

# **Regulation of Principles and Procedures of the Research Ethics Committee, AUTH**

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4. Participant's Informed Consent Form
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## ACRONYMS

<b>AUTH</b>	Aristotle University of Thessaloniki
<b>CEEP</b>	Committee for the Evaluation of Experimental Protocols
<b>EU</b>	European Union
<b>GMO</b>	Genetically Modified Organisms
<b>GMP</b>	Genetically Modified Products
<b>L</b>	Law
<b>LTS</b>	Laboratory Teaching Staff
<b>MAR</b>	Medically Assisted Reproduction
<b>NOM</b>	National Organisation for Medicines
<b>PD</b>	Presidential Decree
<b>REC</b>	Research Ethics Committee
<b>SARF</b>	Special Account for Research Funds
<b>SES</b>	Special Educational Staff
<b>SL</b>	Scientific Leader
<b>SPLS</b>	Special Technical Laboratory Staff
<b>TRS</b>	Teaching and Research Staff
<b>UNO</b>	United Nations Organisation

## REGULATION OF RESEARCH ETHICS

The Postgraduate Programs of School of Health Sciences, Faculty of Medicine AUTH are fully harmonized with the Regulation of Principles and Operation of the Research Ethics and Ethics Committee of the AUTH.

### CHAPTER I: GENERAL PROVISIONS – ESTABLISHMENT, MEMBERSHIP, REMIT AND OPERATION OF THE REC OF THE AUTH

#### ARTICLE 1. SCOPE

1. The Research Committee of the Aristotle University of Thessaloniki draws up this Regulation on **Principles and Procedures** (hereinafter the Regulation) of the **Research Ethics Committee (REC)** of the **Aristotle University of Thessaloniki (AUTH)**. The Regulation details the values and principles of research ethics that apply to any research project carried out at the Aristotle University of Thessaloniki, the procedures for the submission of proposals for approval to the REC of the Aristotle University of Thessaloniki and their accompanying documents, the evaluation process by the Teaching and Research Staff, the forms of cooperation between the REC and other Research Ethics committees or Bioethics committees which operate in Faculties or Departments of the Aristotle University of Thessaloniki, the National Commission for Bioethics, any other competent national AUTHORITY, as well as any other issue related to the operation of the REC. The Regulation is accompanied by an annex which includes the documents submitted by the scientific leader (SL) or used by the REC, namely the application form, the declaration by the SL, the questionnaire and self-assessment report, an informed consent form and the evaluation report.

2. This Regulation is drafted in accordance with the provisions of article 68, Law 4485/2017, and articles 21-27, Law 4521/2018, with the aim to serve as a tool to facilitate cooperation between the AUTH and researchers, the society and research funding bodies and to ensure the observance of basic principles of integrity and ethics (reliability and quality) in the exercise of the research activity of its members.

3. The Regulation applies to all research and development activities carried out under the responsibility, or with the participation, of members of the Aristotle University of Thessaloniki, whether on its premises or outside them, with or without funding. The provisions of the Regulation also apply to activities providing specialized services, training programs or other scientific applications as well as to other development activities carried out in parallel with research activities at the Aristotle University of Thessaloniki. Any individual regulation that has been or will be adopted by Faculties, Schools, Clinics, Laboratories or Academic Units of the AUTH must be aligned to this Regulation.

4. The term “researcher” covers all faculty members, Special Educational Staff, Laboratory teaching staff, Special Technical Laboratory Staff, emeritus professors and retired faculty members, PhD holders and PhD candidates, MA holders and students of Postgraduate Programs, holders of a university degree or other equivalent title issued by a Greek or foreign institution, as well as any other person employed in the ongoing research.

#### ARTICLE 2. ESTABLISHMENT AND PURPOSE

1. The REC is established and operates at the Aristotle University of Thessaloniki in order to comply with the provisions of articles 21-27, Law 4521/2018 and to ensure the application of the accepted fundamental principles of research ethics as analysed below.

2. The purpose of the REC is to provide, on an ethical level, guarantees of reliability of the research projects carried out at the Aristotle University of Thessaloniki. The REC monitors whether a research project is carried out with respect for fundamental human rights, the value of human beings, the autonomy of the persons involved, their privacy and personal data, as well as with care for the natural and cultural environment. It

also monitors compliance with the generally accepted principles of research integrity and the criteria of a fair scientific practice.

### **ARTICLE 3. MEMBERSHIP – TERM OF OFFICE**

**1.** The REC of the Aristotle University of Thessaloniki consists of seven (7) full members with their alternates, as provided for by the relevant decision of the Research Committee of the Aristotle University of Thessaloniki.

Its members shall be scientists, specializing in research, ethics or bioethics and research ethics. Five (5) of its members - and their alternates - shall be members of the staff of the Aristotle University of Thessaloniki. Two (2) of its members - and their alternates - shall be persons from outside the Aristotle University of Thessaloniki (external members). At least one (1) of the seven (7) members - and his/her alternate - shall be specialized in ethics or bioethics. The thematic subjects and/or the general research and scientific work of the members of the REC must ensure, as far as possible, the representation of all thematic subject areas offered at the Aristotle University of Thessaloniki.

**2.** The members of REC are selected following a call for expressions of interest to fill these positions. The call is prepared by the Research Committee of the institution and published on the website of the Aristotle University of Thessaloniki, no later than three (3) months before the end of the term of office of each member. The call shall specify the exact number of members of the REC and the qualifications that its members must possess, depending on the scientific fields within the AUTH. Nominations and all necessary supporting documents are submitted by those interested online through the AUTH website. The Research Committee of the Aristotle University of Thessaloniki shall evaluate nominations and shall decide on the membership of the REC taking into account the following:

1. The need to cover one or more thematic and scientific subjects, which are offered by the AUTH,
2. The applicants' specialization in research, in ethics and bioethics, in research regarding the protection of personal data, etc.,
3. Candidates' knowledge of, or expertise in, national and European institutional framework on issues related to ethics and research ethics,
4. The candidates' publications on research ethics issues,
5. The candidates' participation in other collegiate bodies which take decisions or provide advisory opinions on ethics and research ethics.

The final composition of the REC shall ensure an interdisciplinary approach and a comprehensive coverage of scientific, legal, and ethical issues arising in the context of research.

**3.** The REC shall be constituted by decision of the Rector of the Aristotle University of Thessaloniki. The decision establishing the REC shall designate its Chair and Vice-Chair, as well as the alternate member for each full member.

**4.** The term of office of the members of the REC shall be three years and may be renewed only once. If a member of the REC resigns, passes away or his/her term of office is otherwise terminated, s/he shall be replaced for the remainder of his/her term of office by his/her alternate member.

### **ARTICLE 4. COMPETENCES**

**1.** The main competence of the REC of the Aristotle University of Thessaloniki is to determine whether a specific research project to be carried out at the Aristotle University of Thessaloniki infringes the legislation in force and whether it complies with generally accepted rules of ethics and research ethics in terms of its content and manner it is conducted. In particular:

- a. Funded research projects that, according to a declaration by the SL, involve research on humans, on material derived from humans (genetic material, cells, tissues, and personal data), on animals or on the natural and cultural environment, must be submitted for

approval to the REC before the start of their implementation. If these research proposals are submitted for approval to research ethics committees or to bioethics committees, which operate in Faculties or Departments of the Aristotle University of Thessaloniki, these latter shall make relevant recommendations to the REC, which shall be the decision-making body for the final approval of the research proposal.

- b. In addition to the research projects referred to in the previous case, the REC may examine, at the request of any interested person or following a relevant complaint, any other research project and give an opinion on ethics issues related to an article to be published in a scientific journal or to a bachelor dissertation, a postgraduate thesis or a doctoral dissertation under preparation.
  2. The REC shall evaluate the research proposal and shall either:
    - a. approve it; or
    - b. make recommendations and suggestions for its revision if ethical issues arise. All recommendations and suggestions shall be specifically reasoned.
  3. In the event that the REC makes recommendations and/or suggestions, the applicant(s) must re-submit the application in compliance with them. If the resubmission of the research proposal establishes compliance of the applicant, the REC shall approve the proposal; otherwise, it shall make recommendations again in accordance with case (b) of the previous paragraph. This procedure may not be repeated more than three (3) times.
  4. The REC can, whenever it deems appropriate, request further information or clarifications from the scientific leader of the research project and monitor the progress of the projects it approves, such as to provide and/or submit periodic reports to the REC, on issues related to the respect of the ethical framework, in particular regarding the following points:
    - the number of participants
    - any unforeseen problems encountered, or unexpected findings, as well as information on any unfortunate incidents and ways to deal with them;
    - the withdrawal of participants.
- Whenever it is determined that a research proposal needs additional checks or periodic reassessment, the Chair of the REC shall appoint one of its members (as a priority) or an external expert, to be responsible for carrying out the necessary checks.
5. Furthermore, the competence of the REC includes the training of research staff, students, and doctoral candidates of the Aristotle University of Thessaloniki on issues of research ethics and the provision of advice regarding the drafting of research proposals, so that they comply with the accepted principles of research ethics and ethics.
  6. The REC has the competence to provide advice on issues of integrity in the investigation (plagiarism, construction of results, conflict of interest, etc.). Therefore, it can examine whether a relevant complaint that it has received is sufficiently founded, in order to forward it to the competent bodies (such as the Ethics Committee of the Aristotle University of Thessaloniki or any other competent disciplinary or other body of the Aristotle University of Thessaloniki).
  7. The REC may provide scientific opinions or recommendations on ethical issues to the Research Committee of the Aristotle University of Thessaloniki, if requested.

#### ARTICLE 5. SUBMISSION OF RESEARCH PROPOSALS

1. Any proposal for a research project submitted for approval to the REC shall necessarily be accompanied by:
  - a relevant **Application form**,
  - a relevant **Declaration form** (hereinafter referred to as the **Declaration by the Scientific Leader**),



that s/he has become aware of this Regulation and that s/he undertakes to

comply with its provisions, as well as with the decisions of the REC of the Aristotle University of Thessaloniki related to his/her research. and

- a relevant form with a **Questionnaire and Self-Assessment Report** (hereinafter referred to as Questionnaire and Self-Assessment Report), about the suitability and compatibility of the research project with the applicable international, European, and national legislation. In the Self-Assessment Report, the SL shall determine whether the purpose and methodology of the research project are compatible with the principles of ethics that the Aristotle University of Thessaloniki recognizes as fundamental and with the relevant legislation; s/he shall also describe the intended objectives, the expected scientific benefits and whether care has been taken to ensure that the project complies with the provisions of this Regulation.
- In case the research project involves natural persons, the proposal shall also submit the relevant Informed Consent Form and all other information material that will be distributed to them (separate forms, such as questionnaires).

2. The application and all supporting documents must be submitted by the SL of the project electronically to the following email address [ethics@rc.AUTH.gr](mailto:ethics@rc.AUTH.gr) or in person at the offices of the AUTH SARF Financial and Administrative Support Unit, at the secretariat of the REC. In the case of dissertations, postgraduate theses and doctoral dissertations, the application shall also be signed by the supervising professor.

3. The secretary of the REC shall verify that the application submitted is complete (signed application, full set of accompanying documents as appropriate). If s/he finds that there is something amiss, s/he shall inform the applicant(s) so as to make the necessary corrections and/or additional actions. The application shall be given a file number when it is complete in accordance with the previous subparagraph.

4. The application shall be transmitted without delay electronically to the Chair of the REC, who shall appoint a member of the Committee as a rapporteur prioritizing depending on the scientific subject of the research project. If the subject of the project cannot be covered by any member of the REC, an external expert shall be appointed to provide an opinion and recommend to the REC.

5. If there is a conflict of interest in the person of the rapporteur in accordance with Article 8 para. 2 of this Regulation, s/he must declare this to the Chair of the REC, who shall make sure to replace him/her.

## ARTICLE 6. EVALUATION OF RESEARCH PROPOSALS – DECISION-MAKING

1. The rapporteur shall prepare and transmit his/her report by completing the relevant form of the Evaluation Report. His/her recommendation must contain an assessment of the compliance or non-compliance of the proposal with the accepted fundamental principles of research ethics and with the relevant international, European, and national legislation, as well as the degree of awareness of the researchers involved regarding the ethical and social implications of their research. In addition, if required by the regulatory content governing the specific field of research activity (for example, research into the medical-biological potential of embryonic stem cells), it must contain an opinion on respect for the principle of proportionality<sup>1</sup> of the research methods and protocols to be applied and detailed recommendations regarding improvements or changes deemed necessary. The possible conclusions of the report may be that:

- a. The proposal does not raise any ethical issue and therefore it recommends the approval

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<sup>1</sup> The research procedures used to achieve the objectives pursued must be absolutely necessary and there must be no suitable alternatives.

of the research proposal.

- b. Ethical issues arise but these have been fully addressed and therefore it recommends the approval of the research proposal.
- c. When ethical issues arise that have not been fully addressed, it shall make recommendations in order to revise the research proposal.
- d. It requests additional clarifications.

2. The REC shall discuss the request and reach a decision within a reasonable period that may not exceed fifteen (15) days from the submission of the application and all necessary accompanying documents, as well as the provision of any additional clarification. If, within the period of fifteen (15) days, the REC does not discuss the request, the application shall be considered approved.

3. Whenever it deems necessary, the REC may invite the researcher responsible to present the research protocol or provide clarifications on it.

4. If the legislation provides for the approval or AUTHorisation 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 AUTHorisation. The REC bears no responsibility for the researchers' failure to receive the required AUTHorisations. It is recommended that research proposals submitted to the REC have already obtained the approval required by the relevant administrative bodies or AUTHorities. If, however, the proposal is submitted first to the REC, the REC shall decide on the merits without requiring the prior approval by the competent administrative institution. In its decision, it must remind the researcher of the need for such approval/AUTHorisation in order to carry out the research work. If the REC deals with the proposal at a later stage, it may make additional comments in the form of recommendations to the researcher for the improvement of the research proposal from an ethics viewpoint.

5. The decision of the REC shall be taken by a majority of the members present, after every effort has been made to reach unanimity. In the event of a tie, the Chair shall have the casting vote. The vote is open.

6. The decision shall include: (a) the name and title of the researcher responsible, (b) the exact title of the protocol examined, (c) the accompanying documents examined, (d) the date of the decision, (e) a list of contingent obligations of the researcher, such as the obligation to submit periodic or one-off reports; (f) in the event that the reply requires to review or modify the proposal, a full reasoning; (g) a reminder to the researcher of the obligation to obtain an AUTHorisation from other administrative bodies/AUTHorities (where required), (h) the date and signature of the REC's Chair or, in case of his/her impediment, of its Vice-Chair.

7. The interested party shall be informed in writing of the decision within three (3) working days of the meeting. The decisions of the REC are binding for researchers and the Aristotle University of Thessaloniki.

8. In the event of a complaint, the REC shall take a decision no later than fifteen (15) days after the submission of the complaint. If no decision is taken within that period, the complaint shall be deemed to have been rejected. In the cases where the REC considers that the complaint is well-founded, it shall inform thereof the Research Committee of the Aristotle University of Thessaloniki and all other competent bodies of the Aristotle University of Thessaloniki.

#### **ARTICLE 7. REQUEST FOR REMEDY**

Any interested party may file, before the REC, within ten (10) days from the issuance of the decision, an application for remedy against the recommendations of the Committee by submitting new information. Before the examination of the application for remedy, the REC shall request

the opinion of the National Commission for Bioethics, which must issue it within fifteen (15) days. If the National Commission for Bioethics does not issue an opinion within the above deadline, the REC shall proceed to examine the request for remedy without the opinion of the former.

#### **ARTICLE 8. OPERATION OF THE REC**

1. The REC of the Aristotle University of Thessaloniki shall meet regularly once (1) a month and exceptionally whenever requested by its Chair or the Chair of the Research Committee of the Aristotle University of Thessaloniki.
2. The President of the REC shall be responsible for the proper functioning of the Committee and shall call and direct its meetings. The Vice-Chair shall exercise the duties of the Chair in the event of his/her being prevented from attending. S/he may also be asked by the Chair to perform additional duties, such as supervising part of the agenda.
3. The REC is in quorum when at least four (4) of its members are present, including its Chair or Vice-Chair, as well as one (1) of its members who do not belong to the Aristotle University of Thessaloniki. It shall take decisions by a majority of its members present.
4. If a member of the Committee is prevented from attending, the alternate must be notified by the Secretariat.
5. Meetings of the REC may also be held remotely by electronic means.
6. Members shall receive a calling notice and all relevant files for discussion prior to the meeting. The calling notice shall indicate the agenda points as determined by the Chair. A point not included in the agenda may be discussed if all members present agree.
7. Members of the REC are not entitled to any remuneration or any other form of compensation for their participation in its meetings.
8. The REC shall receive secretarial support by the AUTH SARF Financial and Administrative Support Unit,
9. At each meeting, minutes shall be kept under the responsibility of the secretary of the REC. The minutes shall be communicated to all members of the Committee and shall be signed by all members present at each meeting. The minutes shall include information concerning the place and time of the meeting, the quorum of the Committee, the issues discussed, and the decisions reached, including the result of the relevant votes, if a vote is taken. Any variations of members shall be recorded in the minutes upon request.
10. In order to facilitate its work, the REC may cooperate with the National Commission for Bioethics and any other competent AUTHORITY on issues related to its competences.
11. The REC shall set up a register of rapporteurs and experts to support its work. The register shall be updated annually under the responsibility of the Committee's Chair, depending on the scientific fields served in the faculties of the Aristotle University of Thessaloniki and the subject of the research proposals submitted to the REC, ensuring that both sexes are equally represented, to the extent possible.

#### **ARTICLE 9. INCOMPATIBILITIES – CONFLICT OF INTEREST – OBLIGATION OF CONFIDENTIALITY**

1. Membership of the REC is incompatible with the positions of Rector, Vice-Rector, and Dean, as well as member of the Research Committee or Head of Department of the AUTH.
2. A member of the REC shall be prevented from participating in 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 which may affect or appears to affect the impartial and objective performance of his/her duties. This means any potential advantage in favour of him/her, his/her spouse or first-degree relative. In the event of such an impediment in the examination of a specific proposal under

assessment, the member of the REC shall immediately inform thereof the Chair, who shall arrange for his/her replacement by the alternate member. The member concerned shall leave the meeting before the start of the debate. All the above as well as any other similar issue that may affect the impartiality of the member shall be noted in the minutes of the meeting.

**3.** The members of the REC are obliged to maintain absolute confidentiality regarding any information that comes to their knowledge during the performance of their duties. The obligation also applies to any external expert or rapporteur invited to provide an opinion/recommendation on a specific research proposal, the Secretary of the Committee as well as any other person involved exercising supportive work. They are not allowed to disclose, in any way, confidential information or personal data which became accessible to them by reason of their duties.

#### **ARTICLE 10. RECORD KEEPING - SECRETARIAT**

**1.** The REC shall be obliged to keep an electronic record of the following documents:

- A registry with protocol numbers for all incoming and outgoing mail.
- The CVs of the members of the Committee.
- Minutes and agendas of meetings.
- The applications submitted for approval and the corresponding reasoned decisions.
- The approved research protocols and accompanying documents.
- Copies of the correspondence between the REC and the researchers.

**2.** The collection, processing and keeping of personal data is carried out in accordance with the applicable legislation on the protection of individuals with regard to the processing of their personal data, giving emphasis on the security principles of the systems for processing and retaining personal data.

**3.** 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 such information or documents to any third party.

## CHAPTER II. GENERAL PRINCIPLES OF RESEARCH ETHICS

### ARTICLE 11. GENERAL PRINCIPLES OF RESEARCH ETHICS AND BIOETHICS

1. Research is based on the same ethical values that apply in everyday life, such as honesty, impartiality, objectivity, openness, reliability, and respect for others. In particular regarding biomedical research, the principles of benefit, avoidance of harm, justice and autonomy also apply. The term "scientific standard" refers to the practical application of these values in the context of research. Each researcher must, at every stage of his/her research activities, respect and adhere scrupulously, in combination and to the extent that they arise, these fundamental principles, as enshrined in international declarations, conventions and other official texts, and comply with the applicable scientific standards.

2. Researchers who are members of the Aristotle University of Thessaloniki must:

- a. Ensure the protection of the dignity and identity of all human beings and guarantee, without any discrimination or exception, respect for their physical and mental integrity, rights, and fundamental freedoms.
- b. Ensure that individuals' interests and well-being are placed above the interests of society or science, as the effort to achieve beneficial collective goals does not remove the obligation to respect fundamental human rights and freedoms.
- c. Seek scientific truth in accordance with the appropriate and widely recognized scientific methodology and ethics.
- d. Ensure the welfare and protection of humans, animals, elements of the environment, biodiversity, as well as any other ethically relevant subject matter which is affected by the research or will be affected in the future, or, if this is not possible, the avoidance of causing serious, irreversible and uncompensated damage to them.
- e. Ensure respect for the autonomy, equality, diversity, privacy and other guaranteed individual rights and freedoms of all persons affected by research or who will be affected in the future by it. In addition, whenever the participants in the survey are minors, vulnerable persons, are unable to give their consent or belong to other sensitive population groups, researchers must recognize and respect the particularities that characterize them and ensure their protection.
- f. They comply with the provisions of the applicable national, European, and international legislation, as well as all the procedures (granting of AUTHORIZATIONS, etc.) for the conduct of the research provided by the Aristotle University of Thessaloniki and any other competent public AUTHORITY. In particular, the provisions of the European Charter for Researchers and the European Commission's European Charter for Researchers and Code of Conduct for Recruitment of Researchers.

### ARTICLE 12. RESPONSIBILITIES AND OBLIGATIONS OF RESEARCHERS

1. All AUTH researchers, in relation to their research activities, are personally responsible for acts or omissions related to the compliance with this Regulation, applicable national, European, and international legislation and international declarations and conventions. In particular, researchers are obliged to:

- a. Receive prior written consent from all persons participating in the research or from their legal representatives, after having fully and clearly informed them of the content and objectives of the research. Such consent must not be the result of coercion or deception and may be revoked at any stage of the research. Exceptionally, whenever full or absolutely clear prior information to the participants about the objectives of the research may affect its validity, the receipt of the written consent may follow the completion of

the survey and concern the use of the research data. If a written consent is not required, as in the case of conducting a survey with anonymous questionnaires, instead of the consent form, participants in the survey may be given only the information form and other information material. The obligation to provide information includes, where appropriate, persons who are not directly involved in the research, but who are affected by its conduct.

- b.** Ensure the protection of the personal data of the participants in the research in accordance with the applicable legislation by applying commonly accepted practices of anonymization - pseudonymization.
  - c.** Keep complete records of the development and results of their research activities for a period of ten (10) years.
  - d.** Ensure, in accordance with current practice, that the participants in the research are selected in a manner consistent with the principles of equal treatment and impartiality in conjunction with the sampling criteria dictated by the objectives of the research.
  - e.** Respect the principle of impartiality.
  - f.** Not conceal or distort the results of their research (duty of scientific truth).
  - g.** Participate and cooperate in any quality control and assurance process carried out by the Aristotle University of Thessaloniki or any other public AUTHority.
  - h.** Observe the general and special rules of safety and health in all premises and areas of the AUTH or in any other research premise or other area they implement their researchwork.
  - i.** Adhere to the principles of sound, transparent and efficient financial management.
  - j.** Not accept, when concluding funding agreements, terms that compromise their freedom and integrity, as well as the prestige and interests of the AUTH regarding the design, conduct and publication of their research.
  - k.** Respect the individual ethical principles and ethical rules that apply in every field of science and humanities.
  - l.** Be constantly informed about developments concerning the individual ethical principles and ethical rules that govern the scientific field in which they specialize.
  - m.** Report any conflict of personal, professional, or economic interest which exists before the start of the research activity or arises during its implementation.
  - n.** Respect all ethical commitments relating to their discipline (this provision applies to specific categories of researchers, such as medical doctors, lawyers, psychologists, etc.).
- 2.** In any case of violation of the above, the researchers are controlled in accordance with the applicable national and European legislation and the provisions of the Internal Regulation of the Aristotle University of Thessaloniki.

### **ARTICLE 13. REGULATION OF RELATIONS BETWEEN RESEARCHERS**

Regarding the relationships between researchers, the following rules shall apply:

- a.** Researchers are obliged to respect each other and their contribution to the final result of the research must be duly recognised in accordance with intellectual property law. Concerning in particular publications, the order of co-AUTHors is determined by agreement among the participants, taking into account that the participation and position in the writing team is based on the significance of the researcher's contribution to the design of the research, the acquisition of data, and/or the analysis and interpretation of the results.
- b.** Any SL of a research project must be fully consistent with his/her obligations towards the Research Committee of the AUTH and other involved stakeholders and must ensure that the members of his/her research team comply with this Regulation.

- c. Any SL of a research project may replace researchers participating in the project in case they violate this Regulation or perform their work inadequately.
- d. In case any of the above principles are violated, 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 Aristotle University of Thessaloniki, reporting any such violation.

#### **ARTICLE 14. RESPONSIBILITY AND OBLIGATIONS OF THE AUTH**

The Aristotle University of Thessaloniki, through its competent bodies, is obliged to:

- a. Promote scientific research within its capabilities, making fair and transparent use of available resources.
- b. Ensure the implementation of the principles governing research ethics by the entire academic community, as well as provide continuous relevant information and training to its members.
- c. Ensure the smooth conduct of research and the protection of the rights of researchers and participants in research, in the context of the general principle of academic freedom and of this Regulation.
- d. Take care, within the framework of its responsibilities, to communicate, recognize and disseminate the results of scientific research.

#### **ARTICLE 15. LINKING RESEARCH ACTIVITY WITH THE FUNCTIONS OF AUTH**

1. Research is one of the core mission pillars of higher education institutions and a lever for their development. Its conduct must be in harmony with the other educational processes and functions of the institution.
2. The implementation of the physical scope of research projects and the financial management of research funds is subject to the rules and procedures provided for in the Funding and Management Guide issued by the Research Committee of the SARC Aristotle University of Thessaloniki as well as to the specific regulatory or contractual management framework that may govern them.
3. In the case of funded research projects, the conduct of the research activity requires a written notification to the Department's Director and to the Director of the relevant laboratory/clinic (if any) or research institute by the research SC. In any case, the procedures described in the internal regulation of the laboratory or clinic, if any, shall be followed.

#### **ARTICLE 16. USE OF AUTH FACILITIES AND EQUIPMENT**

1. The facilities and equipment of the Aristotle University of Thessaloniki may be used to conduct research which is not funded by the university. In such a case, a) a certificate is required by the SL that s/he has become aware of this Regulation and that s/he undertakes to comply with it; and b) a relevant approval and certificate is required by the competent administrative body of the structure of the University (Laboratory, Clinic, School, Department, Centre) where the research SL serves, that the use of facilities and equipment of the structure does not hinder the educational processes and other research activities of its members.
2. The use of the facilities or equipment of the Aristotle University of Thessaloniki for research or provision of services, implies the management of the research and its financial results (if it is funded outside the regular budget of the Aristotle University of Thessaloniki) by AUTH's SARC. In any case, regardless of the existence of financial results, the rules of research ethics must be observed.
3. Such use as mentioned above should serve exclusively the purposes of the specific research



project.

#### **ARTICLE 17. RESEARCH SAFETY AND CONTROL PROCEDURES**

1. Researchers of the Aristotle University of Thessaloniki must apply all the safety and health rules recognized in their relevant scientific field, as well as those specifically stipulated in the following provisions, in order to best protect the safety and health of all those involved from accidents, illnesses and other adverse consequences for them. In case the observance of safety rules depends on infrastructure issues (workplaces, electrical installations, ventilation, etc.) or work equipment (instruments, devices, machinery, etc.), they must inform the competent bodies of the Aristotle University of Thessaloniki, so that the necessary measures be taken immediately. Special care must be taken to inform everyone involved about the use of chemicals and medicines, the management of biological material, fresh or preserved with formalin or another preservative, the use or movement of radioactive sources and material and the use of ionizing or non-ionizing radiation, etc. and the use of individual protective measures.
2. Laboratories and other research premises shall meet appropriate safety standards and be certified as appropriate in accordance with internationally recognised standards. Research staff must come from the appropriate scientific specialisation, possess the appropriate scientific expertise, and have completed any necessary training, as required, and/or be certified accordingly.
3. Researchers shall evaluate safety-related information and procedures at least once a year.
4. Researchers shall keep a complete record of the development and results of a research project in order to allow for control, while safeguarding intellectual property rights. In the case of clinical studies of medicinal products, researchers are obliged to follow the guidelines of the National Organization for Medicines regarding the appropriate supervision, monitoring and control of data and incidents related to the safety of participants. (e.g., reporting of serious adverse reactions).

#### **ARTICLE 18. RESPECT FOR THIRD PARTY RIGHTS**

Researchers at the Aristotle University of Thessaloniki must, during the conduct of the research, show due respect for the dignity and individual rights of third parties involved in the research activity. More generally, they shall take care to avoid any form of discrimination vis-à-vis participants on grounds of sex, racial or ethnic origin, disability or illness, religion or belief, age or sexual orientation, membership of a national minority, language or property.

#### **ARTICLE 19. RESPECT FOR INTELLECTUAL PROPERTY RIGHTS**

1. Researchers, when carrying out their research activities, must take into account and not infringe in any way the intellectual property rights of third parties, in accordance with the requirements of the applicable legislation on the protection of intellectual and industrial property and related rights. Through its competent legal services, the Aristotle University of Thessaloniki must take care, in addition to safeguard its own intellectual property rights, to also protect the relevant rights of researchers, regarding the results of research projects.
2. Any person who officially or informally becomes aware of the progress or proceeds of research prior to its completion, publication and validation of its final results shall be bound by absolute confidentiality and must avoid any particular action for his/her own benefit in this regard.
3. Researchers at the Aristotle University of Thessaloniki acquire an intellectual property right over the subject of the research they conduct and its products, depending on the degree of their contribution, without prejudice to the regulatory framework for project management set by the funding bodies, as well as the contractual terms governing the agreements with them. In any case, in the case of an industrial property right, the researcher reserves the moral right of the

creator/inventor, and this must be acknowledged in any publication, disclosure or reference to scientific events, conferences, etc.

4. Plagiarism, the use of evidence, documentation, and data without the required permission, as well as the appropriation of other persons' achievements, are practices that are disapproved by the academic community of the University, are contrary to fundamental scientific values and undermine scientific progress. In addition, they may have adverse consequences for the institution. In this sense, it is prohibited in particular:

a. The construction of data or results (whether intended or unintentional construction of research data or of results that do not exist).

b. The falsification of scientific data or results (the alteration or inaccurate reporting of research data or results).

c. Plagiarism (the use of ideas or expressions of other researchers without proper reference).

5. If the REC finds that unfair practices have occurred in accordance with the preceding paragraph, it shall draw up a report to that effect, which it shall forward to the competent bodies of the institution.

#### **ARTICLE 20. VISIBILITY OF THE RESEARCH**

1. Signs, websites, announcements, and any other 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 brochures of the research teams should be done with care, so as not to create confusion as to the research operator, not to provide the impression of advertising specific products and not to give the impression of a permanent connection of the sponsor with the University.

2. Signs, websites, and all kinds of promotional material for the programmes must indicate all the contributors to the research.

3. Any publication, presentation at conferences, or any other way of publicity of the research results should mention the connection of the researchers with the Aristotle University of Thessaloniki and should use the official insignia and logos of the Aristotle University.

## CHAPTER III: SPECIAL PROVISIONS FOR CONDUCTING RESEARCH AT THE AUTH

Any human activity may have an ethical component and raise ethical issues. When conducting scientific research, which is an evidently crucial and necessary human activity, there is a clear need for thorough evaluation. Good scientific practice implies the application of fundamental ethical principles to research, and all possible areas of scientific research may raise related issues.

The practical application of the rules of ethics does not concern only the relevant scientific theory and complex theoretical analyses of issues of philosophy and logic. While it is true that the application of ethical rules to research activity de facto places restrictions on what is allowed (under certain conditions and perspective, which are often modified over time), it does not aim at regulating research activity or at the absolute control and limitation of the freedom of researchers, but at ensuring the reliability and quality of research activities and their results.

The observations and suggestions that a full evaluation of a research proposal may contain must be respected, so that in cases where specific research practices raise ethical issues, appropriate measures are taken to respect fundamental human rights and freedoms. This aspect of research activity is often ignored or considered minor. Below, we develop more specific issues of research ethics and describe the values and principles that the Aristotle University of Thessaloniki considers fundamental to the research activity implemented in it.

### ARTICLE 21. RESEARCH INVOLVING PERSONS

1. Researchers must follow the proper research design so that risks to participants are non-existent or are minimal. The research procedures must not unreasonably endanger the participants unless these procedures are already part of the diagnosis or of the usual treatment and subsistence of the participants.
2. If there are effects on the persons involved, they should not endanger the lives of individuals or harm their health in an irreversible manner and be outweighed by the expected benefits that will accrue to them.
3. In addition, researchers must not:
  - a. State, promise or imply that positive results will unfailingly occur for the participants in the research.
  - b. Advertise the intervention or the product under research as safe, effective or better than other existing products or interventions.
  - c. Use language such as "new drug" or "new treatment" without explaining that these are under study.
  - d. Promise a free treatment or other benefits, when essentially this means that the participants will not pay to take part in the research.
  - e. Take advantage of a pre-existing unequal relationship they may have with specific individuals (patients, trainees, etc.) in order to secure their participation in the research.

### A. INFORMED CONSENT

1. A prerequisite for the implementation of any research project that requires the participation of persons is the receipt of their consent in writing, after their full and appropriate information. If a written consent is not required, as in the case of conducting a survey with anonymous questionnaires, participants in the survey shall receive, instead of the consent form, only the information form and other information material. The consent of the participants must be achieved ex ante, regardless of the type of research, without prejudice to the above Article 11, paragraph 1.
2. Each research participant shall be adequately informed of the objectives, methods, sources of

funding, potential conflicts of interest, institutional relationships among the researchers and with the facility where the research project is carried out, the expected benefits, possible risks, and any nuisance that his/her participation in the research may entail. Where it is established that the information provided has been understood, the researcher should obtain in writing the freely given consent of the participant. If consent cannot be given in writing, a non-written consent must be documented by recording it in a special file and given in the presence of a third party. The consent process is facilitated on a case-by-case basis and becomes more reliable when additional information material is provided in an appropriate format or if additional meetings are scheduled between the researcher and the candidate participant and/or his/her legal representatives.

**3.** Someone's consent is valid when the following have applied:

- a. S/he has received, orally and in writing, sufficient information, understandable for his/her cognitive and intellectual level, preferably in his/her mother tongue.
- b. S/he has been given sufficient time to study the information and the consent form.
- c. Consent must be given voluntarily and must not be the product of error, manipulation, coercion, or transaction.
- d. S/he has legal capacity.

**4.** The consent form, which is given to the research participants together with the appropriate information form and other information material, should include:

- a. The title of the research to be carried out.
- b. The purpose of the research to be carried out.
- c. The expected duration of the individual's participation in it.
- d. The description of the procedure to be followed.
- e. The identification of the procedures that are under study and at an experimental stage where required.
- f. The description of finite limited risks, if any.
- g. The description of the expected benefit for the participants, for third parties or for scientific research in general.
- h. A detailed report on the procedures that will be followed for the protection of participants' personal data.
- i. The explanation of complications or harm that may arise for participants, as well as the procedures for compensation and provision of treatment in case this result occurs.
- j. The details of the researchers whom the individual may contact if s/he wishes information about the research, including the Data Protection Officer.
- k. The assurance that participation is voluntary, that refusal to participate does not entail any consequences for the person and that s/he can withdraw from the research at any time s/he wishes, without any consequence.
- l. Information about the proper use and provision of all the required personal protective equipment that will be used during the research.
- m. The funding sources.

## **B. VULNERABLE PERSONS & SENSITIVE POPULATION GROUPS**

**1.** Researchers must respect the, even limited, autonomy and the rights of vulnerable persons and vulnerable groups of the population (children, inmates, mentally ill persons, people with a low level of education, members of minority groups, terminal patients, apprentices, subordinates, crime victims, etc.). Research projects involving such individuals are considered justified if it is methodologically necessary to include vulnerable persons and sensitive population groups in the research, or when the implementation of

the research project will bring benefits to the participants or to other individuals with the same vulnerability characteristics and if the risk to the participants is minimal. Criteria of vulnerability include a lack of legal capacity, a lack or limitation of free choice and particular physical, mental, or social characteristics that make individuals more vulnerable to exploitation or risk. When the implementation of a research project requires the participation of vulnerable persons and vulnerable population groups, it is necessary to include in the research protocol a plan to minimize the risk of exploitation and the appropriate protection measures for such individuals.

**2.** In the case of research projects involving minors, researchers shall be bound by the UN Convention on the Rights of the Child and shall:

- a. Ensure that the results of the research cannot be achieved otherwise.
- b. Receive the written consent of their parents/guardians or legal representatives after their appropriate information.
- c. Receive the written consent of other competent persons, who have a statutory relationship with the participants (probation officers, heads of institutions or other official bodies, teachers, etc.), where required.
- d. Respect the wish of minors who can understand the purposes and procedures of the research to participate, not to participate or to withdraw from the research.
- e. Inform the parents/guardians of the minors about the findings of their investigation only when there are serious medical or other reasons, based on the best interests of the child.

These obligations shall be adapted accordingly in other cases of research involving persons who, by law, do not have legal capacity.

**3.** In the case of research projects involving inmates, researchers must comply with the special provisions applicable to them (Penitentiary Code), while taking into account the applicable ethical rules and the protection of human rights. Experiments which aim to seek interrogation methods or other means that may cause risks to their physical and mental health or diminish their moral standing and insult their humanity are not allowed under any circumstances.

### **C. MEDICAL RESEARCH**

**1.** Research involving human beings must be carried out with full respect for fundamental human values and the protection of the physical and mental health, privacy, and anonymity of the participants. Researchers and scientific staff are bound by the basic principles of research ethics, by the medical profession (i.e., respect for autonomy, fairness, benefits and avoidance of harm, and confidentiality) and the obligation to protect, as far as possible, public health.

**2.** In the event that the research project constitutes a clinical study, as defined in Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC, researchers must comply with the provisions of that Regulation and the national legislation that transposes it into the Greek legal order, and apply the Rules of Good Clinical Practice (Guideline ICH E6 (R2) Good clinical practice), the Helsinki Declaration and the International Ethical Guidelines for Biomedical Research Involving Human Subjects by the Council for International Organizations of Medical Sciences (CIOMS). These studies do not fall under the competence of the REC but are approved before their start by the competent national Authorities or administrative bodies, i.e., by the National Organisation for Medicines and the National Ethics Commission (for interventional ones) and the Scientific Council of the hospital or other health structure (for non-interventional ones).

**3.** The REC is competent regarding the carrying out of research medical protocols and of work that does not constitute a clinical study in the sense of the previous paragraph.

#### **D. RESEARCH IN SOCIAL SCIENCES AND HUMANITIES**

1. Issues regarding protection of personal security and privacy, respect for confidentiality, anonymity, respect for the autonomy and dignity of participants or other persons not involved in the research, etc., often arise during the implementation of research projects in the social sciences and humanities (sociology, ethnography, anthropology, psychology, linguistics, education sciences, etc.), inter alia due to the frequent use of observation methods and collecting images of people in their usual environment.
2. In cases where the implementation of the research project presupposes the observation or leads to the disclosure of illegal activities or of any form of abuse of participants or other persons not participating in the research, the researchers must be aware of the relevant applicable legislation regarding the obligation to report such facts and the possibility that they may be forced to disclose part or all of their research data to the AUTHorities. The research protocol should include a reference to this possibility and be committed to pursuing the minimization of all kinds of risks that arise for researchers and participants in such cases.
3. In cases of a covert research or research involving misleading the participants, the researchers must:
  - a. Document the methodological need for choosing this type of research.
  - b. Select the environment where the research project will be implemented (private, public, professional, etc. environment) to minimize the nuisance and restriction of fundamental human rights both of participants and of other individuals who may live in the same environment without participating in the research.
  - c. Ensure, as far as possible, the anonymity of the participants.
  - d. Ensure the consent of participants, even after the research is completed, or adequately substantiate the reasons for not receiving such consent, especially in cases where this will not significantly affect the research results, since the attempt to obtain consent in some cases may result in refusal to participate in the research and alteration of the research results.
  - e. Analyse the potential benefits for the participants or other individuals with the same characteristics and take the necessary measures to ensure that the risk to participants or other persons not participating in the research is kept to a minimum.
  - f. Provide the possibility of a debriefing meeting or sessions with mental health professionals during or after the completion of the research in cases where this is necessary or becomes necessary due to the (active or passive) participation of an individual in the research.
4. In cases of covert research or of research involving misleading the participants, the research protocol shall include detailed documentation of the methodology, the reasons for violating the autonomy of the participants and a plan to minimise the risk to participants and other individuals who may live in the same environment without participating in the research.

#### **ARTICLE 22. RESEARCH INVOLVING THE USE OF HUMAN REPRODUCTIVE MATERIAL**

1. Research on human reproductive material (the term 'human reproductive material' includes: ova and spermatozoa or gametes, fertilised ova or zygotes and embryos) shall only be permitted on surplus gametes, zygotes, or embryos available for research purposes in order to better understand human reproduction, to improve diagnostic and therapeutic approaches to infertility, and to the study of biology and the possibilities of exploitation of embryonic stem cells. Any such research must be preceded by a corresponding one which has used laboratory animals and requires approval by the REC and, where required, permission by the Greek National AUTHority of Assisted Reproduction as well. It also requires the written consent of: (a) the biological parents of the embryo (e.g., couples in an artificial insemination cycle) after a clear understanding of

the partial use of internal embryo structures and (b) gamete donors used to create human embryos after being fully informed of the purposes and conditions of research on human embryos.

**2.** Research using stem cells from embryos shall be governed by the rules applicable to the use of embryos and shall be guaranteed through informed written consent by the biological parents of the embryos. The use of material from public or private stem cell banks, cord blood or blood of other origin is subject to the principles and restrictions by the applicable law. The information provided to participants should ensure that they understand the specificities of stem cell research, especially when they come from embryos that have been deliberately destroyed. Such information should also clearly state the potential risks and likelihood of adverse events as well as the existence of incomplete knowledge about the long-term effects of their possible use. Therefore, the correct selection of participants in treatment protocols, the preservation of their good condition through regular follow-ups, transparency in the dissemination of positive and negative results and the notification of possible complications, adverse events or other discomfort of the participants should be ensured.

**3.** Recipients of stem cell material of any origin shall be informed of the potential risks and likelihood of complications and adverse events, as well as of the existence of incomplete knowledge over the long-term effects of the use of such products. Therefore, the correct selection of participants in experimental treatment protocols using stem cells of any origin should be ensured, as well as regular monitoring of their health, transparency in the dissemination of positive and negative results and the notification of complications and adverse events to the competent European and national Authorities.

#### **ARTICLE 23. RESEARCH INVOLVING THE USE OF HUMAN CELLS AND TISSUES**

**1.** Research using human cells and tissues shall be carried out with the prior express informed consent of the donor, in particular where cells and tissues will be collected for the purpose of creating a bank of biological material or undergo procedures that may lead to heritable changes in the human genome or when there is a suspicion for malicious use of the collected samples and the information related to them by third parties.

**2.** Banks of biological material are facilities for the storage of all types of human biological material (samples of genetic material, cells, tissues, samples of cancerous tumours or blood products, etc.). They may also include clinical and/or phenotypic information of the donor. The reasons and purposes of setting up such banks vary, but in most cases the main objective is to house and facilitate research activities related to the biological materials collected. The creation of such facilities raises issues regarding the protection of personal data, the destiny of the samples and the type of research carried out in them, the type, extent and duration of the consent provided, access to the samples and data collected by third parties and especially by non-donors, access by other researchers, public and other bodies, governments and industry to samples and data, connection with other banks, the possibility of malicious use of samples and data, and the protection of privacy and anonymity of donors and their relatives, as the samples contain genetic information. The establishment of such facilities is, by definition, contrary to the principle of proportionality (i.e., the collection of only the necessary samples and data for the implementation of a specific research project), so it is necessary to adequately substantiate the reasons for their creation. The implementation of research projects that require the collection and storage of biological material makes it necessary to include in the research protocol information regarding the management and fate of biological samples, the time, place and means of their storage, the process of protecting the identity of the donors and the reverse process of connecting the stored biological samples with a specific donor in cases of withdrawal of consent or death and the time and manner of destruction of the samples and data collected.

3. Research using human corpses or human cadaveric tissues may be carried out with the prior express consent of the deceased or with the written consent of the family members concerned. In the case of an unclaimed or unidentified body, research may not begin until at least 40 days have elapsed since death.

#### **ARTICLE 24. SPECIFIC ISSUES OF PERSONAL DATA PROTECTION**

1. Researchers, in compliance with the applicable European and Greek legislation (Regulation (EU) 679/2016 of the European Parliament and of the Council of 27 April 2016 "on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation)" and Law 4624/2019 "Hellenic Data Protection AUTHority, measures implementing Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the transposition into national law of Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 and other provisions"), are obliged to fully ensure the protection of the personal data of the participants during the procedures for selecting participants, obtaining informed consent, and collecting and analysing data. Researchers are required, in addition to seeking the required consent of the participants, to take into account, when designing the research protocol, the extent to which the disclosure of personal data may harm the social or family existence of participants, their ability to seek employment, their coverage by insurance companies or even their legal status. Before giving their consent, participants must be informed about any use of their data, the purpose of their processing, the recipients of the personal data, any transfers to third countries and the period of storage of their personal data. They should also be informed about whether there is an automated decision-making or a profiling intent. In any case, participants must know the contact details of the project SL (or, in the case of an unfunded research, the principal researcher) and of AUTH's Data Protection Officer as well as the ways to exercise their rights.

2. Researchers are obliged to follow detailed and strict procedures for the protection and security of participants' data and to inform them about the procedures followed (e.g., coding, secure storage of data, control of persons having access to the data, removal of data that can be used to identify participants during the analysis or publication of the results of the study).

3. Researchers who use existing personal data (e.g., from a previous project) without consent (secondary use) must provide explanations regarding how such data is obtained, the protection of personal data during the analysis procedures and details about the initial collection of the data, the consent procedures followed and their compatibility with the principles of personal data protection. Researchers' obligations of compatibility with the Principles of Personal Data Protection mentioned above also apply when the personal data are not primarily collected directly from the individuals (e.g., following a request for access to service records).

#### **ARTICLE 25. RESEARCH INVOLVING THE USE OF ANIMALS**

1. Research on animals is governed by the rules stipulated in national legislation, which transposed Directive 2010/63/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.

2. The research protocols on animals are evaluated by the Experimental Protocols Evaluation Committee (EPEC) that operates in each AUTHorized experimental facility of the AUTH that implements research projects using laboratory animals, in accordance with the provisions of Presidential Decree 56/2013. The procedure for the approval of research protocols by the EPEC



is carried out in parallel with the approval process by the REC of the Aristotle University of Thessaloniki. In case the research project involves the administration of drugs in animals (preclinical study) researchers are required to apply the Principles of Good Laboratory Practice (Directives 2004/9/EC and 2004/10/EC, OECD Principles of Good Laboratory Practice - GLP), where required.

**3.** Existing legislation lays down rules on:

- a. Replacing and reducing the use of animals in procedures and improving breeding, housing, care and use of animals in research processes.
- b. The origin, breeding, marking of animals, care and housing and their culling.
- c. The operation of breeders, suppliers, and users.
- d. Evaluation and AUTHorisation of projects involving the use of animals in research processes.

**4.** The above provisions shall apply to the following animals:

- a. living vertebrates, with the exception of humans. including:
  - i) independently-fed larvae and
  - ii) mammalian embryos during the last third of their development.
- b. Live cephalopods.
- c. Animals used in procedures, which are at an earlier stage of development than that mentioned above, if the animal is allowed to live after this stage of its development and if, as a result of the procedures applied, the animal is likely to experience pain, suffering, distress or permanent damage after reaching this stage of development.

**5.** In particular, the following shall apply:

- a. In accordance with the principles of animal protection, research should be guided by the ethical treatment of animals, respect for their genetic identity, and the selection of the species of animal suitable for experimental purposes.
- b. A prerequisite for the proper use of animals for experimental purposes is knowledge of their morphological and physiological characteristics, as well as their "zootechnical" requirements. Thus, housing, feeding, and grooming must be commensurate with the needs and requirements of the animals.
- c. The use of animals for experimental purposes is governed by the basic principle of "3 Rs" (replacement, reduction, refinement). According to the principle of replacement, efforts should be made to replace animals with other lower organisms that have a less developed nervous system and experience less pain, such as plants, microorganisms and metazoa or replace them with models. When it is possible to replace animals, efforts should be made to reduce their number (reduction), using appropriate statistical tools for this purpose. The design of each experiment should be such that it provides reliable results using the smallest possible number of animals. The perfection of research methods and procedures (refinement) helps to minimize the infliction of pain and suffering.
- d. The implementation of experimental protocols using endangered species of wildlife animals shall be prohibited unless the research is aimed at the conservation of these animals.
- e. The use of humanoid apes (non-human primates) because they are the closest species to humans with the most advanced social abilities and behaviour should only be permitted in research aimed at protecting those species, where measures are necessary in relation to a life-threatening or disabling condition for humans and where no other species or alternative method is suitable to achieve the purposes of the procedure.
- f. The use as laboratory animals of tame species, stray animals, animals returning to the

wild or of animals taken from their natural environment shall be prohibited.

- g. The following cases shall not be classified as experimental procedures:
  - a. the marking of an animal or any procedure resulting in that purpose, even if it causes momentary pain or suffering, but not permanent damage.
  - b. agricultural, veterinary or clinical veterinary practices, such as taking blood or tissue samples for diagnostic purposes, injecting medicinal products for the benefit of animals, etc. are not considered experimental methods,
  - c. painful practices in the rearing and management of productive animals, such as castration, are not an experimental procedure; similarly, experiments aimed at increasing the productivity of animals as long as they do not cause permanent damage to them are not subject to experimental procedures. Cases referred to in this paragraph and characterized as a non-experimental procedure or cases involving experimentation despite ensuring adequate analgesia/anesthesia do not constitute a reason to exclude from the process of ethical evaluation by the REC of the AUTH.
- h. The creation and use of transgenic laboratory animals is subject to the rules governing research using non-transgenic laboratory animals, but special consideration is required as to whether their creation is justified. Particular attention should be paid to new research protocols using uncharacterized vectors and new transgenes. The use of transgenic laboratory animals should be fully justified in the sense that the possible benefits of research (e.g., induction of biomedical knowledge, better understanding of pathogenic mechanisms, development of therapeutic approaches and improvement of pharmaceutical formulations) outweigh the risks involved in terms of possible effects on animals. Research on micro-organisms - including genetically modified ones - which pose a risk of contamination, allergy, toxicity and/or transport of genetic material must be carried out in specially designated areas in accordance with internationally accepted standards and in compliance with the provisions of the legislation.
- i. The supply of laboratory animals or microorganisms (whether transgenic, genetically modified or not) must be made by certified suppliers and must be accompanied by the appropriate certificates of origin.

6. The Aristotle University of Thessaloniki encourages research for the development of alternative techniques that can provide the same level of information as that obtained from experiments involving the use of animals but using fewer animals or applying less painful procedures.

#### **ARTICLE 26. RESEARCH IN COUNTRIES OUTSIDE THE EU (THIRD COUNTRIES)**

The implementation of research projects in third countries should ensure that the use of resources and the management of materials (e.g. human or animal tissues, genetic material, laboratory animals, material and objects of historical and cultural value, protected species, etc.), the protection of human life, animals and of the natural and cultural environment, the protection of personal data and the application of accepted rules of research ethics and ethics is done in accordance with the principles and applicable legislation in both the third country and the EU. Adequate information on the import, export, transfer and movement of materials and data between EU member-states and third countries must be provided. All necessary safety and health measures must also be taken to protect the safety and health of researchers when carrying out research projects in third countries.

#### **ARTICLE 27. ENVIRONMENTAL HEALTH AND SAFETY, ENVIRONMENTAL AND BIODIVERSITY**

## **PROTECTION**

1. The conduct of research shall take into account and minimise potential risks to the environment. In particular, based on the constitutionally enshrined principle of sustainability, research must guarantee compliance with the laws adopted and applicable to the protection of the environment, including waste management. More specifically, hazardous laboratory or medical waste or other discarded biological material should be treated in accordance with the rules of the Integrated Waste Management System of the AUTH. Compliance with the legislation adopted to protect biodiversity and endangered species (UN Convention on Biological Diversity, EUROPA Protocol on Biosafety) must also be ensured. Researchers must include in the research protocol information on the potential risks to the environment and a plan regarding their minimisation.

2. Research on Genetically Modified Organisms (GMOs) and Genetically Modified Products (GMPs) shall be carried out in specially designed laboratories/facilities that meet the appropriate standards. The research protocol should contain information on the potential harm to the environment and to humans, as well as on the measures taken to address or mitigate such risks. Especially the use of the CRISPR/Cas9 technology should receive particular attention and be treated in a manner similar to GMOs and GMPs, especially with regard to traceability and its use in organisms living in natural ecosystems. Research on GMOs and GMPs is carried out respecting the legislation in force (Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (GMOs) and GMPs", Directive 2001/18/EC of 12 March 2001 "on the deliberate release into the environment of genetically modified organisms").

### **ARTICLE 28. PROTECTION OF THE INTANGIBLE AND TANGIBLE CULTURAL HERITAGE**

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

### **ARTICLE 29. DUAL-USE RESEARCH (CIVILIAN AND MILITARY)**

In cases of proposals for research projects with potential dual use, civilian or military, or proposals to military organisations, a clear reference to non-civilian uses must be included. The need to carry out such research and the appropriate specific handling to make any sensitive research results public or the need to fully conceal them must be adequately documented.

### **ARTICLE 30. POSSIBLE MISUSE BY THIRD PARTIES OF RESEARCH RESULTS**

1. When designing a research proposal, researchers should consider, in addition to the immediate objectives and intended applications of their research activities, whether their research could be used to serve unethical purposes and assess whether potential risks exist or may arise after the completion of their research. The term "possible malicious use of research results" refers to the possible use of any research product (materials, methods, technologies, or knowledge) for unethical purposes to harm people, animals, or the environment.

2. Possible malicious use of research results may occur as a result of research that:

- a. Provides knowledge, materials and technologies that could be used for illegal or terrorist activities.
- b. could lead to the development of chemical, biological, radiological, or nuclear materials, weapons or explosives and the means for their use.
- c. Includes the development of surveillance and surveillance technologies that could lead to a violation of fundamental human rights and freedoms.
- d. Refers to minorities or other vulnerable groups or to research that includes the collection of

sociological, behavioural, genetic, or other data that could be maliciously used to stigmatize, discriminate, harass, or intimidate people.

3. In any case, it is necessary to include in the research protocol a plan to minimize the risk of malicious use of the research results by third parties, if possible.

### **ARTICLE 31. RESEARCH INVOLVING THE USE OF NEW TECHNOLOGIES**

1. New technological advances (such as those related to nanoscience, neurobiology, biotechnology, information sciences, interaction between humans and machines, etc.) raise unprecedented ethical issues regarding both the research activity related to them and the widespread use of their applications in everyday life.

2. Where the implementation of a research project raises such issues, it is recommended to include, in the research team, independent expert scientists with knowledge on ethics issues, and who are free from conflicts of interest, in order to analyse any ethical implications of an innovative research proposal already during the design phase rather than during its implementation phase, applying the "ethics by design" strategy.

3. Increasingly, sociologists, but also other scientists, collect data using new types of smart devices (phones, wearables, etc.) and/or conduct research by collecting data from the internet (for instance from social media, personal blogs, "chatrooms" etc.). In many cases, data collection involves potentially vulnerable persons (children, adolescents, etc.). Data collection using such technologies is an important tool in studies of qualitative characteristics and behaviour. The use of such a methodology offers advantages (many individuals may refuse to answer questions if they come face to face with the researcher or may not be honest in their replies), but also disadvantages (raising issues of recruitment of participants, identification, privacy, obtaining consent - especially in the case of minors - authenticity of the data collected, etc.). Online communication in cases where the parties can be identified, even when carried out on online platforms that are considered public, is protected as private and data collection requires informed consent, while the principles of privacy and confidentiality apply. Social media posts aimed at a specific audience (they are not "public" even if they are freely accessible to the researcher), are considered as private and the collection of data requires informed consent, while the principles of privacy and confidentiality apply. Exceptionally, consent is not required for the collection and processing of posts accompanied by hashtags or relating to freely accessible posts made by persons who reasonably do not have a privacy requirement (public figures), as long as the researchers accept the relevant terms of use of the respective social media. In such cases, if there is doubt as to the lawful use of the posts/publications, researchers may address a relevant question to the Data Protection Officer of the institution and include his/her answer to the proposal they submit to the REC.

### **ARTICLE 32. RESEARCH CARRIED OUT BY, OR WITH THE ACTIVE PARTICIPATION OF, CITIZENS**

1. Research proposals implemented by citizens with the participation of researchers from the AUTH (citizen-initiated research) or with the active participation of citizens with a dual role of researcher (community-based participatory research, citizen-assisted projects ) constitute a specific category of research projects due to issues related to their research design, the quality and reliability of research data, access to sensitive or other research data, the possibility of providing for the compensation or other form of remuneration of citizens who are research participants, the allocation of responsibility in cases of mismanagement or when scientific or other research misconduct is committed, the settlement of disputes among the various researchers, issues regarding copyright, related rights and intellectual property rights and the publication and publicity of research results.

**2.** Researchers of the Aristotle University of Thessaloniki who participate in research conducted by citizens or who are leading research projects in which citizens participate as researchers or with a dual role of researcher/participant must:

- a.** Ensure that the research protocol is consistent with good scientific practice.
- b.** Ensure the written consent of the citizens-researchers after their being properly informed and make sure that the citizens-researchers are fully informed about their obligations and rights.
- c.** Clarify and address in the best appropriate way issues of potential conflict of interest that often arise due to the active participation of citizens-researchers-participants in the research.
- d.** Check that all necessary safety and health measures have been taken to protect the safety and health of researchers and citizens-researchers-participants, as well as to minimize any foreseeable risk to participants.
- e.** Ensure that citizens-researchers are adequately trained, understand their role, and have the necessary skills to carry out the research work, especially those skills related to the collection, storage, processing, publication and destruction of research data and any type of samples (biological or other) as well as the proper use of the necessary personal protective equipment and collection of all types of samples.
- f.** Ensure the unobstructed access of citizens-researchers-participants to any source of information necessary for the conduct of the research.
- g.** Encourage actions to disseminate the research results generated and ensure that the contribution of all researchers and citizens-researchers-participants is duly acknowledged, including the recognition of these latter's contribution to the publication of research results in scientific or other publications, through their participation in the AUTHors' team.
- h.** Ensure citizens-researchers-participants comply with compliance with the General Data Protection Regulation.
- i.** Inform citizens-researchers-participants that they are obliged to comply with the provisions of this Regulation.

### **ARTICLE 33. ENTRY INTO FORCE AND AMENDMENT OF THE REGULATION**

- 1.** This Regulation shall enter into force upon publication in the Government Gazette of the decision of the Senate of the Aristotle University of Thessaloniki approving its content, following a relevant recommendation by the Research Committee.
- 2.** An amendment of the Regulation is possible, if necessary and if the circumstances require it, following a relevant recommendation by the Research Committee and the approval decision by the Senate.

## ANNEXES

### APPLICATION

The undersigned..... (name/surname) .....  
(father's name) and ..... (mother's name), faculty member in the School of  
..... Faculty..... of the AUTH (telephone)  
..... (e-mail).....as

a. the scientific leader of the research proposal entitled .....

.....  
which is under evaluation with a view to being financed/is being financed by (body, institution,  
structural fund, provision of services to third parties, equity, etc.)  
.....

or

b. the supervising professor of the dissertation/postgraduate thesis/doctoral dissertation  
by .....

entitled .....

request for your actions so that this research proposals receive approval the REC of the AUTH.

I submit in annex:

Research protocol (project proposal)

SL Declaration

Questionnaire & Self-Assessment Report

Participant's Informed Consent Form (if applicable)

Required AUTHorisation(s) by other competent AUTHorities (CEEP, other institutions' REC, NAAR,  
etc.) (if applicable)

Date .....

#### ***The applicant***

*Note by REC: The text of the form may be supplemented by additional information at the discretion of the applicant. It must be completed, signed and submitted to the following email address: ethics@rc. AUTH. gr (with digital signature) or in person at the offices of the EASU of the AUTH SARF, at the secretariat of the REC.*

## DECLARATION BY THE SCIENTIFIC LEADER

The undersigned..... (name/surname).....(father's name) ..... (mother's name), faculty member .....at the School of ..... faculty of.....of the AUTH (telephone) ..... (e-mail).....hereby declare that:

1. a. I am the scientific leader of the research proposal entitled ..... which is under evaluation with a view to being financed/is being financed by (body, institution, structural fund, provision of services to third parties, equity, etc.) .....

or

b. I am the supervising Professor of the dissertation/master's thesis/doctoral dissertation by ..... entitled .....

2. All members of the research team have been informed about the Regulation of Principles and Procedures of the REC of the AUTH.

3. All members of the research team are committed to fully comply with the provisions of the Regulation of Principles and Procedures of the REC of the AUTH.

4. No member of the research team has any direct or indirect conflict of interest related to the research proposal under evaluation.

5. I am obliged to immediately notify the REC of the Aristotle University of Thessaloniki of any material change that arises or any ethical issue that arises during the implementation of the research project and to obtain re-approval from it, if deemed necessary.

Date .....

### ***The applicant***

*Note by REC: The text of the form may be supplemented by additional information at the discretion of the applicant. It must be completed, signed and submitted to the following email address: ethics@rc. AUTH. gr (with digital signature) or in person at the offices of the EASU of the AUTH SARF, at the secretariat of the REC.*

## QUESTIONNAIRE AND SELF ASSESSMENT REPORT

RESEARCH PROPOSAL	YES/NO/PENDING
<b>Has the research proposal been evaluated as to its scientific value?</b>	
<i>If yes or pending, specify the evaluation institution (Evaluation Committee of the Aristotle University of Thessaloniki, Evaluation Committee of the health Institution/Research Implementing Body, Evaluation Committee of the Funding Body, other):</i>	
<b>Is this funded research?</b>	
<i>If yes or pending, please specify all sources of funding and any conditions on the part of the funding body related to the publication of the results of the research project:</i>	
<b>SUMMARY OF THE RESEARCH PROPOSAL (max. 2000 words)</b>	



<b>HUMAN REPRODUCTIVE MATERIAL</b>		YES/NO/UNCLEAR
<b>Does the implementation of the research project require the use of human embryonic stem cells?</b>		
<b>If yes:</b>	- Is this material to be obtained from embryos to be used in the implementation of this research project?	
	- Is it material derived from existing cell lines?	
<b>Does the implementation of the research project require the use of human embryos/ cells</b>		
<b>If yes:</b>	- Will the implementation of the research project lead to their destruction?	
<b>Does the implementation of the research project require the use of human embryonic cells or tissues?</b>		
<b>Does the implementation of the research project require the use of human gametes (ova, spermatozoa);</b>		
<i>Determine the type of gamete and briefly indicate the purpose of its use and the fate of gametes after the completion of the research:</i>		
<b>HUMANS</b>		YES/NO/UNCLEAR
<b>Does the implementation of the research project require the participation of humans?</b>		
<b>If yes:</b>	- Are they volunteers participating in research on social sciences and humanities?	
	- Are these persons who are unable to give their consent?	
	- These are vulnerable persons or vulnerable population groups?	
	- Are these minors (children or teenagers)?	
	- Are these patients participating in biomedical research?	
	- Are these healthy volunteers participating in biomedical research?	
<b>Does the implementation of the research project require physical intervention to the participants?</b>		
<b>If yes:</b>	- Are invasive techniques to be used?	
	- Are biological samples to be collected?	
	- Is a biological sample bank to be set up?	
	- Is this medical research?	
	- Are some patients going to receive sham treatment (pharmaceutical, surgical, psychotherapeutic, other)?	
<b>Can the implementation of the research project, in addition to the intended results, yield random/unexpected results?</b>		
<b>If so, is there a plan to manage random unexpected results?</b> <i>Identify the random/unexpected results management plan:</i>		

HUMAN CELLS AND TISSUES		YES/NO/UNCLEAR
<b>Does the implementation of the research project involve the use of human cells or tissues other than human embryonic cells?</b>		
<b>If yes:</b>	- These are commercially available cells or tissues?	
	- Are these cells or tissues that will be collected in the framework of this research project?	
	- Are these cells or tissues collected in the context of another research project, laboratory, or institution?	
	- Is it material that comes from a biological materials bank?  <i>If so, please specify the type, AUTHorization status and legal status of the bank and whether the samples are branded, anonymous, pseudonymised, etc.:</i>	
<b>Can the implementation of the research project, in addition to the intended results, yield random/unexpected results?</b>		
<b>If so, is there a plan to manage random/unexpected results?</b>  <i>Identify the random/unexpected results management plan:</i>		
PERSONAL DATA		YES/NO/UNCLEAR
<b>Does the implementation of the research project involve the processing of personal data?</b>		
<b>If yes:</b>	- Does it involve the processing of special categories of personal data (sensitive data) (e.g., data on sexual preferences, nationality, political opinions, religious or philosophical beliefs);  <i>Specify the category:</i>	
	- Does it include the processing of health data (e.g. genetic, biometric, other health data)?  <i>Specify the category and type:</i>	
	- Does it provide for profiling, systematic monitoring of individuals, processing of special categories of personal data on a large scale, the use of intrusive methods of collecting and processing personal data (identification, monitoring, recording, videography, geographical location, etc.) or other processing which may restrict fundamental human rights and freedoms;	
<b>Does the implementation of the research project involve the processing of personal data collected in the past?</b>		
<b>Will publicly available personal data be used?</b>		
<b>Is there provision for the export of personal data from the European Union to countries outside the European Union?</b>  <i>Specify the countries and type of data:</i>		
<b>Is it planned to import personal data from outside the European Union into the European Union?</b>  <i>Identify the countries and type of data:</i>		

ANIMALS		YES/NO/UNCLEAR
<b>Does the implementation of the research project presuppose the use of animals?</b>		
<b>If yes:</b>	- Invertebrates;	
	- Vertebrates?	
	- Non-human primates?	
	- Genetically modified?	
	- Cloned productive animals?	
	- Endangered species?	
<i>Please specify the animal species and the number of animals to be used:</i>		
RESEARCH IN COUNTRIES OUTSIDE THE EUROPEAN UNION (THIRD COUNTRIES)		YES/NO/UNCLEAR
<b>If the implementation of the research project is to take place in a country outside the European Union, are possible ethical issues raised due to the involvement of third countries?</b>		
<i>Please indicate the countries and the ethical issues raised:</i>		
<b>Does the implementation of the research project require the use of local resources (e.g. tissue samples of animal or human origin, genetic material, animals, human corpses, objects of historical value, species of animals or plants threatened with extinction, etc.)?</b>		
<b>Is there any provision for the import of material or other resources from third countries into the European Union?</b>		
<b>If yes:</b>	<i>Please specify the countries and material:</i>	
<b>Is there any provision for the export of material or other resources from the European Union to third countries?</b>		
<b>If yes:</b>	<i>Please specify the countries and materials:</i>	
<b>If the implementation of the research project is to take place in a country outside the European Union, is it a low or low-middle income country?</b>		
<b>If so, what measures have been taken to mutually share the benefits of implementing the research project?</b>		
<i>Please specify the measures taken and actions planned:</i>		
<b>Is it possible that the internal situation in the third country put the researchers or the research participants at risk?</b>		
<b>If so, what measures have been taken to protect researchers and research participants?</b>		
<i>Briefly identify the measures taken and the actions planned:</i>		

<b>ENVIRONMENT, ENVIRONMENTAL HEALTH AND BIODIVERSITY PROTECTION</b>	YES/NO/UNCLEAR
Does the implementation of the research project require the use of elements, methods or material that may be harmful to the environment, animals, and plants?	
Does the implementation of the research project require the use of genetically modified plants?	
Will endangered plant or animal species or protected areas be affected?	
Does the implementation of the research project require the use of elements, methods or material that may be harmful to humans (including the researchers)?	
If you answered yes to any of the above questions, please specify the measures taken and actions planned to minimize the risks:	
<b>DUAL-USE RESEARCH</b>	YES/NO/UNCLEAR
Does the research proposal concern dual-use research objects (civilian and military) that fall under the provisions of Regulation 428/2009, or other research subjects for which special licensing is required?	
<b>DOUBTS REGARDING EXCLUSIVE USE FOR POLITICAL PURPOSES</b>	YES/NO/UNCLEAR
Can the implementation of the research project give rise to concern regarding the exclusive use of its results for civilian purposes?	
<b>MALICIOUS USE OF RESEARCH RESULTS</b>	YES/NO/UNCLEAR
Is there a possibility of malicious use of research results by third parties?	
If so, have you drawn up a plan to minimize the possibility of malicious use of the research results?  Identify the measures taken and actions planned to minimize risks:	
<b>USE OF NEW TECHNOLOGIES WITH A DOUBTFUL/NON-EXISTENT ETHICAL FRAMEWORK</b>	
If so, please specify the type of technology:	
<b>OTHER ETHICAL ISSUES</b>	YES/NO/UNCLEAR
Are there any other ethical issues that you consider important or likely to arise during the implementation of the research project, which have not been mentioned?  Briefly describe additional ethical issues related to the implementation of the research project:	

**FORM FOR THE PROVISION OF INFORMED CONSENT FOR THE PARTICIPATION IN RESEARCH CARRIED OUT IN THE FRAMEWORK OF A RESEARCH PROJECT**

The undersigned.....(name/surname).....(father's name).....  
.....(mother's name) ..... residing  
in.....(permanent address).....(telephone) ..... (e-mail).

or

The undersigned ..... ((name/surname)  
..... ((father's name ..... (mother's name)  
..... residing in ((permanent address)  
..... (telephone) ..... (e-mail) as the  
parent/guardian/legal representative ..... (delete or complete accordingly) of  
..... (write the name of the person participating in  
the research).

Hereby declare that:

I have been adequately informed and in a way that is understandable by ..... (Name and capacity of researcher) for the purposes of the research in which I will participate and is part of the research project ..... (Name of research project) with the AUTH SARF Code ..... (if any).

-I have been adequately informed in an understandable way about the way and sources of the research funding.

-I have been adequately informed in an understandable way about what my participation in this research entails. In particular, I have been informed of all the rights and obligations I will have as a participant in the research including the obligation of confidentiality (if required).

-I have been adequately informed in an understandable way about any positive or negative, and immediate, short-term or long-term consequences, my participation in this research is expected to have in relation to me or to third parties.

-I have been adequately informed in an understandable way on how my personal data related to this research will be treated and protected.

-I have been adequately informed in an understandable way for the provision and proper use of medicines/devices/personal protective equipment/.....

(fill in accordingly) I will use by participating in this research.

I am aware that my participation is voluntary and that, at any time, I can withdraw from the research for any reason and without any consequence (and that the same applies to the person I represent).

I know the responsible researcher, whom I can contact to withdraw from the research or for any problem that arises during my participation or after the completion of the research.

I was not put under any pressure, and I was given sufficient time to reflect and decide.

And that ***I consent*** to participate in the above research. *Or*

that ***I consent, in my capacity as*** parent/guardian/legal representative/...../ as to the participation of .....

Date .....

***The applicant***

***REC Note:***

*This form is submitted together with the information form and other information material that will be given to participants before obtaining their consent and which includes what is specified in Article 21 A of the Regulation, depending on the type and content of the research project.*

*The researchers may add other information on a case-by-case basis.*