



ΠΑΝΕΠΙΣΤΗΜΙΟ
ΘΕΣΣΑΛΙΑΣ

**REGULATIONS GOVERNING THE OPERATION
OF THE RESEARCH ETHICS COMMITTEE
OF THE UNIVERSITY OF THESSALY**



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Chapter 1: Establishment – Governing Bodies of the Research Ethics Committee (REC)

Article 1 Establishment - Mission

1.1. The Research Ethics Committee (REC) of the University of Thessaly is established and operates in accordance with the provisions of Law 4957/2022, Articles 277–282.

1.2. The mission of the Research Ethics Committee (REC) is to provide, from the perspective of research ethics and integrity, a guarantee of reliability for the research projects conducted at the University of Thessaly. Research Ethics Committee (REC) examines whether a research project is carried out with respect for the value of human beings, the autonomy of participants, their private life and personal data, as well as with due care for the natural and cultural environment. The Committee also monitors compliance with the generally accepted principles of research integrity and the criteria for good scientific practice. The ethical review of research constitutes an essential guarantee of reliability, contributes to the achievement of excellence, and is a prerequisite for strengthening public trust in and acceptance of the research conducted at the University of Thessaly.

Article 2 - Composition- Term of Office

2.1. The Research Ethics Committee (REC) consists of seven (7) regular members and their substitute members.

2.2. The members must be scientists with expertise in matters of research, ethics/bioethics, and research integrity. The academic fields of two of the members must fall within disciplines related to research involving humans, children, gametes and embryos (through human reproduction), and animals, while ensuring, to the greatest extent possible, representation of the academic disciplines of the Institution. The composition of the Research Ethics Committee (REC) is determined by a decision of the Research Committee of the University of Thessaly, taking into account the following parameters:

- a. Five (5) of its members - and their substitute members - must be faculty members of the Institution, preferably Professors or Associate Professors, as well as Emeritus Professors of the University of Thessaly.
- b. At least two (2) of the members - and their substitute members - must be individuals external to the University of Thessaly. Candidates for the positions of external members may include



researchers from Research Centers, preferably of Grade A or B, and scientists with expertise in matters of research, ethics/bioethics, and research integrity.

c. At least one (1) of the seven members - and their substitute member - must specialise in ethics/bioethics.

2.3. The members of the Research Ethics Committee (REC) are selected as follows:

a. The Research and Management Committee (RMC) of the University of Thessaly prepares and publishes on the Institution's website a call for expressions 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 call specifies the exact number of members of the Research Ethics Committee (REC) and details the qualifications required for its members. Applications and the necessary supporting documents are submitted electronically by the interested parties.

b. The Research and Management Committee of the University of Thessaly evaluates the applications and decides on the composition of the Research Ethics Committee (REC). In its decision, the Research and Management Committee takes into account the following factors:

- The experience of candidates in implementing and managing projects as Principal Investigator.
- The prior participation of candidates in similar ethics/bioethics committees.
- The representation, within the composition of the Research Ethics Committee (REC), of the academic disciplines of all Schools of the Institution.
- The formation of the final composition of the Research Ethics Committee (REC) in a way that ensures an interdisciplinary approach and a comprehensive examination of the ethical, and legal issues arising in the context of research.

2.4. The Research Ethics Committee (REC) is established by decision of the Rector of the University of Thessaly. The decision on its establishment appoints the Chair and the Vice-Chair of the Committee.

2.5. Each Research Ethics Committee (REC) member must be familiar with the principles of research ethics and the principles of scientific integrity, as defined by the European Union, international regulatory frameworks, and Greek legislation, and must not have been convicted for violations of participants' rights or for harm to the welfare of laboratory animals in research

they conducted or in which they actively participated, nor for any breach of the principles of scientific integrity (such as plagiarism, data falsification, etc.), or for violations of legislation concerning the protection of personal data. The participation of more than one member with specialised studies in research ethics/bioethics (e.g., MA or MSc in Bioethics) is desirable.

2.6. The term of office of the members of the Research Ethics Committee (REC) is three (3) years and may be renewed only once.

2.7. If a Research Ethics Committee (REC) member resigns, passes away, or otherwise ceases to hold office, they are replaced for the remainder of the term by their substitute member.

2.8. The Chair of the Research Ethics Committee (REC) is responsible for the operation of the Committee, convenes its meetings, and represents the Committee before the Research and Management Committee, the Senate, and wherever else necessary. The Research Ethics Committee (REC) may authorise its Chair to access and sign the notification form of an approved research protocol.

2.9. The Vice-Chair performs the duties of the Chair in the event that the latter is unable to fulfil them. The Vice-Chair may also be requested by the Chair to perform additional duties, such as supervising part of the agenda.

Article 3 – Incompatibilities – Conflicts of Interest

3.1. The status of Research Ethics Committee (REC) members is incompatible with the positions of: Rector, Vice-Rector, and Dean, as well as with membership in the Research and Management Committee or the Head of a Department of the University of Thessaly.

3.2. A member of the Research Ethics Committee (REC) is prevented from participating in a meeting in any case where a conflict of interest may arise. A conflict of interest arises when a member of the Research Ethics Committee (REC) has an interest (financial, personal, or other) that may influence, or appear to influence, the impartial and objective performance of their duties. Such an interest includes any potential advantage for the member, their spouse, or first-degree relative.

3.3. In the event of such an impediment concerning a specific proposal under evaluation, the Research Ethics Committee member shall immediately inform the Chair, who shall ensure their replacement by the substitute member. The member in question shall withdraw from the meeting before the discussion begins. All declarations, or any other similar matters that may



affect the member's impartiality, are recorded in the minutes of the meeting.

Article 4 – Obligation of confidentiality

4.1. Research Ethics Committee (REC) members are obliged to maintain strict confidentiality regarding any information that comes to their knowledge in the course of performing their duties. This obligation also applies to any external expert or rapporteur invited to provide an opinion or report on a specific research project.

4.2. The obligation of confidentiality also applies to the Secretary of the Committee and to any staff member or person providing administrative support. The disclosure, in any manner whatsoever, of confidential information or personal data accessible to the above persons in the course of their duties is not permitted.

4.3. The obligation of confidentiality also extends to the content of deliberations among the Research Ethics Committee (REC) members, which are necessary for the evaluation of projects and the adoption of a final decision.

Chapter 2: Responsibilities – Evaluation & Approval Procedures

Article 5 - Responsibilities

5.1. The competence of the Research Ethics Committee (REC) is to determine whether a specific research project to be carried out at the University of Thessaly complies with applicable legislation and whether it is consistent with generally accepted principles of research ethics, and research integrity, both in terms of its content and the manner in which it is conducted. In particular, the responsibilities of the Research Ethics Committee (REC) include:

- a) The review of funded research projects which, according to the declaration of the Principal Investigator, involve research on humans, human-derived material such as genetic material, cells, tissues and personal data, animals, or the natural and cultural environment, and which are mandatorily submitted for approval to the Research Ethics Committee (REC). The project cannot commence implementation at the University of Thessaly unless it has first received the relevant approval of the Committee.
- b) The review, beyond the research projects referred to in case a) above, of any other research project, following a request by an interested party or a complaint, and the issuance of an opinion on ethical issues concerning an article intended for publication in a scientific journal, or a diploma thesis or doctoral dissertation under preparation.



c) The monitoring of proposed amendments to already approved and ongoing research projects.

d) The protection of the individual in the processing of their personal data arising from any relevant research.

5.2. The Committee verifies the receipt of approvals from the competent authorities, where these are required, and checks compliance with the ethical, and legal framework. It also has the ability to conduct reviews after approval has been granted, during the course of the specific research until its completion, issuing recommendations for its more ethically sound conduct.

5.3. The Research Ethics Committee (REC) recommends to the Research and Management Committee of the University of Thessaly the suspension of a research project, where there is a violation of legislation and the Code of Research Ethics and Conduct.

5.4. The Research Ethics Committee (REC) may provide a scientific opinion/recommendation to the Research and Management Committee of the University of Thessaly, upon request.

5.5. The decisions of the Research Ethics Committee (REC) are binding for the University of Thessaly.

5.6. If the legislation provides for the approval or licensing of a research project by another competent public service, administrative body, or independent administrative authority, the relevant decision of the Research Ethics Committee (REC) does not substitute for such approval or licensing

5.7. The Research Ethics Committee (REC) informs and raises awareness among the academic staff, administrative staff, and students of the University of Thessaly on matters of research ethics and integrity through lectures, workshops, and the publication of informational material, as well as any other appropriate means.

Article 6 – Subject matter of the Research Ethics Committee (REC)

6.1. The subject matter of the Committee's review is:

a) compliance with the ethical, and legal framework governing research, as specifically defined in the Code of Research Ethics and Conduct of the University of Thessaly.

b) verification that no form of pressure or other undue influence in general, including financial influence, has been exerted on individuals participating in the research to induce them to take part in it. The Research Ethics Committee (REC) pays particular attention to research involving

vulnerable or dependent individuals or population groups.

c) the accuracy and completeness of the written information provided to prospective research participants and/or their legal representatives, in order to determine whether such information is provided in a simple and comprehensible manner; the procedure applied for obtaining the consent of research participants and the consent of legal representatives or persons exercising custody over individuals lacking legal capacity and unable to provide consent; and the justification for the participation in research of children, minors, and persons lacking legal capacity.

d) the free and uncoerced consent of the participant or their legal representative. The Committee approves the consent document, which includes the elements referred to in the Code of Research Ethics and Conduct, depending on the nature of the proposed research. If, during the course of the research, information arises that participants ought to be informed of, the document must be amended accordingly and resubmitted to the Research Ethics Committee (REC) for approval.

e) compliance with the principle of respect for the physical and mental integrity of the participants, their right to privacy, the protection of personal data, and the manner in which confidentiality and their privacy are safeguarded.

f) the voluntary nature of participation and the method of selecting and enrolling participants.

g) the individual and social implications of the research.

h) compliance with the fundamental principles of protection and ethical treatment of animals, concerning research involving animals.

i) compliance with rules concerning the protection of the cultural and natural environment, as well as waste management.

6.2. The Committee examines whether the risks to the individual or group participating in the research and the existing burden or discomfort are not disproportionate to the potential benefit of the research. The risk, burden, or discomfort may, in addition to being physical, also be psychological or social. If the research is not expected to provide any direct benefit to the participants, the Research Ethics Committee (REC) shall ensure that the risk and burden are kept to the minimum possible level.

6.3. The Research Ethics Committee (REC) examines the impact of the proposed research on the local community and, in particular, on the specific communities from which the

participants originate. In particular, the Research Ethics Committee (REC) assesses the likelihood that participation in the specific research, or the publication and dissemination of the research results, may create or exacerbate conditions of vulnerability, social marginalisation, stigmatisation, prejudice, and social or other forms of negative discrimination.

6.4. The Research Ethics Committee (REC) examines the manner in which the results are communicated to the relevant community and the participants. In particular, in the cases referred to in paragraph 3 of this Article, the Research Ethics Committee (REC) examines the measures proposed by the researcher in order to minimize the risk arising from the negative consequences of participation in the research and from the publication and dissemination of the results of such research.

6.5. The Research Ethics Committee (REC) takes into account, during the evaluation of research proposals, and proposes improvements where it deems necessary, on issues related, indicatively, to: (a) the characteristics of the population group from which participants will be recruited, including gender, age, education, economic status, nationality, and cultural background; (b) the method of approaching participants; (c) the manner in which participants are informed; (d) the inclusion and exclusion criteria for participants; (e) the method of publication and dissemination of research results referred to in paragraph 3 of this Article; (f) in the case of the use of additional assessment tools such as written examinations, the grading of candidates in these is clearly stated in the evaluation report and their written work is submitted to the Financial and Administrative Support Unit of the Special Account for Research Funds (EAKE) as an appendix to the report.

Article 7 – Submission and receipt of proposals

7.1. Applications and supporting documents are electronically submitted by the Principal Investigator of the project, via a specific website of the Research Ethics Committee (REC).

7.2. The Secretary of the Research Ethics Committee (REC) confirms to the applicant that the research proposal has been received, after first verifying the completeness of the submitted supporting documents and officially registering it.

7.3. The Research Ethics Committee (REC) members, upon receiving the research proposal, are required to inform the Chair and the Secretary if there is any case of conflict of interest that prevents their participation in its evaluation.



7.4. The Chair of the Research Ethics Committee (REC) appoints a rapporteur for each submitted application, prioritizing a member of the Research Ethics Committee (REC) in accordance with the scientific field of the research project. If the subject area of the project cannot be covered by Research Ethics Committee (REC) members, an external expert is appointed, who acts as rapporteur.

7.5. Meetings of the Research Ethics Committee (REC) may be held remotely using electronic means.

Article 8 - General procedure for the approval of a research project

8.1. For the approval of the conduct of a research project, each submitted research proposal must include the following supporting documents:

- (I) An application to the Research Ethics Committee (REC) for approval of the research project, which must necessarily include a reference table/questionnaire. The application also includes a declaration by the researcher that they have been informed of the Code of Research Ethics and Conduct of the University of Thessaly, undertaking the obligation to comply with and adhere to it.
- (II) The research proposal
- (III) Consent form of the research participants stating that they have been previously informed and have given their consent (where required).
- (IV) Any other document or supporting material of the study.
- (V) Any requirement set by the Institute of Educational Policy of the Ministry of Education, Religious Affairs and Sports

<https://iep.edu.gr/el/dieksagogi-erevnon-approval-procedures>.

8.2. Funding of research by private entities related to the commercial exploitation of research results (such as a pharmaceutical company or a company manufacturing or supplying medical, mechanical or other equipment) presupposes acceptance of the Code of Research Ethics and Conduct governing the research activity of the University of Thessaly, which is confirmed through the signing of the funding agreement.

Article 9 – Research protocol in studies involving human subjects

In particular, for the approval of a research project involving a study on human subjects, the



following procedure is followed:

A. For all research activities involving human participants (e.g., healthy members of the general population, students, and patient groups outside hospitals settings) conducted under the responsibility of the academic staff of the University of Thessaly, the following is required:

- (I) Application to the Research Ethics Committee (REC) for the approval of the research project with all required supporting documents (see article 8.1.)
- (II) The research protocol.
- (III) Consent form of the research participants, stating that they have been previously informed and have given their consent.
- (IV) Research Ethics Committee's (REC) approval.

a. Funded research projects which, according to the declaration of the Principal Investigator (PI), include activities involving research on humans, on human-derived material such as genetic material, cells, tissues and personal data, on animals, or on the natural and cultural environment, must be mandatorily submitted for approval to the Research Ethics Committee (REC). The above project activities cannot commence implementation at the Higher Education Institution or research institution unless they have first received the relevant approval.

b. Apart from the research projects referred to in case (a), the Research Ethics Committee (REC) may also examine, upon request by an interested party or following a complaint, other research work and issue an opinion on ethical matters concerning an article intended for publication in a scientific journal, or a diploma thesis in progress, or a doctoral dissertation.

c. The decisions of the Research Ethics Committee (REC) are binding for the Higher Education Institution and the research body.

B. Clinical interventional and non-interventional studies:

Regarding research proposals which, according to the declaration of the Principal Investigator, include studies or trials involving humans (Law 4957/2022, Article 279, para. 3), if the legislation provides for approval or licensing of the project by another competent public authority, administrative body, or independent administrative authority, the relevant decision of the Research Ethics Committee (REC) does not replace such approval or licensing. By way of exception, interventional and non-interventional clinical studies do not fall within the scope of

the Research Ethics Committee (REC) responsibilities, and for their implementation only approval for conduct by the competent public authority, administrative body, or independent administrative authority is required, in accordance with the provisions of the applicable legislation on the conduct of clinical studies.

C. For research on human embryos:

- (I) Application to the Research Ethics Committee (REC) for the approval of the research project with all required supporting documents.
- (II) The research protocol.
- (III) A written declaration by the donors, stating that they have been previously informed and have given their consent.
- (IV) A declaration by the researcher regarding prior similar research on animal models, unless this is not scientifically feasible.
- (V) Research Ethics Committee (REC) approval.
- (VI) Permit from the National Authority for Medically Assisted Reproduction.

D. The consent form relating to research based on any form of processing of participants' personal data requires full written information, which must include the following:

(I) the details of the data controller and the data protection officer, the purposes of the processing, and an explicit statement that the processing of the participant's personal data will be carried out solely for the aforementioned purposes; the type of personal data that is strictly necessary for the purposes of the processing. If special categories of personal data are to be collected (health data, genetic or biometric data, data concerning a natural person's sex life or sexual orientation, data on racial or ethnic origin, religious or philosophical beliefs, political opinions, or trade union membership), this must be specifically and explicitly stated, along with a description of the exact use of the data; it must be explicitly indicated if a profile will be created, as well as a clear commitment that there will be no other recipients of the data (or, if there are, their identities must be specified); also a statement must be included stating the period for which the personal data will be retained (defined precisely, and that thereafter it will be deleted, or alternatively that renewed consent will be requested from the data subject and, if not granted, the data will be deleted immediately), that the participant may refuse

consent or withdraw it at any time, that they have the right to exercise their rights of access, deletion, or rectification, and that they have the right to lodge a complaint with the Hellenic Data Protection Authority.

(II) The participant's consent in research must be in writing or must meet the conditions specified in Article 7.2 of the Code of Research Ethics and Conduct. The participant may withdraw their consent at any time, without providing justification and without any consequences.

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 justification and without any consequences.

Article 10 – Special cases (deceased - prisoners)

10.1. The implementation of a research protocol involving deceased persons requires a declaration of consent from their relatives.

10.2. In the case of research involving prisoners, researchers are required to comply with the specific provisions of the Penal Code and the relevant Codes of Ethics in Criminology or Criminal Research. The Committee examines whether the proposed research aims at developing interrogation methods, whether the research may pose risks to the physical or mental health of prisoners, or whether it may diminish their moral integrity or infringe upon their human dignity; in such cases, the research is excluded.

Article 11- Approval of research protocol in studies involving animals

11.1. For projects involving experiments using animals or animal models that require approval from the Committee for the Evaluation of Experimental Protocols, established in accordance with the applicable legislation and comprising specialised scientists to assess ethical issues, the Research Ethics Committee (REC) shall accept the substantiated recommendation of the specialised Committee and shall examine only matters not covered by it.

The Research Ethics Committee (REC) evaluates research proposals which, according to the declaration of the Principal Investigator, involve research on animals (Law 4957/2022, Article 279, para. 2a), without substituting the competent Protocol Evaluation Committee (PEC) of the University of Thessaly. It shall mandatorily consider any prior substantiated evaluation of the

specific research proposal by the latter and shall verify whether the submitted research proposal is covered by the approval of the competent PEC. Research Ethics Committee's decision does not replace the authorisation provided for in Presidential Decree 56/2013. For the convenience of applicants, the application form to the PEC may be the same as that used for submission to the Research Ethics Committee (REC) for approval.

In this case, the applicant must note the application's recipient accordingly.

11.2. The Principal Investigator is required to substantiate the necessity and the manner of use of animals in the laboratory.

11.3. The research protocol submitted by the Principal Investigator must state: (i) whether the research on animals will be conducted on clinical cases or on experimental animals, and (ii) from where (breeding unit for experimental animals) these experimental animals will be sourced. The researcher must also provide the relevant permit from the Region of Thessaly Directorate of Veterinary Services, except in cases where there is a certificate of non-requirement for authorisation of the experimental protocol, or where the researcher justifies the non-submission of the permit, specifying the timeframe within which it will be submitted. The researcher is also required to demonstrate that:

- a) the research team is informed, aware, and appropriately trained and qualified in the use of animals, having thorough knowledge of and applying both the accepted principles of the ethical treatment of animals, and national and European legislation;
- b) the possibility of achieving the same results without the use of animals through alternative methods not requiring animal models has been exhausted;
- c) the benefit arising from the research outweighs any potential harm or distress that may be caused to the animals;
- d) the objectives of the protocol can be achieved with the available infrastructure, training, and experience of the existing personnel;
- e) appropriate measures can be taken for the ethically proper use of animals, the safeguarding of their health and welfare, as well as for the training, supervision, and management of the personnel involved in the research program.

Article 12 - Research concerning the natural, built, and cultural environment

12.1. Any research concerning the environment must be conducted with due care for its protection and in accordance with good practices for the management of biological resources based on

the principle of sustainability.

12.2. Access to biological resources must be carried out in accordance with applicable national legislation and international treaties, and only after securing any required permits from the competent authorities.

12.3. Research that may affect biodiversity must be conducted in accordance with applicable legislation, including but not limited to the United Nations Convention on Biological Diversity (Rio de Janeiro Convention) and the accompanying Cartagena Protocol on Biosafety, as incorporated into Greek legislation by Law 2204/1994.]

12.4. Research involving genetically modified organisms and microorganisms must be conducted in accordance with applicable legislation, including but not limited to the provisions of EU 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 microorganisms, as incorporated into Greek legislation by Ministerial Decision ΗΠ/11648/1943/2002].

12.5. The use, handling, transportation, and disposal of radioactive substances require a special license from the Hellenic Atomic Energy Commission (HAEC), in accordance with the applicable provisions in force at any given time (including, but not limited to: Laws 1733/1987 and 2480/1997, Legislative Decree 854/1971, and Presidential Decree 22/1997).

12.6. In the case of the use of ionising or non-ionising radiation, specific protective measures must be taken both for researchers and for the general public, in accordance with the applicable legislation in force at any given time.

12.7. No research justifies environmental harm in violation of the laws enacted for its protection, as well as waste management.

12.8. No research justifies harm to cultural heritage in violation of the applicable legislation in force at any given time (Law 3028/2002).

12.9. During the execution of technical works within the framework of a research project, the rules of ethics of the applicable Professional Code of Greek Engineers must be observed (as issued pursuant to Articles 24 and 26 of the Presidential Decree of 27-11/14-12-1926 on the “Codification of provisions concerning the establishment of the Technical Chamber of Greece”).

Chapter 3: Research Ethics Committee (REC) operation and decisions

Article 13- Research Ethics Committee (REC) operation

13.1. The Research Ethics Committee (REC) meets regularly once (1) per month and extraordinarily whenever requested by its Chair, or by the Chair of the Research Committee of the University of Thessaly.

13.2. The Chair of the Research Ethics Committee (REC) is responsible for the smooth operation of the Committee and convenes and presides over its meetings.

13.3. The Research Ethics Committee (REC) has a quorum when at least four (4) of its members are present, including the Chair or the Vice-Chair, as well as one of the members who does not belong to the University of Thessaly.

13.4. In the event that a regular member of the Committee is unable to participate, the Secretariat must notify the corresponding substitute member.

13.5. The members of the Research Ethics Committee (REC) are not entitled to remuneration or any other compensation for their participation in the meetings.

13.6. To facilitate its work, the Research Ethics Committee (REC) may cooperate with the National Bioethics Committee and any other competent authority on matters within its remit.

13.7. Minutes are kept at each meeting under the responsibility of the Chair and are approved by the members at the next meeting.

Article 14- Consultation and decision-making

14.1. The Chair may appoint one of the Committee members as Rapporteur for a specific research proposal. The Rapporteur submits their report, in electronic form, within seven (7) days of receiving the proposal.

14.2. If the Committee deems it necessary, it may invite the Principal Investigator to present the research protocol or to provide clarifications thereon.

14.3. The Research Ethics Committee (REC) may invite external experts to provide an opinion on the protocol under review. Where relevant, specialist experts from within or outside the institution in the relevant fields may be called upon to provide their opinion to the Research Ethics Committee (REC).

14.4. The Research Ethics Committee (REC) shall reach a decision within a reasonable time period, not exceeding fifteen (15) working days from the submission of the application and the collection of all required supporting documents. It shall decide in the absence of any invited

party, and only provided that the researcher has submitted all required documentation. Its recommendations and proposals must be reasoned and shall be communicated in writing or electronically to the interested parties.

14.5. In the event of a complaint, the Research Ethics Committee (REC) shall issue a decision no later than fifteen (15) days from its submission. If no decision is made within this deadline, the complaint shall be deemed rejected.

14.6. Decisions are preferably taken unanimously. If unanimity cannot be achieved, decisions are taken by a majority of the members present. In the event of a tie, the Chair's vote shall prevail.

14.7. Voting is open, except in cases of decisions concerning impediments of Committee members, in which case voting is secret.

Article 15- Discussion and evaluation of the working methods of the Research Ethics Committee (REC)

15.1. The Chair may periodically designate a meeting dedicated to the discussion and evaluation of the Committee's working methods and procedures. During such meetings, members are encouraged to express concerns and propose ways to improve the Committee's work.

15.2. Meetings may also be held upon request by members of the Research Ethics Committee (REC).

15.3. External invited experts or members of other Research Ethics Committees of research institutions in the country, or other specialised scientists, may participate in the meetings.

Article 16- Notifications of decisions

16.1. The interested party shall be informed in writing of the decision within three (3) working days of the meeting, and an excerpt of the decision shall be sent to them.

16.2. The decision includes:

- a) the name and title of the Principal Investigator;
- b) the exact title of the project under review;
- c) the exact version of the project or any amendments on which the decision was based;
- d) the supporting documents that were examined (e.g. information sheet, consent form);

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- e) the date of the decision;
 - f) in the case of a conditional approval, all required amendments and the procedure for re-evaluation of the protocol;
 - g) in the case of a positive decision, a list of any obligations of the researcher, e.g., submission of periodic or one-off reports, the need to inform the Committee of any possible future necessary amendments to the protocol, and the need to report serious, adverse, or accidental events during the conduct of the research;
 - h) in the case of a request for revision or amendment, full justification;
 - i) the date and signature of the Chair or, in case of incapacity, the Vice-Chair of the Research Ethics Committee (REC).

Article 17- Request for reconsideration

17.1. Any interested party may submit, before the Research Ethics Committee (REC), within ten (10) days from the issuance of the decision, a request for reconsideration against the Committee's recommendations, submitting new evidence.

17.2. For the examination of the request for reconsideration, the Research Ethics Committee (REC) shall request the opinion of the National Bioethics Committee, which is required to issue its opinion within fifteen (15) days. If the National Bioethics Committee does not issue an opinion within the aforementioned deadline, the Research Ethics Committee (REC) shall proceed with the examination of the request for reconsideration without the Committee's opinion.

Article 18- Monitoring of the research

18.1. During the conduct of the research and depending on its subject matter, the Committee has the discretion to request from the principal investigator a periodic or ad hoc report on issues related to compliance with the ethical framework, as well as on the following: (a) the number of participants, (b) any unforeseen problems that arose, as well as information on any adverse incidents and how they were addressed, (c) participant withdrawals.

18.2. If the Research Ethics Committee (REC) determines that a specific research project, either in its content or due to the manner of its conduct, contravenes the law, generally accepted ethical principles, or the provisions of the Code of Research Ethics and Conduct of the



University of Thessaly, it shall issue comments and recommendations to the researcher for compliance.

18.3. If the principal investigator fails to submit the above information to the Committee, the Committee shall inform them of its possible decision to suspend the conduct of the research, also notifying the Research and Management Committee of the University of Thessaly.

Article 19- Suspension of the research project

19.1. Within the framework of the evaluation of research projects or subsequently, the Research Ethics Committee (REC) may propose changes to the protocol concerning a specific action of the project and/or the entire proposal, and even the suspension of the research in the specific work package (or the entire project), insofar as there is a reason related to research ethics and deontology.

19.2. The Research Ethics Committee (REC) may recommend to the Research and Management Committee the suspension of the continuation of the research if it determines, following a relevant written and signed complaint, that it is being conducted in deviation from the Research Ethics Committee (REC) guidelines, or that it has been associated with unforeseen serious consequences for participants or laboratory animals. The decision to suspend the research is taken by the Research and Management Committee, is fully reasoned, and is communicated to the principal investigator, as well as to the School and Department in which the research is being conducted.

19.3. Prior to any recommendation by the Research Ethics Committee (REC), both the complainant and the principal investigator are invited before the Committee in order to present their views orally and/or in writing regarding the complaint.

Chapter 4: Special provisions

Article 20 – Electronic archive – Secretariat

20.1. The Committee is required to maintain an electronic archive with the following documents:

- a) Incoming and outgoing correspondence log.
- b) The *curricula vitae* of the Committee members.
- c) Minutes of meetings and agendas.
- d) Submitted applications for approval and the corresponding reasoned decisions.
- e) Approved research protocols and accompanying documents.



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- f) Copies of correspondence between the Research Ethics Committee (REC) and principal investigators, including any recommendations to the researcher and all information relating to the possible suspension of approved research.

20.2. The collection, processing, and archiving of personal data shall be carried out in accordance with applicable legislation on the protection of individuals with regard to the processing of personal data and on the free movement of such data, with emphasis on the principles of security of processing systems and the safeguarding of personal data.

20.3. The Secretariat shall maintain a separate electronic protocol and the record of the Research Ethics Committee (REC). The records shall be kept electronically in a secure manner for at least five (5) years after the completion of the research project, unless a longer period is specified by the funding body or applicable legislation. Storage conditions must ensure the protection of confidentiality. Members of the Secretariat must treat and handle as confidential all information and documents related to the requests submitted to it and must not disclose such information or documents to third parties.

20.4. The Research Ethics Committee (REC) shall be provided by the University of Thessaly with appropriate premises and modern, suitable equipment (IT, etc.) for the management of all information produced by the Committee. The relevant costs shall be borne by the budget of the University of Thessaly.

Article 21- Record-destruction protocol

21.1. After the lapse of the time period specified in Article 20 above, the following shall be destroyed, following a relevant decision of the Committee:

- submitted applications for approval
- approved research protocols and accompanying documents
- copies of correspondence between the Committee and principal investigators, including any recommendations to the researcher and all information relating to the possible suspension or termination of approved research.

21.2. The destruction of digital records is governed by the provisions of Presidential Decree 25/2014 (Government Gazette 44/A/25.02.2014) on “Electronic Records and Digitalization of Documents,” Article 11, “Appraisal and Destruction of Printed and Electronic Documents,” as in force.



21.3. The following shall not be destroyed and shall be retained:

- the minutes of meetings and the approval decisions of the Research Ethics Committee (REC)-
- the *curricula vitae* of the Committee members.

21.4. Finally, a destruction protocol is maintained, and for this purpose a Records Destruction Committee is established by the Research Ethics Committee (REC).

Article 22- Revision and amendment of the Articles of the Regulation

22.1. This Internal Regulation shall be reviewed two (2) years after its initial implementation.

22.2. Prior to this period, any proposed amendments shall be approved, upon recommendation of the Research Ethics Committee (REC) by the Research and Management Committee of the University of Thessaly, provided that they are supported by two-thirds (2/3) of its members.

Article 23- Clarification

Among the responsibilities of the Research Ethics Committee (REC) also falls the examination of ethical issues of the University of Thessaly, such as matters of plagiarism (in postgraduate theses, doctoral dissertations, and more generally in research protocols), which fall within the scope of research ethics and integrity matters. The Research Ethics Committee (REC) makes recommendations—without its recommendation being binding—as a first-instance body to the corresponding Ethics Committee of the University of Thessaly.