OF THE E.I.D.E..	13
Article 12 Operation of the E.I.D.E.....	13
Article 13 Consultation and decision-making	14
Article 14 Discussion and evaluation of working methods of the REC	14
Article 15 Notification of decisions	14
Article 16 Submit a request for treatment	15
Article 17 Research protocol monitoring.....	15
Article 18 Suspension of the research protocol	15
CHAPTER D	16
OTHER PROVISIONS	16
Article 19 Record keeping - Secretariat	16
Article 20 File corruption	16

CHAPTER E	17
RELATIONS BETWEEN RESEARCHERS AND NKUA	17
Article 21	17
Article 22 Revision and amendment of Rules of Procedure	19
Article 23 Clarification	19

CHAPTER A

ESTABLISHMENT - GOVERNING BODIES OF E.I.D.E.

Article 1

Recommendation – purpose

The Research Ethics Committee of the National and Kapodistrian University of Athens (EKPA) is established and operates in accordance with the provisions of articles 21 to 28 of Law 4521/2018.

The mission of REC is to provide, on an ethical and ethical level, a guarantee of reliability of research projects carried out at the National and Kapodistrian University of Athens. The REC checks whether a research project, in addition to scientific competence, is carried out with respect for the value of human beings, health, autonomy of the persons involved, their privacy and personal data, compliance with the principles of equality and non-discrimination, protection of intellectual property as well as care for the natural and cultural environment.

Article 2

Composition – Tenure

1. The E.I.D.E. of EKPA consists of seven (7) regular members with their alternates. Members must be scientists, specialized in research, ethics / bioethics and research ethics and cover as far as possible one or more of the scientific-cognitive fields of the National and Kapodistrian University of Athens.

Five (5) of the members – and their alternates – should be faculty members of the National and Kapodistrian University of Athens, preferably Professors or Associate Professors, as well as Emeritus Professors of the National and Kapodistrian University of Athens.

Two (2) of the members – and their alternates – must be persons outside the National and Kapodistrian University of Athens. Emeritus Professors of other Greek and foreign Universities and researchers of Research Centers, prioritizing A or B level, may apply for the positions of external members.

At least one (1) of the seven members – and his/her alternate – must be specialized in ethics/bioethics.

2. The members of the REC shall be selected as follows:

a. The Research and Management Committee of the Special Account for Research Funds prepares and publishes on the website of the National and Kapodistrian University of Athens a call for expression of interest for the filling of positions no later than three (3) months before the end of the term of office of each member. The invitation specifies the exact number of members of the REC and specifies the qualifications that its members must have. Applications and the necessary supporting documents are submitted electronically by interested parties.

b. The Research and Management Committee of the Special Account for Research Funds evaluates the candidacies and decides on the composition of the REC. The decision of the Research Committee shall take into account:

The experience of candidates in the implementation and management of projects as Scientific Coordinators.

- Participation in collective bodies in a national and international institutional framework that had as their object the decision-making or provision of advisory opinion on issues of ethics, bioethics and research ethics.

Written work related to issues of ethics or bioethics or research ethics and related teaching.

- The representation in the composition of the H.E.D.E. of the subjects of the nine Faculties of the Foundation.

- The formulation of the final composition of the REC so as to ensure an interdisciplinary approach and a comprehensive examination of ethical, ethical and legal issues arising in the context of research and the representation of ages of both sexes.

3. The E.I.D.E. is established by decision of the Rector of the National and Kapodistrian University of Athens. The decision setting it up shall designate the President and Vice-President of the Commission, as well as the alternate member of each member.

4. Each member of the REC must be aware of the Greek legislation, the regulation of the National and Kapodistrian University of Athens, the principles of research ethics and ethics and the principles of scientific integrity defined by the European Union, the international normative texts and must not have been convicted of violating the rights of participants. Also, he must not have been convicted of any violation of the principles of scientific integrity (plagiarism, falsification of data, etc.), as well as for violation of the welfare of laboratory animals.

5. The term of office of the members of the E.I.D.E. is three years and can be renewed only once (1).

6. If a member of the REC resigns, in the absence or in any other way terminates his term of office, he shall be replaced for the remainder of his term of office by his alternate.

Article 3

Incompatibilities - Conflict of interest

1. The membership of the E.I.D.E. is incompatible with the functions of Rector, Vice-Rector and Dean, as well as a member of the Research and Management Committee or Head of Department of the National and Kapodistrian University of Athens.
2. A member of the REC shall be prevented from attending the meeting in any case where a conflict of interest may arise. A conflict of interest arises when a member of the REC has an interest (financial, personal or other) which may affect, or appears to affect, the impartial and objective performance of his duties. Such means any possible advantage in favor of himself or his spouse or a relative of the first and second degree, by blood or marriage. In case of such an impediment regarding a specific proposal under evaluation, the member of the REC shall immediately inform the President, who shall arrange for his replacement by his deputy. The member

concerned shall leave the meeting before the start of the debate. All statements, or other similar matter that may affect the impartiality of the member, shall be noted in the minutes of the meeting.

Article 4

Obligation of confidentiality

1. The members of the REC are obliged to maintain absolute confidentiality regarding any information that comes to their knowledge in the exercise of their duties. The obligation also lies with any external expert or rapporteur invited to provide an opinion/recommendation on a specific research protocol.
2. The obligation of confidentiality shall also apply to the Secretary of the Commission and to any member involved who may perform support work. It is not allowed to disclose in any way confidential data or personal data that are accessible to the above persons due to their duties.
3. The obligation of confidentiality extends to the content of the consultations between the members of the REC, which are necessary for the evaluation of the protocols and the final decision.

CHAPTER B

RESPONSIBILITIES – EVALUATION & APPROVAL PROCEDURES

Article 5

Responsibilities

1. The competence of the REC is to check whether a specific research project to be carried out at the NKUA is in accordance with the applicable legislation and complies with generally accepted rules of research ethics and ethics and research integrity in terms of its content and manner of conduct. In particular, the responsibilities of the REC include:
 - a) The examination of funded research projects which, according to the declaration of the scientific coordinator, include research on humans, on material derived from humans, such as genetic material, cells, tissues and personal data, research on animals or on the environment, natural and cultural, which must be submitted for approval to the REC. The project cannot start to be implemented at the National and Kapodistrian University of Athens without the prior approval of the Commission.
 - b) The examination, in addition to the research projects referred to in point (a) above, of another research project, following an application by an interested person or a complaint.
 - c) The opinion on ethics and ethics issues concerning an article to be published in a scientific journal or a diploma thesis or doctoral dissertation in preparation.
 - d) The monitoring of proposed changes in already approved and implemented research.
 - e) The protection of individuals during the processing of their personal data, resulting from any relevant research, in cooperation with the responsible DPO.

2. The REC shall ascertain the receipt of approvals from the competent authorities, if required, check compliance with the ethical, ethical and legal framework and shall have the possibility to carry out audits after approval, during the progress of the specific investigation until its completion, making recommendations for the most complete, ethically and ethically, carrying it out.
3. The REC may, before the approval of the protocol, make comments on ethical and ethical issues and request the resubmission of the protocol, may recommend to the Research and Management Committee of ELKE the suspension of an ongoing research project, if there is a violation of the legislation and this Regulation.
4. The REC may provide a scientific opinion-recommendation to the Research Committee of ELKE, if requested.
5. If the legislation provides for approval or licensing of a research project by another competent public service, administrative body or independent administrative authority, the relevant decision of the REC shall not replace such approval or licensing.
6. The REC seeks to inform and sensitize the scientific staff, administrative staff and students of the National and Kapodistrian University of Athens to issues of research ethics through speeches, workshops and publication of information material and any other appropriate means.
7. E.I.D.E. cooperates with the National Bioethics Committee and with similar committees in our country and abroad and to represent EKPA in these organizations.
8. The REC shall give its opinion on each case of investigation conducted at the National and Kapodistrian University of Athens, if there is no corresponding other authority.
9. The REC submits to the Research and Management Committee of ELKE an annual activity report.
10. The decisions of the E.I.D.E. are binding on the EKPA.

Article 6
Object of control of the E.I.D.E.

1. The Commission's audit shall focus on matters relating to:
 - a) adherence to the ethical, ethical and legal framework of research, as specifically defined in the law and in this Code of Research Ethics and Ethics of the National and Kapodistrian University of Athens;
 - (b) verifying that persons participating in the investigation have not been subjected to any form of pressure or other undue influence in general, including financial influence, to take part in the investigation. The REC pays particular attention to research involving vulnerable or dependent individuals or population groups,
 - (c) the correctness and completeness of the written information provided to prospective research subjects and/or their legal representatives in order to determine whether it is provided in a simple and comprehensible manner; the procedure in place to obtain the consent of research subjects, or the consent of the legal representatives of persons who lack legal capacity and cannot consent; the justification for the participation in a search of children, minors and incapacitated persons;
 - (d) the free and unforced consent of the subject or his or her legal representative. The Commission shall adopt the consent document, which shall include the

elements referred to in the Code of Research Ethics and Ethics, depending on the type of research proposed. If information that the participants should have known becomes available during the survey, then the document must be amended accordingly and resubmitted to the REC for approval;

- (e) respect for the principle of respect for the physical and mental integrity of subjects, their right to privacy, the protection of personal data and the manner in which their confidentiality and privacy are safeguarded;
- (f) the voluntary nature of participation and the manner in which participants are selected and included;
- (g) the individual and social impact of the research;
- (h) compliance with the basic principles of animal protection and ethical treatment as regards animal research;
- (i) compliance with rules relating to the protection of the cultural and natural environment and waste management.

2. The Commission shall verify whether the risks to the individual or group participating in the investigation and the suffering or distress experienced are not disproportionate to the potential benefit of the research. The danger, suffering, or discomfort may, in addition to being physical, be psychological or social. In the case of research which is not likely to be of direct benefit to the participants, the REC confirms that the risk and inconvenience are kept to a minimum.

3. The REC shall examine the impact of the proposed research on the local community and in particular on the specific communities from which the participants come. In particular, the REC assesses the possibility that participation in this research, or the publication and dissemination of research results, may create, or worsen, conditions of vulnerability, social marginalization, stigmatization, prejudice and social and other negative discrimination.

4. The REC shall control the manner in which the results are communicated to the community concerned and the participants. In particular in the cases referred to in paragraph 3 of this Article, the REC shall consider the measures proposed by the investigator in order to minimise the risk of the negative consequences of participation in research and of the publication and dissemination of the results of such research.

5. The REC shall take into account during the evaluation of research proposals and propose improvements, if necessary, on issues related, indicatively, to: (a) the characteristics of the population group in which participants will be sought, including gender, age, education, economic status, nationality and cultural origin, (b) how to approach participants, (c) how to inform participants, (d) the criteria for participation and rejection of participants, and (e) how the results of the research described in paragraph 3 of this Article are made public and disseminated.

Article 7

Submission and receipt of applications

1. Applications and accompanying documents are submitted by the Scientific Coordinator (CR) of the project electronically, at: resethic@uoa.gr, through the website of the National and Kapodistrian University of Athens. In the case of diploma or postgraduate theses and doctoral dissertations, the application is signed by the supervising Professor.

2. The Secretary of the REC confirms to the submitter that he/she has received the application, after verifying the completeness of the submitted supporting documents and registering it.
3. As soon as the members of the REC become aware of the application, they must inform the President and the Secretary if there is a conflict of interest which prevents their participation in its evaluation.
4. The President of the REC shall appoint for each application submitted a rapporteur, as a priority member of the REC, depending on the scientific subject of the research project. If the subject of the project cannot be covered by the members of the REC, an external expert is appointed, who makes a recommendation to the REC in writing.

Article 8

General procedure for the adoption of a research protocol

1. For approval to carry out a research project, each application submitted shall include the following supporting documents:

I. Completed application form to the REC for the approval of the research protocol, which necessarily includes a reference table / questionnaire and a summary report on the suitability and compatibility of the research project with the applicable legislation. In this report, the scientific coordinator shall determine whether the purpose and methodology of the research project are compatible with the principles of scientific integrity, those of research ethics and ethics and legislation. The application also includes a statement by the researcher that he has become aware of the Code of Research Ethics and Ethics of the National and Kapodistrian University of Athens, undertaking the obligation to comply and comply with it (Accompanying Form 1).

II. It is accompanied by a summary of three (3) lines maximum for the content of the survey and the name of the person responsible.

III. The Research Protocol.

IV. Model of a solemn declaration of the survey participants, stating their prior information and consent (if required).

V. Any other document or supporting material of the study.

2. The funding of research by private bodies related to the commercial exploitation of research results (such as a pharmaceutical company or a company producing or trading mechanical or other equipment) is permitted, provided that in addition a written acceptance by the company of the Code of Research Ethics and Ethics of the National and Kapodistrian University of Athens, which governs its research activity, is submitted to the REC.

Article 9

Procedure for approval of a research protocol in human studies

In particular, for the approval of a research protocol concerning a human study, the following procedure is followed, subject to the provision of article 100 of law 4692/2020

Research on human beings must be carried out with full respect for their bioethical, physical and spiritual existence. Researchers are bound, in addition to the law, by the generally

recognized principles of human value and protection of fundamental rights, freedom and equality, protection of public health, protection of children and vulnerable groups, personal data.

A. For all research activities with participating people:

(e.g. healthy subjects from the general population, students, patient groups outside hospitals) conducted under the responsibility of the scientific staff of the National and Kapodistrian University of Athens, the following are required:

I. Application to the REC for the approval of the research protocol, with all the necessary accompanying forms (see article 8.I - Accompanying Form 1)

II. The Research Protocol.

III. Model of a solemn declaration of the survey participants, stating their prior exhaustive, complete and clear information and consent (Consent Form).

B. For research on human embryos: I. Application to the REC for the approval of the research protocol, with all the necessary accompanying forms (see article 5.1.I - Accompanying Form 1)

II. The Research Protocol.

III. Model of solemn declaration of donors, stating their prior information and consent.

IV. Statement by the investigator of previous corresponding research on animal models, unless this is not scientifically possible.

V. Approval of the E.I.D.E.

VI. License of the National ART Authority.

C. The consent form concerning research based on the processing of personal data of subject subjects requires full written information, which must include the following:

(I)

- the details of the controller and the data protection officer

- the purposes of the processing

- an explicit indication that the processing of the subject's data will concern only the purposes mentioned above;

- the type of data strictly necessary for the purposes of the processing. If special personal data are to be collected (health data, genetic or biometric data, data on religion, political and trade union beliefs, etc.), it should be specifically and specifically stated;

a description of the exact use of the data. If a profile is to be created, it should be specifically mentioned;

- an explicit commitment that there will be no other recipients of their data (or, if any, who they are);

- a reference to the period for which his/her personal data will be retained (it is precisely defined and that they will subsequently be deleted, or that otherwise the consent of the subject will be requested again, and if this is not given, they will be deleted immediately);
- that he may refuse or withdraw his consent at any time;
- that he/she has the right to exercise his/her rights of access, deletion or correction thereof, as well as that he/she has the right to complain to the Personal Data Protection Authority.

(II)

The consent of the research participant must be in writing or meet the requirements set forth in the law and in this Code of Research Ethics and Ethics. The consent form must explicitly state that the subject, or his/her legal representative in the case of minors or persons lacking legal capacity, may withdraw his/her consent at any time without any consequences. The participant should be able to withdraw consent.

D. Other

In order to carry out an investigative protocol on a corpse, a declaration of consent of the relatives is required.

For possible investigations of detainees, investigators must comply with the specific provisions of the Penitentiary Code, while taking into account the requirements of the Code of Ethics of Criminology. The Commission checks whether the proposed investigation is aimed at seeking methods of interrogation, whether they are likely to endanger the physical and mental health of detainees or diminish their moral standing and offend against their humanity, in which case the investigation is excluded.

Article 10

Special cases

Special investigations, which must be carried out in accordance with Greek and European legislation following international and European treaties, are in particular those mentioned below:

A. Environmental health and safety, Protection of the environment and biodiversity

Research must take into account and minimise potential risks to the environment. In particular, on the basis of the constitutionally enshrined principle of sustainability, compliance with the laws adopted and in force for the protection of the environment, including waste management, must be ensured. Compliance with laws adopted to protect biodiversity and endangered species must also be ensured. Researchers should include in the research protocol information on potential risks to the environment and a plan to minimize them.

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

Research on genetically modified organisms and micro-organisms must be carried out on the basis of the legislation in force [indicatively and not restrictively, the provisions of

Community Directive 2001/18, as incorporated into Greek legislation by ministerial decision 38639/2017 and those of EU Directive 1998/81, on the contained use of genetically modified micro-organisms, as incorporated into Greek legislation by ministerial decision US/11648/1943/2002].

For the use, handling and collection, movement of radioactive substances, a special permit of EEAE is required, in accordance with the applicable provisions (indicatively and not restrictively: Law 1733/1987, 2480/1997, Legislative Decree 854/1971, Presidential Decree 22/1997).

In case of use of ionising or non-ionising radiation, special protective measures must be taken for both researchers and the general population, in accordance with the legislation in force at the time.

No investigation justifies an attack on the environment in violation of laws adopted for its protection, as well as for waste management.

B. Protection of intangible and tangible cultural heritage

No research activity justifies infringement of the intangible and tangible cultural heritage in violation of the provisions of applicable law.

C. Dual-use research (civil, military)

When proposing research projects with potential dual use, civilian or military, or proposing to military organisations, clear reference should be made to non-civil uses. The need to carry out such investigations shall be adequately substantiated, as well as the appropriate specific treatment for the disclosure of any sensitive research results or the need to conceal them altogether.

Article 11

Procedure for approval of a research protocol in animal studies

Projects involving experiments using animals or animal models require the approval of the relevant School or Department. The REC will accept the documented recommendation of the relevant School or Department.

- Research on animals is governed by the rules described in national legislation, transposing Directive /63/EU, and supplemented by interpretative circular 2215/117550/2013 of the General Directorate of Veterinary Medicine of the Ministry of Rural Development on the protection of animals used for scientific purposes.
- In case the research project involves the administration of drugs to animals (preclinical study), researchers must apply the Rules of Good Laboratory Practice (Directives 2004/9/EC & 2004/10/EC, OECD Principles of Good Laboratory Practice (GLP), where provided. Also, medical and animal studies are carried out in accordance with the applicable provisions (in accordance with the Internal Regulation of Operation of the National and Kapodistrian University of Athens).

The decision of the E.I.D.E. does not replace the licensing provided for by Presidential Decree 56/2013.

CHAPTER C

OPERATION AND DECISIONS OF E.I.D.E.

Article 12

Operation of E.I.D.E.

1. The E.I.D.E. of E.K.P.A. meets regularly once (1) a month and extraordinarily whenever requested by its President or the Chairman of the Research and Management Committee of ELKE. It may, following its decision, also meet in chambers in compliance with paragraph 3 hereof.
2. The President of the REC shall be responsible for the proper functioning of the Committee and shall convene and direct its meetings. If he/she is prevented from attending, he/she shall be replaced in all his/her duties by the Vice-President, who may also perform any additional function assigned to him by the President.
3. The REC shall constitute a quorum when at least four (4) of its members are present, including its President or Vice-President, as well as one of its members who do not belong to the EKPA.
4. If a full member of the Commission is prevented from attending, the alternate shall be notified by the Secretariat.
5. The meetings of the REC may be held remotely by electronic means.
6. The members of the REC shall not be entitled to remuneration or any other compensation for their participation in its meetings.
7. In order to facilitate its work, REC may cooperate with the National Bioethics Committee and any other competent authority on issues related to its competences.

Article 13

Consultation and decision-making

1. The President may appoint any of the members of the Commission as rapporteur for a specific research proposal. The rapporteur shall send his/her contribution, in electronic form, within seven (7) days of receipt of the proposal.
2. Where the Commission considers it necessary, it may invite the investigator responsible to present the research protocol or to provide clarification thereof.
3. The REC may invite external experts to provide an opinion on a protocol under consideration. When there is a relevant issue, specialized scientists in the relevant disciplines may be invited to give their opinion.
4. The REC shall decide within a reasonable period of time, which shall not exceed fifteen (15) working days from the submission of the application and the collection of all necessary accompanying documents. If the deadline of fifteen (15) working days expires, the application is considered approved. It decides in the absence of any invitees and only if the researcher has submitted all the supporting documents. Its recommendations and suggestions must be justified.

5. In case of complaint, the REC shall decide no later than fifteen (15) working days from the submission of the complaint and notify the complaint to the Research and Management Committee of ELKE. If no decision is taken within this period, the complaint shall be deemed to have been rejected

6. The decisions of the REC shall be taken by a majority of the members present, after an effort of unanimity. In the event of a tie, the President shall have a casting vote.

7. Voting shall be open, except in the case of decisions concerning the impediment of members of the Commission, in which case it shall be secret

Article 14

Discussion and evaluation of working methods of REC

1. The President may periodically arrange a meeting devoted to discussing and evaluating the Commission's methods and methods of work. During the meeting, members are encouraged to express concerns and suggest ways to improve the work of the Commission.

2. Meetings may also take place at the request of the members of the REC.

3. The meetings may be attended by invited external experts or members of other Ethics and Ethics Committees of research bodies of the country or other specialists.

Article 15

Notification of decisions

1. The person concerned shall be informed of the decision in writing within three working days of the meeting and the extract from the decision shall be sent to him/her.

2. The decision shall include:

(a) the name and title of the investigator responsible;

(b) the exact title of the protocol examined;

(c) the exact version of the Protocol or its possible amendment on which the decision was based;

(d) the accompanying documents examined (e.g. information material, consent form);

(e) the date of the decision;

(f) in the case of a conditional decision, all amendments requested and the procedure for reviewing the Protocol;

(g) in the case of a positive decision, an enumeration of possible obligations of the investigator, e.g. submission of periodic or one-off reports, the need to inform the Commission of possible future necessary amendments to the protocol, the need to report serious or undesirable or accidental events during the conduct of the investigation;

(i) in case of a reply for revision or amendment, full justification;

(j) date and signature of the President or, in case of his impediment, of the Vice-President of the REC.

Article 16

Submit a request for treatment

Any interested party may file, within ten (10) days from the issuance of the decision, an application for remedy against the Commission's recommendations by submitting new evidence. For the examination of the application for treatment, the REC seeks the opinion of the National Bioethics Committee, which must formulate it within fifteen (15) days. If the National Bioethics Committee does not formulate an opinion within the above deadline, the REC proceeds with the examination of the request for treatment without the opinion of the National Bioethics Committee.

Article 17

Research protocol monitoring

1. During the conduct of the investigation and depending on its subject matter, the Commission shall have the discretion to request from the investigator responsible periodic or one-off reporting on issues related to compliance with the ethical and ethical framework as well as on the following data: a) the number of participants, b) any unforeseen problems that occurred, as well as information on any unfortunate incidents and how to deal with them, c) the departures of participants.
2. If the REC finds that a specific research, either in its content or because of the way it is conducted, contravenes the legislation, generally accepted rules of ethics and ethics or the provisions of the Code of Research Ethics and Ethics of the National and Kapodistrian University of Athens, it shall make observations and recommendations to the researcher for his compliance.
3. In case the responsible investigator does not submit the above information to the Commission, the Commission shall inform him of its possible decision to suspend the investigation, notifying the information also to the Research and Management Committee of ELKE of the National and Kapodistrian University of Athens

Article 18

Suspension of the research protocol

1. In the context of the examination of the research protocols or at a later date, the REC may propose changes to the protocol, even if the investigation may be conducted, the suspension of the research to the extent that there is a reason related to the ethics and ethics of the research.
2. The REC may recommend to the Research Committee the suspension of the continuation of the investigation, if it finds, following a written and signed complaint, that it is carried out in derogation from the instructions of the REC, or that it has been associated with unforeseen serious effects on participants or laboratory animals. The decision to suspend the investigation is taken by the Research Committee, is fully reasoned and is notified to the person in charge of the research and the School and Department in which the investigation is conducted.

3. Prior to any suggestion by the REC, both the complainant and the person responsible for the investigation shall be invited before it to present orally and/or in writing their views on the complaint.

CHAPTER D

OTHER PROVISIONS

Article 19

Record keeping - Secretariat

1. The REC is obliged to keep an electronic file with the following documents:
 - (a) Protocol for incoming and outgoing correspondence.
 - b) The curriculum vitae of the members of the Committee.
 - c) Minutes of meetings and agendas under the responsibility of the secretary of the REC.
 - (d) applications submitted for approval and corresponding reasoned decisions;
 - (e) The approved research protocols and accompanying documents.
 - f) Copies of correspondence between the REC and the investigators responsible, including possible recommendations to the investigator and all information concerning a possible suspension of an approved investigation.

2. The collection, processing and keeping in a file of personal data is carried out in accordance with the applicable legislation on the protection of individuals from the processing of personal data, with emphasis on the security principles of personal data processing and storage systems

3. The Secretariat shall keep an independent electronic protocol and the archive of the NQAA, which shall be ensured in accordance with the provisions for the security of the electronic archive of the National and Kapodistrian University of Athens. The records shall be kept electronically, in a secure manner, for at least 3 years after the completion of the research project, unless otherwise specified by the funder. Storage conditions must guarantee the protection of confidentiality.

Members of the Secretariat shall keep and treat as confidential all information and documents relating to requests referred to it, and shall not disclose information or documents to third parties.

4. The NKUDE shall provide appropriate premises and modern and appropriate IT equipment for the management of all information produced by the Commission. The relevant expenses shall be borne by the budget of the National and Kapodistrian University of Athens.

Article 20

File corruption

1. At the end of the period laid down in Article 19, the following shall be destroyed, following a Commission decision:

- applications submitted for approval;
- approved research protocols and accompanying documents
- copies of correspondence between the Commission and the investigators responsible, including possible recommendations to the investigator and all information concerning a possible suspension or termination of an authorised investigation.

2. The destruction of digital files 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 "Clearance and Destruction of Printed and Electronic Documents".

3. The following shall not be destroyed and preserved:

- The minutes of the meetings and the approval decisions of the REC.
- The CVs of the members of the Committee

4. Finally, a protocol of destruction is observed and for this reason a Committee for the destruction of records is established by the REC.

CHAPTER E

RELATIONS BETWEEN RESEARCHERS AND N.K.U.A.

Article 21

They must keep complete records of the progress and results of a programme so that they can be monitored, while at the same time safeguarding intellectual property rights in any case.

Researchers conducting research at the National and Kapodistrian University of Athens, who direct research programs, must take all necessary and necessary scientific measures to protect the health of employees in the programs from accidents or other side effects that may arise under the particular conditions of the research.

They must comply with the general and special safety rules of the National and Kapodistrian University of Athens in the research areas.

All researchers of EKPA in relation to their research activities are personally responsible for acts or omissions related to the observance of this Regulation, applicable national, European and international legislation and international declarations and conventions. In particular, researchers are required to:

- a. Obtain written consent from all persons participating in the survey or from their legal representatives prior to conducting the investigation, after fully and clearly informing them of the content and objectives of the survey. This consent may not be the result of coercion or deception and may be withdrawn at any stage of the investigation. Exceptionally, when the prior full or absolutely clear information of the participants about the objectives of the survey may affect its validity, the receipt of written consent may follow the completion of the research and concern the use of research data. If written consent is not required, as in the case of conducting a survey with anonymous questionnaires, only the information form and other information material are given to survey participants instead of the consent form. The obligation

to provide information includes, where appropriate, persons who are not directly involved in the investigation but are affected by its conduct.

- b. Ensure the protection of the personal data of research participants in accordance with applicable law by applying commonly accepted anonymization - pseudonymization practices.
 - c. Keep complete records on the development and results of their research activities for a period of ten (10) years.
 - d. Ensure, in accordance with current practice, the selection of research subjects in a manner consistent with the principles of equal treatment and non-discrimination in conjunction with the sampling criteria dictated by the objectives of the survey.
 - e. Respect the principle of impartiality.
 - f. Do not conceal or alter the results of their research (duty of scientific truth).
 - g. Participate and cooperate in any quality control and assurance process carried out by the National and Kapodistrian University of Athens or other public authorities.
 - h. Comply with the general and special rules of safety and hygiene in all areas of the National and Kapodistrian University of Athens or in any other research or other area that implements their research work.
 - i. Respect the principles of sound, transparent and efficient financial management.
 - j. Do not accept, when concluding funding agreements, conditions that jeopardize their freedom and integrity, as well as the prestige and interests of EKPA regarding the design, conduct and publication of their research.
- la. They respect the individual ethical principles and ethical rules that apply in every field of science and humanities.
- lb. They are constantly informed about developments concerning the individual ethical principles and rules governing the scientific field in which they specialize
- M. They shall report any conflict of personal, professional or financial interest which pre-exists at the beginning of the research activity or arises during its execution.
- N. They respect the ethical and ethical commitments relating to their disciplines (applies to specific categories of researchers (doctors, lawyers, psychologists, etc.)).

In any case of violation of the above, researchers are checked in accordance with the applicable national and European legislation and the provisions of the Internal Regulation of the National and Kapodistrian University of Athens.

Regarding relations between researchers, the following apply:

- a. Researchers are obliged to respect each other and their contribution to the final result must be duly recognised in accordance with intellectual property law. Especially for publications, the order of co-authors is determined by agreement of the participants, taking into account that the participation and position in the writing team is based on the significant contribution of the researcher to the design of the research, the acquisition of the data, and/or the analysis and interpretation of the results.
- b. The HCPs of research projects must be fully consistent with their obligations towards the Research and Management Committee of ELKE and other stakeholders and ensure that the members of their research team comply with this Regulation

- c. HCPs of research projects may replace researchers participating in the project in case they violate this Regulation or perform their work improperly.
- d. In case of violation of the above principles, all those involved in the research process must immediately contact the competent university authorities, in accordance with the provisions of the Internal Regulation of the National and Kapodistrian University of Athens, notifying them of the violations.

Signs, websites, announcements and general means of promotion of research programs are designed and used in a way that serves to inform the scientific community and any interested party, without creating false expectations regarding the use of their results or giving misleading information of any nature about them. The mention of potential sponsors in activities, websites or publications of research teams should be made with care, so as not to create confusion as to the research entity, not to give the impression of advertising specific products and not to give the impression of permanent connection of the sponsor with the EKPA.

Signs, websites and all kinds of brochures promoting the programs must mention all those involved in the research.

In any publication of the results of the research, its presentation at conferences or in any way its publication, the connection of the researchers with the National and Kapodistrian University of Athens should be mentioned and its official insignia and logos should be used.

Article 22

Revision and amendment of Articles of the Rules of Procedure

The present Regulation of Principles and Operation of the Research Ethics Committee of the Special Account for Research Funds of the National and Kapodistrian University of Athens is subject to amendment by proposal of the REC. The proposed changes are approved, upon the recommendation of the REC, by the Research Committee of ELKE, provided that they have the support of 2/3 of its members and are sent by the latter to the Senate for approval

Article 23

Clarification

It is not within the competence of the Research Ethics Committee to examine ethical issues among faculty members, nor among NKUA students.