



ΠΑΝΕΠΙΣΤΗΜΙΟ
ΘΕΣΣΑΛΙΑΣ

**CODE OF RESEARCH ETHICS AND CONDUCT
OF THE UNIVERSITY OF THESSALY**



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Chapter 1: General principles

Article 1. Scope of Implementation

This Code applies to all research activities, as well as to activities involving the provision of specialized services, training programs, or other scientific applications, conducted within or outside the premises of the University of Thessaly (UTH), under the responsibility of its scientific staff, with or without funding.

Article 2. Research Ethics Committee (REC)

2.1. The mission of the Research Ethics Committee (REC) is to provide, from the perspective of research ethics and integrity, assurance of the reliability of the research projects conducted at the University of Thessaly (UTH).

2.2. Within the framework of the above mission, the Research Ethics Committee (REC) reviews:

- a) whether a research project is conducted with respect for the value of human beings and animals, for the autonomy of the individuals who participate, for their private life and personal data, as well as for the natural and cultural environment.
- b) the compliance with the generally accepted principles of research integrity and the criteria of proper scientific practice, in accordance with the “Regulation for the Implementation of Principles and Operation of the Research Ethics Committee (REC) of the University of Thessaly.”

Article 3. Written information and compliance declaration

The researchers, upon submission of research proposals, applications, or contracts shall declare in writing to the Research and Management Committee of the University of Thessaly Special Account for Research Funds that they have been informed of this Code. This includes, the obligation to comply with and adhere to its terms and provisions, and to promptly inform the Committee of any changes or modifications that occur in the research project during the course of the research.

Article 4. The value of research activity, and the independence and responsibility of researchers

4.1. Research conducted at the University of Thessaly aims at the advancement of scientific knowledge which, through its application, contributes to the well-being of society. For the Institution, scientific research constitutes both a social good and the subject of a fundamental right of the person who conducts it. As a social good, it promotes human knowledge and innovation and thus contributes to



improving the quality of individual and collective life. This dimension is inseparably linked to the freedom of researchers, without which research cannot be carried out. Research activity is an integral element of the researcher's freedom and is institutionally reflected in its recognition as an individual right (Greek Constitution, UNESCO Declarations). These two dimensions of the value of research are inextricably and organically connected.

4.2. Researchers enjoy constitutionally guaranteed academic freedom within the University of Thessaly. Freedom of research is safeguarded by the public character and institutional autonomy of the University, which ensures its independence from political and economic pressures.

4.3. Oversight of research ethics and integrity by the research community itself constitutes a guarantee of research independence within the framework of self-regulatory procedures, as developed within the relevant scientific field, since researchers primarily possess the specialized knowledge and the interest in ensuring the integrity and trustworthiness of their activities.

4.4. Researchers must disclose the sources of funding for their research project. When concluding a funding agreement, they are required to review and reject any terms that compromise their freedom in the design, conduct, or publication of their research.

Article 5. Guarantees for respecting the independence of researchers

5.1. The University of Thessaly guarantees the independence of researchers. It is responsible for transparency regarding its financial resources, particularly the terms under which private funding is accepted.

5.2. Within the framework of guarantees for researchers' independence and integrity, the University of Thessaly ensures compliance with safety regulations, both for the protection of the researchers themselves and for the protection of public health and the environment, in relation to research conducted within its facilities.

5.3. The University of Thessaly is obliged to provide support for the lifelong learning of its researchers, including education in the principles of research ethics and ethical conduct, as well as scientific integrity, and to facilitate by all appropriate means their access to information on international scientific developments.

5.4. The University of Thessaly ensures the dissemination of knowledge produced within the



framework of its research activities to the international scientific community. It also ensures, in cooperation with its researchers, communication of the knowledge generated to the wider public, by all appropriate means and in a responsible manner. This contributes to the social application of science and, through it, to social progress and the improvement of the quality of human life.

Chapter 2: Key principles of Research Ethics

Article 6. Principles of Scientific Integrity

6.1. Researchers' Responsibility

Research must be conducted with integrity, dedication to scientific truth, respect for human dignity, personal autonomy, and the biological and intellectual integrity of individuals, as well as for intellectual property and personal data. It must also take care to protect life, nature, and the environment. Researchers at the University of Thessaly accept that scientific responsibility and social responsibility equally concern humans, animals, the natural environment, and sustainability.

6.2. Scientific integrity

Scientific integrity is understood as the commitment not to compromise scientific values for financial gain or recognition. Integrity is specified through epistemological and methodological obligations, which vary in different scientific areas.

Scientific integrity is understood as the refusal to violate scientific values for the sake of financial gain or public recognition. Integrity is specified through epistemological and methodological obligations, which vary in different scientific areas.

6.3. Reliability

Each scientific research project to ensure high quality must be conducted in a manner that guarantees reliability. This is reflected by its design, methodology, analysis, and use of resources, as well as the communication of its results.

6.4. Impartiality / Fairness

All members of the research community of the University of Thessaly are bound by the principle of fair treatment of all people with whom they collaborate, as well as by adherence to the principles of justice, meritocracy, and impartiality. They must refrain from any activities or actions that could constitute or suggest favouritism, bias, or negative predisposition toward collaborating individuals. The development, conduct, monitoring, reporting, and provision of information regarding a research project must be promoted in a transparent, fair, complete, and impartial manner.



6.5. Equal treatment

All members of the research community of the University of Thessaly enjoy the right to equal treatment, and are obliged to respect the corresponding right of other researchers and collaborators, without any form of direct or indirect discrimination based on racial, national, or cultural characteristics, language, gender and sexual orientation, religious, political, or philosophical beliefs, private life, health and physical ability, as well as the financial and/or social status of individuals.

6.6. Respect and people's rights

During any research activity, all persons involved are obliged to behave with appropriate respect for the rights and freedoms of the people with whom they collaborate, rejecting any form of deception, coercion, or harassment. The conduct of researchers is governed by respect for human biological and intellectual integrity, as well as care for nature and the environment. Furthermore, all research activities are governed by due respect for intellectual property rights of members of the Institution and collaborating bodies at both international and national level

6.7. Accountability and Transparency

Every researcher, or the team in which they participate, has the obligation to allow access to the full results obtained from a specific research project. The research methodology must be transparent. Research protocols, in each relevant field, must be applied in any appropriate and verifiable manner so that research results can be verified. Commitments to accountability and transparency apply to research from the conception of the idea through to publication, management and organization, training, supervision and guidance, as well as its broader impacts.

6.8. Respect for intellectual property

Plagiarism, the appropriation of others' achievements, as well as the falsification of results, are unacceptable and are subject to sanctions under the University of Thessaly Regulations and the provisions on rights protection (Article 16).

Chapter 3: Principles of research involving human subjects

Article 7. Bioethical principles of research involving human subjects

7.1. Those conducting research involving human subjects must be aware of the ethical principles and the specific rules of professional conduct governing their field. In particular, any research involving humans must be carried out in accordance with fundamental bioethical principles:



-
- autonomy,
 - beneficence,
 - non-maleficence, and
 - justice.

7.2. Respect for human dignity and the associated principle of the primary importance (“inherent worth”) of human beings constitute the core of bioethical principles, which are reflected in international conventions and declarations (the Oviedo Convention, the UNESCO Universal Declaration on Bioethics and Human Rights, the UNESCO Declaration on the Human Genome), as well as in the Constitution and legislation of Greece.

7.3. The interests and welfare of individuals participating in research always take precedence over the sole interests of science and society. In cases of conflict, priority must always be given to the protection and well-being of the individual.

7.4. Social research in particular primarily aims at contributing to the development of knowledge and the advancement of the social sciences in order to improve the lives of individuals and society as a whole. The special nature and significant importance of research involving human subjects require the establishment of specific regulatory guidelines.

Article 8. Respect for human dignity and individual rights and avoidance of discrimination

Researchers of the University of Thessaly, when conducting their research, are required to show due respect for the dignity, personal autonomy, and individual rights of third parties involved in the research activity. They must respect their private and family life, as well as their beliefs and values. They are required to avoid any form of adverse discrimination on the basis of ethnicity, race, national origin, language, gender, religion, private life, physical ability, socioeconomic status, or any other factor unrelated to scientific competence and integrity

Article 9. Obligation to inform the individuals participating in the research

9.1. Researchers of the University of Thessaly are required to inform, in a concise yet clear and as comprehensive as possible manner, with honesty and adequacy, the individuals who are to participate in their research about its objectives. The information must be complete and must include the methodology to be used, the aims of the research, and any possible risks, burdens, or discomfort for the participants. The information must be provided in a transparent, comprehensible, and easily



accessible form, in a way that can be understood by the participants in the research. The information is provided in written form or by other means, including, where appropriate, electronic means.

9.2. The obligation to inform also applies to individuals who, although not participating in the research, are directly affected by its conduct.

Article 10. Obligation to obtain the consent of the people participating in the research

10.1. No social research involving human subjects may be conducted without prior consent, given after the participant has been thoroughly informed about the purpose, scope, and possible risks, in accordance with the previous article. The consent of individuals who are to participate in the research must be provided in writing. In cases where written consent is not possible, or is not appropriate due to the nature of the research or specific cultural and other characteristics of the participants or groups involved, consent may be justifiably provided through any clear affirmative action that constitutes a free, specific, explicit, and informed indication of the subject's agreement to the processing of their data, for example, by a written statement, including electronic means, or by audio recording.

Obtaining informed consent from participants does not always, nor exclusively, guarantee the protection of the individuals concerned. A significant part of the responsibility for their protection remains with those responsible for the design and conduct of the specific research.

10.2. Persons who are legally incapable of entering into legal transactions and minors may participate in research only if it is conducted in their best interests, following written consent from their legal representatives, in accordance with the Oviedo Convention and applicable legislation on the protection of personal data, and with due regard to their own views and their right to freely withdraw consent at any time. The written consent of the legal representatives of persons lacking legal capacity and of minors does not relieve the researcher of the obligation to obtain the consent of the minors themselves and of persons lacking legal capacity.

Article 11. Obligation for special justification regarding the decision to include minors in the research

11.1. Research involving minors must be specifically justified, and its results must not be obtainable by other means or through the participation of other groups. In such cases, researchers of the University of Thessaly are required to take particular care to protect the rights of children, minors, and vulnerable groups, when their participation in research projects is deemed necessary.

Inter alia:



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- a. Researchers may not use any research procedure that could be harmful to the child, either physically or psychologically. Regardless of the children's age, their rights take precedence over those of the researcher.
 - b. Before the start of the research, researchers must obtain participants' informed consent. They are required to inform the child of all aspects of the research that could affect their willingness to participate and to answer their questions in terms appropriate to their level of understanding. Researchers must respect the child's freedom to choose whether or not to participate in the research, as well as to withdraw at any time. Participants must voluntarily agree to take part in the research after being informed in a manner appropriate to their age and maturity. In addition to the above, written consent must also be obtained from their parents or guardians.
 - c. When research involves infants, researchers must provide all necessary explanations to the parents and be particularly sensitive to signs of distress in the infants, in order to obtain the parents' written informed consent.
 - d. For the participation of children and minors in research, in addition to their own assent, written consent from their parents or from the people exercising parental responsibility is required. The consent of the parents or of those exercising parental responsibility, or of those acting in place of the parents (e.g. directors of institutions, etc.), after being informed, should preferably be obtained in written form.
 - e. Written consent—following appropriate information—must also be obtained from any person whose interaction with the child constitutes the subject of the study (e.g. teachers).
 - f. The personal information provided by participants during the research must remain confidential. The anonymity of participants should be maintained, and no use should be made of any information for which there is no authorization. In cases of named participation in research [or in cases where named participation is deemed necessary or desirable] (e.g. research on artistic practices and/or artists/artworks, testimonies within oral history research), the explicit consent of the participants is required, in accordance with article 10 of the Code of Ethics.

Article 12. Obligation for special justification regarding the selection of individuals who are vulnerable to coercion to participate in the research

12.1. The responsibility of researchers of the University of Thessaly increases proportionally depending on the social environment in which they will recruit volunteers and conduct the research. In certain



environments and situations, conditions prevail that may objectively and decisively affect a person's will and, consequently, limit their freedom and self-determination, such as detention in correctional facilities, hospitalisation in psychiatric institutions or even in intensive care units and emergency treatment units, residence in nursing homes or refugee and migrant accommodation facilities, conditions of domestic, social or political violence, and situations of emergency due to natural or other disasters, etc. In such cases, researchers have heightened responsibilities and must provide reasoned and well-documented justification that they ensure the necessary conditions so that research participants are not treated merely as means for experimentation or research.

12.2. For research involving refugee populations, the principles contained in the General European Rules and Codes of Ethics must be adhered to, (DG for Research and Innovation, Guidance note – Research on refugees, asylum seekers and migrants, H2020 Programme, Guidance. V6.1, 04.02.2019).

12.3. In any potential research involving prisoners, researchers are required to comply with the specific provisions applicable to them (Penitentiary Code, special Codes of Ethics in Criminology or Forensic Research). Under no circumstances are experiments permitted that aim at developing interrogation methods or other means that may pose risks to their physical and mental health, or that may diminish their personal integrity and infringe upon their human dignity.

Article 13. Obligation to respect diversity

13.1. In all social research (including those conducted in an interdisciplinary context), researchers of the University of Thessaly are required to respect cultural and individual differences of roles and positions, including those arising from age, gender, race, minority status, national origin, religion, sexual orientation, disability, language, and socioeconomic level. They must be sensitive to actual or perceived hierarchies and inequalities in relationships between researchers and research participants and ensure the necessary theoretical, methodological, and research conditions for the expression of participants' authentic voice and perspective. They must not exploit individuals with whom they have a counselling or similar relationship that objectively creates inequality (e.g. patients, clients, etc.) and avoid in any way causing harm or exposing research participants to risk.

13.2. They create, maintain, store, share, preserve, and provide access to records and data related to their research in accordance with the applicable legislation and with this Code of Research Ethics and Conduct.



Article 14. Protection of the privacy and data of the participants in the research

14.1. The University of Thessaly receives and processes various types of information, including personal data and private information. Researchers of the University of Thessaly are committed to protecting the privacy of the participants in the research, as well as to safeguarding them during the processing of their personal data, whether carried out electronically or in any other form. Researchers acting as processors are required to process personal data exclusively of the processing and by the means determined by the Data Controller. Any other processing of such data for different purposes, even related ones, is excluded. The University of Thessaly, as the data controller, and the researchers acting as processors are bound to implement the necessary technical and organizational measures to ensure compliance with the principle of data minimization, to guarantee an appropriate level of protection and security during processing, and to protect the data from destruction, loss, alteration, and unauthorised access, disclosure, or transmission by any means.

Appropriate measures may include the use of pseudonyms, codes, or other methods that completely prevent the identification of participating subjects. If, by way of exception, the possibility of identification must be retained of the specific processing, this must be specially justified and appropriate protective measures must be provided.

14.2. Researchers are obliged to strictly comply, before, during, and after the research, with the principles of protection and integrity of personal data collected and processed, as well as with the applicable legislation on their protection. Each research project is conducted in accordance with the principles and rules of the General Data Protection Regulation (GDPR) and applicable Greek legislation.

Researchers acting as data processors are required, throughout the entire processing period, to comply with the requirements of the legal framework on the protection of personal data, in particular the GDPR and relevant Greek legislation, as well as the decisions and guidelines of the Hellenic Data Protection Authority (HDPa).

14.3. If, within the framework of research conducted at the University of Thessaly, a request is made by the Principal Investigator for the transfer of personal data to a country outside the European Union, such a request must be accompanied by appropriate documentation, namely an official certificate stating, first, the contract number with the data recipient in the third country, and second, that this contract ensures compliance with the personal data protection safeguards provided for by EU Regulation. If no such contract exists, the Principal Investigator must state the reason and is required



to provide for the specific written consent of the data subjects participating in the research for the transfer of their data, provided that the consent form explicitly informs them that in the third country (which must be named) the EU data protection safeguards do not apply.

14.4. Researchers who process personal data of subjects participating in research and who are not themselves bound by statutory confidentiality nor are in a dependent relationship with the University of Thessaly, that is, those who are not officials or employees of the Institution and are not connected to it in relation to the conduct of the specific research through an employment relationship (but not through a project-based or independent services contract, etc.), shall conclude with the University of Thessaly an additional Agreement on the Terms of Processing of Personal Data.

14.5. All individuals participating in research have the right to be forgotten or to have their data erased. In order to strengthen the right to be forgotten in the online environment, as well as the right to the erasure of personal data, if a relevant request is made by a participant in the research, the data processor is obliged to inform the data controller so that any links, copies, or any reproduction of the relevant personal data are deleted.

14.6. Processing of special categories of personal data. In particular, for the processing of special categories of personal data, all strict safeguards applicable to them under current legislation shall be observed.

14.7. For all matters concerning the protection of personal data, researchers are required to comply with the instructions of the University of Thessaly's Data Protection Officer (DPO). If they act otherwise, they must provide a written justification for their decision and assume civil and criminal liability for any adverse or harmful consequences that may arise as a result.

Article 15. Observance of safety rules

15.1. Researchers of the University of Thessaly are required to apply all safety rules recognised in their respective scientific field. In cases where compliance with safety regulations depends on infrastructure or equipment issues, they must inform the competent authorities so that the necessary measures can be taken immediately.

15.2. Researchers of the University of Thessaly who direct research projects are required to inform participants fully and honestly, and to take all necessary and scientifically required measures to protect the health of participants and project staff from accidents or side effects that may arise from



the particular conditions of the research.

15.3. System security. The fundamental principles that all secure systems must incorporate are confidentiality, integrity, and availability:

Confidentiality: Data must be able to remain confidential and must not be disclosed. It is necessary to control access to data so that it is granted only to authorised individuals, as well as to implement mechanisms that regulate the creation of copies and record all forms of access to the data.

Integrity: The system must guarantee data integrity, meaning it must ensure that data has not been altered through unauthorised intervention. If any change has occurred, it must be detectable (e.g. through the creation of logs that record all forms of access to the data, through encryption, which can ensure both the confidentiality and integrity of the data, etc).

Availability: The system must be available to users when they need it. If a system becomes unavailable (e.g. due to failure or malicious action), it should be able to return to normal operation within a reasonable period of time or be replaced as necessary (e.g. through an alternative system available to take over operations, in accordance with the principle of restoring availability).

Article 16. Respect for intellectual property

16.1. Researchers of the University of Thessaly, when conducting research activities, are required to consider and in no way infringe the intellectual property rights of third parties.

16.2. Any person who, formally or informally, becomes aware of the progress or results of research prior to the completion and publication of its outcomes is obliged to maintain complete confidentiality and to refrain from any act of exploiting that knowledge or the research output for personal gain.

16.3. Researchers acquire intellectual property rights over the subject of the research they conduct and its results, in accordance with the extent of their contribution, the contract under which they acted, their relationship with the University of Thessaly, and in any case in accordance with the relevant provisions of applicable legislation.

16.4. Intellectual property includes the right to exploit the research work (economic right) and the right to the protection of the personal connection with it (moral right).



Chapter 4. Relations between the members of the Research Team

Article 17. Relations between researchers

17.1. Researchers have a duty of mutual respect and a right to equal treatment. Junior researchers are entitled to respect for their personality and a fair assessment of their abilities. Conversely, they have an obligation to respect and acknowledge the experience of senior researchers.

17.2. The individual contribution of each researcher in collective research efforts must be recognised. Accurately reflecting this contribution, whether in scientific publications or in any public presentation of the research project, constitutes a right of the researcher. The corresponding responsibility lies with all members of the scientific team, and especially with the project leaders.

Article 18. Collaborators' obligations

18.1. Collaborators in research must:

- a. carry out their research activity with the primary aim of advancing scientific knowledge and benefiting society as a whole.
- b. comply with the provisions of the legislation relating to their research fields, the principles of ethics, the rules of good research practice, and the codes of professional conduct of their profession and of this Code.

18.2. During the conduct of research, collaborators enjoy freedom of expression and opinion. At the same time, they must respect the guidelines imposed for the organisation and coordination of research activity by the person leading the research.

18.3. Violation of the provisions of this Code by research collaborators, or their failure to comply with instructions issued by those responsible regarding breaches of ethical principles and rules of conduct, may result in their replacement.

Article 19. Obligations of Principal Investigator

19.1. The Principal Investigator of the research must, during the conduct of the research:

- a. comply with the provisions of applicable legislation, fundamental ethical principles, the rules of professional conduct, as well as this present Code; and
- b. monitor compliance with the aforementioned rules by their collaborators during the conduct of the research, as defined in the preceding article.



19.2. Those responsible for collective research must not appropriate research findings for their own individual promotion, nor present the results of the research as their personal work.

In collective research, the group leader is obliged to ensure compliance with fundamental ethical principles and rules of conduct by all members of the team. Respect for and recognition of each researcher's individual contribution, as well as adherence to the principles of transparency and mutual communication, are obligations of all participants in the research. Honesty in the publication and reporting of scientific findings, integrity in keeping promises and assumed obligations, confidentiality regarding data disclosed during private meetings or during the evaluation of proposals submitted for funding or works submitted for publication, social responsibility, the protection of volunteers and respect for their personality, especially when vulnerable groups are involved, constitute fundamental principles of good research practice and must be observed by all researchers.

19.3. Any assignment of part of the research or supporting research tasks to third parties is carried out under the responsibility and supervision of the person in charge of the research project.

19.4. In the event of more than one person in charge, compliance with the obligations of this article is borne equally by all.

19.5. Violation of the provisions of this article by those responsible for the research may constitute grounds for termination of the specific research project. The termination is decided by the Senate of the University of Thessaly, following a recommendation by the Research and Management Committee of the University of Thessaly Special Account for Research Funds and the relevant Research Ethics Committee (REC), issued after a relevant written and signed complaint. Before to any recommendation by the Research Ethics Committee, both the complainant and the person responsible for the research are called before it to present their views, either orally or in writing, regarding the complaint.

Article 20. Publicity for research projects

20.1. Signs, announcements, and generally any means of promoting research programs shall be designed and used in a manner that serves the purpose of informing the scientific community or the wider public, and not for the unfair professional promotion of research activities. Reference to possible sponsors in activities or publications of research groups must be made with care, so as not to create confusion regarding the research institution, nor to give the impression of advertising a specific product or a permanent association of the sponsor with the University.



20.2. Signs and publicity materials of the research programs must include all the scientists participating in the research.

Article 21. Teaching and research staff of the University of Thessaly working on research projects outside the University of Thessaly

Members of the teaching and research staff of the University of Thessaly are required to notify the Research and Management Committee of the University of Thessaly Special Account for Research Funds of their participation in research projects conducted at institutions, centres, or institutes outside the University of Thessaly.



ANNEX

1. Model application – questionnaire to obtain approval by the Research Ethics Committee (REC)
2. Supplementary Agreement on the terms for the processing of personal data.
3. Obligations of confidentiality for rapporteurs regarding the protection of personal data and the confidentiality, secrecy, and discretion requirements.
4. Obligations of confidentiality for researchers regarding the protection of personal data and the confidentiality, secrecy, and discretion requirements.
5. Decision of the Research Ethics Committee (REC) of the University of Thessaly for the approval of research work.
6. Information form for the participants in the research study.
7. Model consent form for participation in a study/research.
8. Video recording of research and clinical trials, “Information on the processing of participants’ personal data and provision of consent.”
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APPLICATION AND QUESTIONNAIRE

(Application for approval of a research project by the Research Ethics Committee (REC)
of the University of Thessaly)

The application is submitted in electronic form

To be completed by the Principal Investigator of the Research Work

Date/Month/Year/Time of Application Submission

Title of research work for which the application is submitted

To be completed by the Research Ethics Committee

Date that the application was received by the Research Ethics Committee

Registration Number of the Research Ethics Committee

Note: When this form is filled in, details that do not apply for the research work for which the application is submitted, the applicant notes down the phrase **"NOT APPLICABLE"**.

Filled in by the Principal Investigator of the Research Work

A1. Title of the Scientific Project

A2. Name of the Principal Investigator, the Department/Laboratory/Institute to which they belong, and their full contact details

A3. Full name and position (affiliation) of the members of the research team, and the role of each of them in the research project under approval

A4. Summary of the research project on one page (it should include at least the purpose, the justification, and the objectives of the proposed program. The summary may also be in English; in that case, the remainder of the application may also be completed in English.)

A5. Type of study (e.g pilot, clinical, genetics, social, interviews, questionnaires etc)

A6. Social or other contribution of the research project

A7. Declaration of "no conflict of interest" by the researchers

All of us participating in the research project as researchers (at all levels), by signing below, hereby declare responsibly that we have no direct or indirect conflicts of interest in relation to the research project in which we are involved. In the event of any additions or modifications to the research team, these must be reported and declarations of "no conflict of interest" must be submitted (under the responsibility of the Principal Investigator and the Research Committee of the University of Thessaly Special Account for Research Funds) to the Research Ethics Committee).

Name

Signature

Date



B. GENERAL INFORMATION		
Which of the following ethical issues (Law 4957/2022) are involved in the research project under approval?		
B1. Involvement of human subjects	YES	NO
<i>(If the answer to the previous question is YES, please answer the next questions of B1)</i>		
B1.1. Adults participating in social research	YES	NO
B1.2. Individuals, members of socially vulnerable group	YES	NO
B1.3. Individuals 16 - 18 years of age	YES	NO
B1.4. Individuals under 16 years of age	YES	NO
B1.5. Individuals lacking legal capacity (unable to provide consent on their own)	YES	NO
B1.6. Healthy individuals participating in clinical/medical research	YES	NO
B1.7. Patients	YES	NO
B1.8. Use of medication	YES	NO
B1.9. Use of placebos	YES	NO
B1.10. Known side-effects of the drugs to be used	YES	NO
B1.11. Accidental or unexpected findings	YES	NO
B2. Use of any human biological samples and tissues	YES	NO
<i>(If the answer to the previous question is YES, answer the next questions of B2.)</i>		
B2.1. Use of human genetic material	YES	NO
B2.2. Use of stem cells	YES	NO
B2.3. Use of stem cells from human embryos	YES	NO
B2.4. Use of stem cells from humans	YES	NO
B2.5. Use of embryonic tissue	YES	NO
B2.6. Use of human embryos	YES	NO
B2.7. Use of human oocytes (eggs)	YES	NO



B2.8. Use of human sperm cells	YES	NO
B2.9. Retrieval by invasive procedures	YES	NO
B2.10. Available online, royalty-free, for non-profit research purposes	YES	NO
B2.11. Commercially available	YES	NO
B2.12. Available via another project	YES	NO
B2.13. Retrieval in the context of this project	YES	NO
B2.14. Available from biobank/archive of third party	YES	NO
B2.15. Mutagenesis using chemical, biological or other agents	YES	NO
B2.16. Treatment of biological material for reuse	YES	NO
B2.17. Use of established human cell lines	YES	NO
B2.18. Human material not included above	YES	NO
Describe:		
B3. Development and application of immunotherapeutic agents for humans	YES	NO
<i>(If the answer to the previous question is YES, please answer the following questions of B3.)</i>		
B3.1. Use of antibodies	YES	NO
B3.2. Use of immune cells	YES	NO
B3.3. Use of immune cell products	YES	NO
B3.4. Use of combination therapies	YES	NO
B3.5. Others	YES	NO
B4. Personal data management	YES	NO
<i>(If the answer to the previous question is YES, please answer the following questions of B4.)</i>		
B4.1. Special category personal data	YES	NO
B4.2. Health data	YES	NO
B4.3. Genetic data	YES	NO
B4.4. Biometric data	YES	NO
B4.5. Biochemical data	YES	NO



B4.6. Tracking and surveillance of individuals	YES	NO
B4.7. Profile creation	YES	NO
B4.8. Secondary personal data analysis	YES	NO
B5. Use of animals or animal tissues/samples	YES	NO
<i>(If the answer to the previous question is YES, please answer the following questions of B5.)</i>		
B5.1. Use of vertebrate animals	YES	NO
B5.2. Creation or use of transgenic organisms	YES	NO
B5.3. Use of animal stem cells	YES	NO
B5.4. Mutagenesis using chemical, biological, or other agents	YES	NO
B5.5. Use of animal stem cells	YES	NO
B5.6. Use of biological samples of animal origin	YES	NO
B6. Environment, Health - Safety & Biodiversity Protection	YES	NO
<i>(If the answer to the previous question is YES, please answer the following questions of B6.)</i>		
B6.1. Use of genetically modified microorganisms/organisms	YES	NO
B6.2. Use of genetically modified plants	YES	NO
B6.3. Use of invasive species	YES	NO
B6.4. Genetic modification of microorganisms and/or plants	YES	NO
B6.5. Release into the environment of genetically modified microorganisms and/or organisms and/or plants	YES	NO
B6.6. Research on or involving protected species (animal or plant) or protected areas.	YES	NO
B6.7. Does the implementation of the research project require the use of data, methods, or materials that may be harmful to the environment, animals, or plants?	YES	NO
B6.8. Does the implementation of the research project require the use of genetically modified plants?	YES	NO
B6.9. Will species of plants or animals that are threatened with extinction, or protected areas, be affected?	YES	NO
<i>If you answered yes to any of the above questions B6.7, B6.8, B6.9, specify the measures that have been taken and the actions planned to minimize the risks</i>		



B6.10. Can the research project, during the development phase, generate waste/residues?	YES	NO
<i>If yes, please answer the following:</i>		
B6.10.1. What is the type of waste/residues generated (solid, liquid, gaseous)?	YES	NO
<i>If the answer is YES, please elaborate:</i>		
B6.10.2. Waste category (Class I: Hazardous / Class II: Non-hazardous / Class III: Non-inert or inert)?	YES	NO
<i>If the answer is YES, please explain:</i>		
B6.10.3. Will this waste be stored?	YES	NO
<i>If the answer is YES, please explain:</i>		
B6.10.4. Is there a possibility for the treatment of the generated waste/residues?	YES	NO
<i>If the answer is YES, please elaborate:</i>		
B6.10.5. Is the type of container for the collection and storage of waste/residues specified?	YES	NO
B6.10.6. Is the researcher aware of the existence of clean technologies in their field of research?	YES	NO
B6.10.7. Regarding protective equipment, are there filters or other systems capable of absorbing potential air pollution?	YES	NO



If you answered YES to any of the above questions B6.10.5, B6.10.6, or B6.10.7, specify the measures that have been taken and the actions planned to minimize the risks		
B6.11. Potential risks to the environment, researchers, or third parties during the conduct of the research, methods of minimizing these risks, and procedures for handling accidents.	YES	NO
If the answer is YES, elaborate:		
B7. Third countries	YES	NO
(If the answer to the previous question is YES, please answer the following questions of B7.)		
B7.1. Use of resources (e.g. human or animal tissues, genetic material, animals, material of historical and cultural value, protected species, etc.)	YES	NO
B7.2. Import/export of materials and data between the EU and a third country	YES	NO
B7.3. Risks to the safety of researchers and participants	YES	NO
B.8		
B8.1. Dual use research	YES	NO
B8.2. Possibility of malicious use of research results (by third parties)	YES	NO
B8.3. Potential risks to researchers or third parties during the conduct of the research, methods for minimizing these risks, and procedures for handling accidents	YES	NO
If the answer is YES, elaborate:		
B9. Other research ethics issues that may arise and are not covered by the above	YES	NO
If the answer is YES, elaborate:		
C. BRIEF DESCRIPTION OF ISSUES OF ETHICS		
C1. Considerations of ethics governing the proposed project to be recorded by the Principal Investigator	YES	NO



D. DETAILED DESCRIPTION OF ISSUES OF ETHICS.

Filled in only if you have answered YES to B1 or B4.

In cases where specific data of an activity (related to B1 or B4) are not initially available (at the proposal submission stage) because prior project activities are required to determine them, these should be completed (submitted) at a later stage once they have been specified within the framework of the relevant activity protocol (related to B1 or B4).

D1. Describe the population to be studied

D2. Clarify the method of selecting participants in the research

D3. Attach any forms used for the selection of research participants (information sheets, etc)

D4. Describe the procedures through which participants in the project (volunteers—patients and healthy individuals) can submit complaints or grievances

D5. Will individuals who are members of vulnerable groups participate in the research project?

YES

NO

D5.1. If the answer above is YES, clarify how lawful consent for the participation of these individuals in the project will be obtained.

D5.2. If the answer above is YES, clarify why the participation of these individuals in the project is considered necessary

D6. Will individuals who are not capable of giving their consent participate in the project?

YES

NO

D6.1. If the answer above is YES, clarify how lawful consent for the participation of these individuals in the project will be obtained.

D6.2. If the answer above is YES, clarify why the participation of these individuals in the project is considered necessary.



D7. Will minors participate in the project?	YES	NO
D7.1. If the answer above is YES, clarify how lawful consent for the participation of these individuals in the project will be obtained.		
D7.2. If the answer above is YES, clarify why the participation of these individuals in the project is considered necessary.		
D8. Is there a need for access to previous medical records of the individuals who will participate in the project?	YES	NO
D8.1. If the answer above is YES, how will permission to access the previous medical records of the individuals participating in the study be obtained?		
D9. Ensuring the protection of personal data concerning the individuals who will participate in the project (information from the GDPR officer of the University of Thessaly).		
D9.1. Clarify the administrative mechanisms that will be in place [e.g. categories of data subjects (children, adults), categories of data, sources and methods of collection, any transfer to third-party recipients, retention period, etc.		
D9.2 Clarify the technical mechanisms that will be in place [e.g. anonymisation, pseudonymisation, encryption, data access rights and by whom, method of data destruction]		
D9.3 Clarify the physical mechanisms that will be in place [location and method of storage/security of physical and/or electronic records]		
D10. Clarify the manner in which the persons responsible of the proposed project will be able to continuously inform the individuals participating in the research on matters concerning their safety and participation in the project.		
E. Funding/Financial Agreements		
E1. Clarifications regarding any potential financial burdens/costs incurred by the research participants		
E2. Provide clarifications on how the rights of researchers to publish the project results will be safeguarded		



E3. Provide clarifications as to whether any conditions have been imposed by the funding body regarding publications related to the project results

E4. Provide clarifications as to whether, at the present stage (start of the research), there are confirmed funding sources from a private or public entity.

E4.1 If the answer above is YES, the Principal Investigator of the project should document the sponsor's relationship with to the project and any intellectual property rights held by the sponsor.

F. ATTACHMENT OF PROJECT PROPOSAL AND REFERENCES

F1. The complete project proposal must be attached, which—depending on the adopted methodological approach—should include the following, with references to the pages of the proposal where each relevant section is addressed

If certain specific elements (e.g. sample size) of an activity (particularly those related to B1 or B4) are not initially available (at the proposal submission stage) because prior project activities are required to determine them, then these must be declared and submitted at a later stage once they have been specified within the framework of the relevant activity protocol.

Subject	pages
Type of research project	
Number of institutions participating in the project	
Total number of individuals participating in the project	
Justification of the study	
Background of the research project	
Hypotheses of the project	
Aim of the research project	
Specific objectives of the research project	
Benefit arising from the project	
Design of the research project	
Sample size	
Justification of the sample size	
Inclusion criteria	
Exclusion criteria	
Procedures and methods	
Methods of measuring or evaluating results	
Statistical analysis	
Informed consent for participation in the research project	
Civil liability for individuals participating in the research project (who will bear responsibility?)	
Legal or other compensation for individuals participating in the research project or any limitations to their legal compensation	
Justification for the use of genetic data	
Clarifications regarding the personal data that will accompany the population sample of the research project	



Clarifications regarding the demographic data that will accompany the population sample of the research project	
Dissemination of personal data	
Dissemination of genetic data	
Dissemination of genetic material samples or other biological samples	
Access to information from project participants as well as their relatives	
Storage duration and destruction of samples and data	
Procedure for submitting complaints or grievances	
Secondary use of data in future research	
F2. Attach all relevant information sheets and consent forms that will be used in the project. <i>If certain specific elements (e.g. sample size) of an activity (particularly those related to B1 or B4) are not initially available (at the proposal submission stage) because prior project activities are required to determine them, then these must be declared and submitted at a later stage once they have been specified within the framework of the relevant activity protocol.</i>	
The Principal Investigator of project declares and undertakes that: (a) has read and understood the Code of Research Ethics and Conduct of the University of Thessaly and undertake the obligation of compliance with and adherence to it; and (b) no changes will be made to the research project as presented in this application. In the event that changes occur, they will be immediately reported to the Research Ethics Committee (REC), which will decide whether the approval granted remains valid or whether a new application must be submitted for approval. (c) they will declare and obtain the relevant authorisation(s) arising from the use of various tools for data collection and processing during the implementation of the research project.	
Name	
Date	
Signature	



ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΙΑΣ

RESEARCH ETHICS COMMITTEE (REC)

Supplementary Agreement on Terms

(for personal data processing)

I. IDENTITY OF THE CONTRACT AND THE CONTRACTING PARTIES

1. Place and time: Volos,
2. Data Controller: The University of Thessaly, headquartered in Volos, Argonafton and Filellinon Streets, 38221, a Legal Entity of Public Law.
3. Legal Representative,
4. Vice-Rector for Research and Lifelong Learning, Chair of the Research Committee
5. Principal Investigator:
6. Contract with Reg. No.:/.....
7. Data Processor:
8. Resident (street no.....)

II. CONTENT OF THE SUPPLEMENTARY AGREEMENT

The above contracting parties, having regard to

- a) the importance of protecting natural persons for the processing of their personal data, the provisions of Regulation (EU) 2016/679 (General Data Protection Regulation) and Law 4624/2019, and their obligation to fully comply with them;
- b) the above agreement between the contracting parties, hereinafter referred to as the *Agreement*, to which this document is annexed and forms an integral part; c) the fact that the Processor will process personal data on behalf of the Controller, in accordance with its instructions and the terms of the Agreement and this document, agree and jointly consent to the following additional provisions:



1. Definitions:

Regulation: 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 on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (L119/1).

Law 4624/2019: Law 4624/2019 “Data Protection Authority, implementing measures for 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, incorporation into national legislation of Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016, and other provisions.”

Data Protection Authority (DPA): The Hellenic Data Protection Authority.

Processing: Any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, correction, storage, adaptation, alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, association, combination, restriction, erasure or destruction

Personal Data: The type of personal data referred to in the Annex that is processed by the Processor on behalf of the Controller.

Subjects of Personal Data: The natural persons to whom the Personal Data processed under the Agreement, as referred to in the Annex, relates.

2. **a. Personal Data Processing:** Within the framework of the terms of the Agreement, the Processor also undertakes the processing of the Subjects’ Personal Data, in accordance with the written instructions and directions of the competent bodies of the Controller. The Processor shall process the Personal Data exclusively for the processing purposes and by the processing means determined as aforesaid by the Controller, as described in the Agreement and recorded in the Annex hereto, excluding any other processing thereof for other purposes, even related ones, whether for its own benefit or that of third parties. The Processor shall, throughout the duration of the processing, comply with the requirements of the legal framework on data protection, in particular with the Regulation and the relevant European Union and Greek legislation on the protection of personal data, as well as with the decisions and guidelines of the Hellenic Data Protection Authority, and shall provide all necessary assistance to the Controller for its compliance with the above. No provision herein shall release the Processor from its independent obligations to comply with the personal data protection legal framework. Both before and during the performance of any processing activity, the Processor shall verify the lawfulness and security of the processing in accordance with the GDPR and the applicable regulatory framework in force from time to time, and shall refrain from any processing activity that it considers to be contrary thereto. In the latter case, the Processor shall immediately inform the Controller by means of a full and reasoned written report.

2. **b. Processing of special categories of personal data:** For the processing of special



categories of personal data, all strict provisions applicable thereto under the legislation in force shall be observed.

3. Security and Protection of Personal Data: For the security and protection of Personal Data, the Processor unreservedly declares that:

(a) The processing carried out pursuant to the Agreement and this document is entirely separate from any other processing conducted by the Processor, whether on its own behalf or on behalf of a third party, and it takes all necessary organizational and technical measures to ensure such separation.

(b) It maintains complete, accurate, and up-to-date written records of all categories of processing activities carried out on behalf of the Controller.

(c) It implements appropriate technical and organizational measures to ensure an appropriate level of protection and security for the Personal Data it processes and to protect such data against destruction, loss, alteration, unauthorised access, disclosure, or transmission by any means, as well as against any other type of breach, even if not expressly described herein, in accordance with personal data protection legislation and the decisions or guidelines of the Hellenic Data Protection Authority. When messages containing personal data are transmitted between the Processor and the Controller through digital technology, encryption methods shall be used in order to ensure, in particular, the confidentiality of the information, the integrity of the message content, and its verification.

(d) It possesses the appropriate, suitable, and necessary technical and organizational means and takes every measure by which the loss, alteration, and any form of breach of the data under processing are effectively prevented.

(e) It applies appropriate procedures for the security and protection of the Personal Data it processes.

(f) It undertakes the obligation to assist the Controller, through appropriate technical and organizational measures, in fulfilling the Controller's obligation to respond to requests from Data Subjects exercising their rights under the Regulation. In this regard, the Processor shall promptly inform the Controller of the submission of requests or any complaints by Data Subjects and shall provide the necessary information thereto, as well as undertake the relevant actions requested by the Controller in relation to any request or complaint by a Data Subject, within the timelines set by the Controller. The Controller shall also refrain from responding to any request or complaint without the prior written approval of the Controller.

(g) It undertakes the obligation to assist the Controller in implementing the appropriate organizational and technical measures that the Controller is required to adopt for the protection of the Personal Data it processes.

(h) It undertakes the obligation to immediately notify the Controller in writing of any incident falling within the obligations set out under points (a) through (h) above, as well as of the measures it takes to address the situation.

4. Confidentiality Obligation: The Processor shall be obliged to ensure the confidentiality of the Personal Data and shall bear full and exclusive responsibility in any case of breach thereof, including, indicatively, any leakage, publication, or disclosure of the Personal Data.



5. Obligation to Notify Personal Data Breaches: In the event of any breach of Personal Data (whether confirmed or suspected), the Processor shall inform the Controller in writing immediately and, in any case, no later than within 24 hours from becoming aware of the breach. Such notification shall include, at a minimum:

- (a) a detailed description of the Personal Data breach;
- (b) a record of the Personal Data that was breached;
- (c) the identity of the affected Data Subjects or, where this is impossible, a reference to the categories and approximate number of affected Data Subjects, their categories, and the approximate number of affected records;
- (d) a description of the possible consequences that the Personal Data breach may entail;
- (e) a description of the measures taken or proposed to be taken by the Processor to address the Personal Data breach and mitigate the adverse effects of the breach on the Data Subjects;
- (f) the name and contact details of any Data Protection Officer or any other contact point from which further information may be obtained. In such cases, the Controller shall be entitled to request any additional information regarding the incident and the technical or other circumstances under which the breach occurred, and the Processor shall be obliged to respond promptly to such request. The Processor shall, without undue delay, investigate the security breach, identify and prevent it, and make every possible effort to mitigate the effects of any security breach, in accordance with the terms hereof. It shall immediately take all possible measures to limit its impact, as well as any necessary measures to restore the situation. The Processor shall be obliged to assist the Controller in fulfilling its obligation to notify the Personal Data Protection Authority of any Personal Data breach and to communicate the breach to the Data Subjects. The Processor is prohibited from disclosing any security breach without the prior written consent of the Controller. The actions described in this Article shall be carried out at the expense of the Processor, and the Controller reserves the right to seek recourse against the Processor for the recovery of its expenses and any other related damage incurred as a result of the above security breach.

6. Data Protection Impact Assessment: Upon a relevant request by the Controller, the Processor shall effectively assist the Controller in carrying out Data Protection Impact Assessments, as well as in conducting prior consultation with the Hellenic Data Protection Authority in cases where the aforementioned assessment indicates that the intended processing entails a high risk to Personal Data. The Processor shall also cooperate in implementing the mitigation measures indicated by the Controller in order to address any risks identified during the Data Protection Impact Assessment with regard to the protection of Personal Data.

7. Provision of information – Right to Audit: The Processor shall promptly make available to the Controller, upon the latter's request, copies of the above-mentioned records, as well as any kind of information requested by the Controller in order to demonstrate compliance with its obligations arising from personal data protection legislation, this Agreement, and the Contract, including detailed information regarding the technical and organizational measures it implements. In order to ensure compliance by the Processor with the terms hereof, the Controller shall have the right to carry out sample audits at

the Processor's premises, computers, information systems, records, documents, and contracts, through its representatives or an external auditor appointed on a case-by-case basis. The Controller shall bear all costs that may arise in connection with such audit, unless the audit reveals non-compliance by the Processor with the applicable personal data protection legislation or with the terms of the Contract and this Agreement, in which case the Processor shall be obliged to fully cover the Controller's relevant costs. The Processor shall immediately resolve, at its own expense, all security and data protection issues identified by the Controller and notified to it regarding actual or potential breaches of the above obligations by the Processor. The Processor shall promptly inform the Controller of any inspections or audits carried out at its premises by the Hellenic Data Protection Authority or other competent authorities in relation to breaches of any civil, criminal, or administrative legal or regulatory provisions, insofar as they relate to the Contract or this Agreement. The Processor shall not disclose Personal Data to any third party unless required by law and after having previously informed and consulted with the Controller.

- 8. Copies of Personal Data:** The Processor shall not retain copies of the Personal Data it processes, in any form or on any medium, without the prior written authorization of the Controller, with the exception of backup copies and those required for compliance with legal obligations. In such cases, the Processor shall duly inform the Controller.
- 9. Duration - Termination:** This Agreement shall enter into force upon its signing and shall expire upon the expiry or termination of the Contract for any reason, including termination. The provisions of this Agreement shall also apply to any processing that may have taken place prior to the date of signing hereof. Termination of this Agreement independently by either of the Parties is excluded.
- 10. Transfer of Personal Data outside the EU:** The Processor may transfer Personal Data to a third country or an international organization outside the EU only upon the explicit written consent of the Controller, which shall follow the approval of the competent Research Ethics Committee (REC), unless the Processor is required to carry out such transfer by law, in which case it shall inform the Controller prior to the processing.
- 11. Liability:** In the event of non-compliance by the Processor with the provisions of the legal framework on the protection of personal data, or in the event of any breach by it of any term of this Agreement, or in the event that any action of the Processor is contrary to the Controller's instructions and orders as set out above, as well as in the event of any breach by any means and any disclosure of Personal Data due to an act or omission of the Processor or due to an event falling within its sphere of responsibility, the Processor shall, on the one hand, be liable for the full compensation of any damage and loss that the Controller may suffer (including, indicatively, positive or consequential damage, material or non-material damage, moral harm, imposition of fines, contractual penalties, payment of compensation to Data Subjects or third parties, legal expenses and other costs of remediation or compliance, etc.) arising from such breach, irrespective of any other compensation paid by the Processor under the Agreement; and, on the other hand, the Controller shall be entitled to terminate the Agreement with immediate effect, even if such termination is not expressly provided for as a termination ground in the Agreement.



12. Prohibition of Assignment: The Processor may not assign or transfer in any manner its rights and obligations arising from this Agreement without the prior written consent of the Controller.

13. For all matters relating to the protection of personal data, the Parties shall comply with the instructions of the Data Protection Officer of the University of Thessaly (DPO), and if they act otherwise, they shall be obliged to provide a written justification for their decision and assume civil and criminal liability for any adverse or harmful consequences arising therefrom.

14. General Terms: This document, together with its Annex, constitutes an integral part of the Agreement. Any amendments to this document shall be evidenced only in writing, any other means of proof being excluded. If any provision of this document is deemed void, in whole or in part, such invalidity shall not affect the validity of any other provision of this document or the validity of the Agreement, which shall remain in full force and effect. In the event of any conflict between a provision or provisions of the Agreement and this document, the provisions of this document shall prevail as being more specific

In witness whereof, this document has been drawn up in two identical originals, one for each Party.

For the Controller

The Chair of the Research and Management Committee

.....

The Processor.....



ANNEX

[filled in by the processor / Principal Investigator of the project]

1. SUBJECT OF PROCESSING:

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2. DURATION OF PROCESSING:

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3. NATURE AND OBJECTIVE OF PROCESSING:

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4. TYPE OF PERSONAL DATA:

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5. CATEGORIES OF SUBJECTS OF PERSONAL DATA:

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ΠΑΝΕΠΙΣΤΗΜΙΟ
ΘΕΣΣΑΛΙΑΣ

RESEARCH ETHICS COMMITTEE (REC)

CONFIDENTIALITY OBLIGATIONS OF PRESENTERS
FOR THE PROTECTION OF PERSONAL DATA &
CONFIDENTIALITY, SECRECY, NON-DISCLOSURE

In addition to the obligations arising from legal provisions or professional codes of conduct, hereby expressly undertakes the obligation to maintain the confidentiality and secrecy of data, information, and any other material that will be disclosed or come to their knowledge in any manner whatsoever in the context of their participation in the research project..... specifically

In particular:

He/she undertakes the obligation **not to** disclose, communicate, or make available confidential information, or to permit or enable any third party, directly or indirectly, to access, communicate, or publish such confidential information to any third party. This obligation shall apply without prejudice to the application of any legal provision that requires the disclosure of such information or where such disclosure is necessary for the exercise, establishment, or defence of a right before a court, supervisory authority, or disciplinary body.

The term “**CONFIDENTIAL INFORMATION**”, as used in this declaration, means all information, data, methods, techniques, and procedures relating to the organization, operation, competencies, duties, work, reports, questionnaires, forms, positions, findings, documents, projects, research and development planning, know-how, systems, and resources, which contain personal data and related information.



Confidential information also includes any personal data, i.e., any information relating to an identified or identifiable person. Such data may relate to researchers/employees/personnel of the University of Thessaly (UTH), to persons with whom the UTH engages in research or other collaborations, or to persons whose data are contained in files or are subject to processing within the framework of research activities, research projects, work, experiments, methodologies, reports, questionnaires, interviews, measurements, records, systems databases, deliverables, etc. of the UTH.

Confidential information may also be contained in physical audio or visual media, diskettes or digital computer disks, machines, prototypes of any kind and application, drawings, definitions and explanations, objects of any form of construction, visual representations, documents readable by machines or by humans, or may also take the form of oral statements.

The undersigned declarant undertakes to use the **confidential information** of which they become aware solely for the purposes of the assigned project and/or for the purposes for which such information was disclosed to them (**providing input for a research project**), and to uphold the principle of confidentiality even after the termination, in any manner whatsoever, of their capacity as reviewer of the specific research project.

Date:

The Declarant

Name, Signature



ΠΑΝΕΠΙΣΤΗΜΙΟ
ΘΕΣΣΑΛΙΑΣ

RESEARCH ETHICS COMMITTEE (REC)

CONFIDENTIALITY OBLIGATIONS OF RESEARCHERS FOR THE PROTECTION OF PERSONAL DATA & CONFIDENTIALITY, SECRECY, NON-DISCLOSURE

In addition to the obligations arising from legal provisions or professional codes of conduct,
..... hereby expressly undertakes the obligation to maintain the
confidentiality and secrecy of data, information, and any other material that will be disclosed
or come to their knowledge in any manner whatsoever in the context of their participation in
the research project.....
specifically

In particular:

He/she undertakes the obligation **not to** disclose, communicate, or make available confidential information, or to permit or enable any third party, directly or indirectly, to access, communicate, or publish such confidential information to any third party. This obligation shall apply without prejudice to the application of any legal provision that requires the disclosure of such information or where such disclosure is necessary for the exercise, establishment, or defence of a right before a court, supervisory authority, or disciplinary body.

The term “**CONFIDENTIAL INFORMATION**”, as used in this declaration, means all information, data, methods, techniques, and procedures relating to the organization, operation, competences, duties, work, reports, questionnaires, forms, positions, findings, documents, projects, research and development planning, know-how, systems, and resources, which



contain personal data and related information.

Confidential information also includes any personal data, i.e., any information relating to an identified or identifiable person. Such data may relate to researchers/employees/personnel of the University of Thessaly (UTH), to persons with whom the UTH engages in research or other collaborations, or to persons whose data are contained in files or are subject to processing within the framework of research activities, research projects, work, experiments, methodologies, reports, questionnaires, interviews, measurements, records, databases, systems, deliverables, etc. of the UTH.

Confidential information may also be contained in physical audio or visual media, diskettes or digital computer disks, machines, prototypes of any kind and application, drawings, definitions and explanations, objects of any form of construction, visual representations, documents readable by machines or by humans, or may also take the form of oral statements.

The undersigned declarant undertakes to use the **confidential information** of which they become aware solely for the assigned project and/or for the purposes for which such information was disclosed to them (**providing input for a research project**), and to uphold the principle of confidentiality even after the termination, in any manner whatsoever, of their capacity as reviewer of the specific research project.

Date:

The Declarant:

Name, Signature:



ΠΑΝΕΠΙΣΤΗΜΙΟ
ΘΕΣΣΑΛΙΑΣ

RESEARCH ETHICS COMMITTEE (REC)

DECISION OF THE
RESEARCH ETHICS COMMITTEE (REC)
OF THE UNIVERSITY OF THESSALY

FOR THE APPROVAL OF A RESEARCH PROJECT

**CONFIDENTIAL DOCUMENT**

Title of the research project/study for which approval was requested:
Principal Investigator of the project/study:
Type of proposed study:
Reg. No. of the Research Ethics Committee (REC):
Decision Number & Date of the Research Ethics Committee (REC):
Decision of the Research Ethics Committee (REC) (electronically)
Approved (or clarification and re-submission of the request/documents requested)
Committee Members who took the decision
Comments by the Research Ethics Committee (REC) on the basis of which the decision for the submitted application was taken



Having reviewed the research project and all relevant supporting documents/additional approvals as submitted to the Research Ethics Committee, and taking into account the aims and expected benefits, the research methodology, the absence of undue inducement for participation, the absence of conflicts of interest on the part of the researchers, and the absence of potential risks for the research subjects,

Research Ethics Committee (REC)

finds and unanimously decides to approve, in accordance with Article 279 para. 1(a) of Law 4957/2025, the submitted application [initial submission ... submission of clarifications, etc.],

since, in its judgment [or subject to the condition that...], the established rules of ethics, and research integrity are observed with regard to both the content and the conduct of the research project under review, as well as the statutory requirements provided by law.

Or [alternatively]

identifies omissions in the following points

.....
.....

It is recommended that the Principal Investigator of the research team re-examine the points highlighted and resubmit the application to the Committee [or submit corrected forms, or provide clarifications through a response letter on behalf of the

Principal Investigator].

This decision of the Research Ethics Committee (REC) shall in no case replace any approval or authorization of this research project/study that may additionally be required by law from any other competent public service, administrative body, or independent administrative authority.

Issuance date of the decision

Year:

Month:

Day:

Signature of the Chair of the Committee

Position

Name

Surname

Signature

Chair



ΠΑΝΕΠΙΣΤΗΜΙΟ
ΘΕΣΣΑΛΙΑΣ

RESEARCH ETHICS COMMITTEE

SCHOOL _____ DEPARTMENT _____

LABORATORY _____

INFORMATION FOR PARTICIPANTS IN THE RESEARCH STUDY

Purpose and rationale of the “Information Sheet for Prospective Volunteer”:

Patients or healthy volunteers who may participate in a research study must be provided with sufficient information to enable them to decide whether or not they wish to participate. This information is provided through the Information Sheet for Prospective Volunteers, prepared by the Principal Investigator.

The purpose of the present document is to provide guidance and assistance to researchers and students who wish to draft the Information Sheet for Prospective Volunteers. It is also addressed to students whose study/research involves, in any manner, volunteers or data/information from volunteers that could be considered personal.

General:

It is important that the Information Sheet for Prospective Volunteers simply presents information in a simple manner, avoiding the use of technical terms so that even a layperson can understand the study/research. Sentences and paragraphs should be short. *If the research is conducted in a Hospital or Research Centre, it is advisable to also use the logo of the Hospital/Research Centre.* The information sheet must include information in the order specified by the present template. If any of the following items do not apply to the type of study/research, they should simply be deleted.





Information Sheet for Prospective Volunteer

1. [Title of the Study]

Use a simplified title if the original one is too technical and difficult for the average participant to understand.

Then, and in this paragraph, fill in the following information:

[Details of the Principal Investigator]

The details of other collaborators should also be provided, if any

In the present study, the **PERSON(S) RESPONSIBLE** and the **RESEARCHERS** are:

Principal Investigator:

Name:	Capacity:
Department:	
Address:	
Telephone No.:	Email:

Researchers:

Do other researchers participate? Yes ☐ No ☐

Name:	Capacity:
Department:	
Address:	
Telephone No.:	Email:

Name:	Capacity:
Department:	
Address:	
Telephone No.:	Email:



2. Presentation

You are invited to participate in this research study. Before giving your consent and deciding whether to take part, you should ensure that you fully understand the information provided.

Example:

"You are invited to participate in the research study X, which focuses on Y. Before you decide whether or not to participate, it is important that you understand why this research is being conducted. Please take some time to carefully read the following information and discuss it with others if you wish. Feel free to ask us if anything is unclear or if you do not understand something, or if you would like more information about this information sheet or the consent form. Take the time you need to decide whether or not you wish to participate. Thank you for taking the time to read this."

3. Invitation to participate in the research:

his paragraph should invite the individual to take part in the study/research.

Example

"You are invited to participate in the research conducted by our Institution. Before deciding whether you wish to take part, it is important that you read the following information in order to understand why we are carrying out this study/research and what we are trying to find out. You do not need to respond immediately; if you wish, you may also discuss it with others and then let us know whether you would like to participate or not. If anything is unclear, you may ask us for further information."

4. Study aim

The background, aim, and duration of the study should be provided here in general terms. Explain the research question in simple language. Use plain and easily understood words instead of scientific terminology and professional jargon. Consider the local beliefs and knowledge of the participants before deciding how best to present the information. It is important that researchers take care not to mislead participants by implying research interests that do not actually exist.

5. Type of research intervention

***Briefly** describe the type of intervention that will be carried out. This will be explained in more detail in the procedures section, but it may be useful for the participant to know from the outset whether, for example, the study involves biological samples, a vaccine, an interview, a questionnaire, or data collection.*

6. Reason you have been chosen

You should explain how the participant was selected and how many other participants will be included. People may wonder why they have been chosen and may feel afraid, confused, or concerned.

Example:

You are invited to participate in this research because we believe that your experience as a social worker (or as a mother or as a responsible citizen) may greatly contribute to the understanding and knowledge of local health practices.

7. Volunteer Participation

You must explain that participation in the research is entirely voluntary and that if participants do not wish to take part, there will be no negative consequences (this will depend on the context of the research—for example, if the participants are your students, they may need reassurance that refusal will not affect their grades. Similarly, if the participants are patients, they may wish to know that



refusing to participate will not affect their care in any way). In addition, the information sheet must state that the participant may withdraw from the study at any time and clearly explain what they should do in such a case.

Example:

"Your participation in this research study is entirely voluntary. If you decide to participate, you will be given this information sheet and asked to sign a consent form. You may still withdraw your consent at any time without any negative consequences. However, the withdrawal of your consent does not affect the lawfulness of any prior processing of the data you have provided. You are not required to justify your decision. If you wish to withdraw from the study, please contact ..."

If there is a point beyond which a participant's data can no longer be withdrawn from the research (for example, when the data have already been analyzed and incorporated into a larger dataset), this should be made clear. Participants should be informed that, although they may withdraw from any ongoing or future data collection, their data cannot be removed from the study after that point. Ideally, a specific date or timeframe should be provided.

8. Procedure for participation in the research

A brief description of the nature of the study should be provided. You should state how long the participant will take part in the research, the overall duration of the study (if different), how often participation will be required, and for how long each time. You should also explain whether travel expenses are available. You should include the type of information that will be collected and explain why gathering this information is important for achieving the objectives of the research project.

The research methods to be used must be described simply and clearly, and it should be explained exactly what will happen in practical terms (e.g., blood tests, interviews, etc.). If feasible, you should design a simple flowchart or diagram showing what will happen in each procedure in which participants will take part. You should also explain the responsibilities of the participants, clearly specifying what is expected of them, and state whether there are any lifestyle restrictions resulting from participation.

In the case of an interview with a participant, a summary of the topics to be covered by the questions should be provided, and the manner of responding should be explained (e.g., clarify whether the questions will allow open-ended or closed-ended responses regarding a specific topic, and specify which aspects of the topic participants should be able to discuss in depth and which they should not). If the research includes questions or discussions that may involve sensitive personal data or could potentially cause embarrassment, the participant should be informed accordingly.

9. Duration of research

Include a statement regarding the time commitments required from the participant, including both the duration of the study and any follow-up, if applicable.

Example:

The research will be conducted over a total period of(number) days / or(number) months. During this period, we will visit you three times within one month to conduct interviews, and each interview will last approximately one hour. The group discussion will take place once and will last approximately two hours.

10. Participation risks/ Limitations

Explain and describe the risks that are expected or considered likely. Risks depend on the nature and type of the intervention and should be adapted to the specific context. Any reasonably foreseeable



inconvenience, disadvantage, or risk must be stated. Researchers must disclose to participants any foreseeable harm arising from the proposed research procedure. Any unexpected difficulties, disadvantages, or risks to participants that may arise during the course of the research must be immediately brought to their attention. You should also specify any restrictions that will be imposed on the volunteer, for example, whether they will be prohibited from exercising or from eating certain foods.

*If the discussion concerns sensitive and personal matters, such as reproductive and sexual health, personal habits, etc., then an **example** of text could be:*

"We are asking you to share with us some very personal and confidential information, and you may feel uncomfortable when discussing some of these topics. You do not have to answer any question or take part in the discussion/interview/survey if you do not wish to do so, and this will be fully respected. There is absolutely no need to provide any justification if you choose not to answer a question or if you decide not to take part in the interview.

11. Side-effects

Patients/volunteers must be informed of any possible side effects. Side effects should be described clearly and understandably, avoiding scientific terminology. For example, it is preferable to use the expression "lower back pain" instead of "herniated intervertebral disc." It is mandatory to record the patient's/volunteer's telephone number so that immediate contact can be made in case of need. If the research is innovative, the patient/volunteer must also be informed about possible side effects that are not yet known.

12. Benefits from participating in the research

Benefits can be divided into benefits for the individual, benefits for the community in which the individual lives, and benefits for society as a whole. Any reasonably expected benefits for participants should be stated. However, when there is no anticipated benefit for the participant from taking part in the study, this must be clearly stated. It is important not to overstate the potential benefits for the individual participant, as this could be considered coercive.

Example:

There will be no direct benefit to you, but your participation is likely to help us learn more about how malaria can be prevented and managed in your area.

13. For incidental findings/new information:

Inform participants about how any incidental findings or new information that may arise will be handled, and obtain their consent for this in the consent form.

Example:

If findings arise during the course of the research that concern you and may be relevant to your health or relate to your genetic data, but fall outside the original purpose of the study for which you have given your consent, would you like to be informed about them? If you wish to be informed, you should indicate this in the consent form.

14. How the collected data and the results of the study will be used

You should provide participants with assurances regarding the extent and manner in which their identity will be protected. Explain how the research team will maintain the confidentiality of the data, both in terms of information identifying the participant and the information shared by the participant. You should also describe any limits to confidentiality.



It is good practice to consider possible future uses of the data, including opportunities for wider data sharing, possibly also in line with the requirements of research funding terms. Therefore, it is recommended that a statement be included indicating how the data collected during the project may be shared and/or used for additional or future research (this should also be clearly stated in the participant's consent form).

Example 1:

*Access to the samples shall be granted exclusively to the above-mentioned **Principal Investigator** and the named main researchers, as well as to the personnel involved in the above research. Access to and use of the patients' records will take place within the Hospital Archives, where the files are kept, and only those data that are, in the researchers' scientific judgment, necessary and required for the completion of the specific research project will be extracted from the records. If you consent and participate in the study/research, your medical file will be made available to the research team conducting the study so that they may evaluate and analyze the results. Your data may also be made available to the Research Review Committee. Your data will not be disclosed elsewhere. In this way, it is ensured that the information contained in the records is not at risk of alteration, loss, or destruction that could occur during transfer outside the Archives.*

The above Scientific Responsible and the researchers explicitly commit to fully protecting the personal data of the participants in the above process, including their collection and analysis. The information will be anonymised, and the names of participants will not be disclosed. The researchers are obliged to follow a specific design and protocol according to which participants' data will remain confidential (e.g. coding using pseudonyms or initials and numbers, secure storage of data, restriction of access to authorised persons only), and removal of any identifying information during analysis or publication of results, unless you have given your explicit consent for otherwise. The principles of research ethics will be fully observed and followed.

Example 2:

Due to the nature of this research, it is highly likely that other researchers may also find the data we collect useful in addressing future research questions. For this reason, we will retain the information that identifies you for ten (10) years, stored separately from the rest of the data you provide. We will request your explicit consent to share your data in this way.

In the case that the research is conducted online, and given that issues of consent and the quality of informed consent also arise, the researchers must ensure: a) that through digital communication consent is informed and clearly understood by participants, while also providing safeguards against fake participant profiles (e.g. in online forums, chat rooms, virtual worlds/gaming environments, including cases of personas or avatars), with appropriate participant authentication measures (minors/adults); and b) that issues of deception, covert observation, or data collection through intrusive methods are properly addressed.

15. What happens when the research ends?

Information must be provided to the patient regarding what will happen after the end of the research with their personal data/biological material, etc.

16. In case the results are not as expected or something goes wrong: *Patients should be informed, if they make a complaint, how it will be handled and used. They should be told whether they are entitled to compensation. It must be made clear whether complaints relate to the conduct of staff (doctor, physiotherapist, nurses), or whether they relate to the outcome of the study/research, or whether they arise from negligence or lack of care or attention.*



17. Potential Conflict of Interest

Researchers must explicitly state whether or not there is a conflict of interest.

Finally, the researchers must in all cases state the following:

If you have any questions or would like additional information about the research before or after participation, you may contact [insert the full name and contact details of the Principal Investigator].

If your concern is not resolved, you may contact the Research Ethics Committee of the University of Thessaly (ehde@uth.gr)

[Information on the funding scheme of the Study]

SIGNATURE OF THE PRINCIPAL INVESTIGATOR

ANNEX I

Next, sample consent forms that may be used in a research study are provided. It should be noted that for any processing of personal data for a purpose other than that for which they were originally collected, consent must be obtained. Also, for the purposes of scientific or historical research, or the collection and maintenance of statistical data, consent may be considered in light of Article 30 of Law 4624



RESEARCH ETHICS COMMITTEE

SCHOOL _____ DEPARTMENT _____

LABORATORY _____

MODEL CONSENT / INFORMED CONSENT FORM FOR PARTICIPATION IN A STUDY/RESEARCH

Participant's consent in the research

Prior to agreeing to participate in the research, make sure that:

☐ *You have read and understood the information sheet regarding the processing of your personal data in the context of this research (hereinafter the "Information Sheet"), and any questions you had regarding it have been satisfactorily answered.*

☐ *You have been informed, through the Information Sheet, about the processing and use of your personal data in the context of your participation in the research.*

☐ *You are aware that your participation in this scientific research is voluntary. You may withdraw from the study at any time, without any consequence or penalty, by withdrawing your consent via email at: [to be completed by the Principal Investigator], or in person at the following address: [to be completed by the Principal Investigator].*

- ☐ I have read the above information [or it has been read to me] and I have understood it.
- ☐ I have had the opportunity to ask questions about the content of the information provided, and all my questions have been answered satisfactorily.
- ☐ I am aware that I will be given a copy of this consent form and that the researcher will retain another copy on file.
- ☐ I voluntarily agree to participate in this study/research.

Participant's Name



Signature

Date

Parent's or Legal Representative's consent

(Delete everything that does not apply)

I have read the above information [or it has been read to me] and I have understood it. I have had the opportunity to ask questions about the content of the information provided, and all my questions have been answered satisfactorily. I am aware that I will be given a copy of this consent form and that the researcher will retain another copy on file. I voluntarily agree that *[my child or "the participant's name"]* will participate in this study/research.

Participant's Name

Parent's or Legal Representative's Name

Relation with the Participant: ☐Parent ☐Legal Representative ☐Other

Signature

Date



Statement of the researcher / person obtaining the participant's consent.

A researcher or the person obtaining informed consent must sign each consent form. Since certification is an integral part of informed consent and not a standalone document, this statement forms part of the consent form.

- I have accurately read the information sheet to the potential participant to the best of my ability and I am satisfied that the participant understands it.
- I confirm that the participant was allowed to ask questions about the study and that all questions raised by the participant have been answered properly and to the best possible extent.
- I confirm that the individual has not been coerced into giving consent and that consent has been given freely and voluntarily.

Volunteer's name (patient): _____

Patient identification number in the present study (#ID): _____

Date of Birth: ____/____/____

Principal Investigator - presenter: _____

Student/researcher: _____

Physician in charge: _____

Male ☐ Female ☐ I do not wish to declare ☐

Volunteer (patient) characteristics:

Other information:

This form was prepared in two identical copies, and one copy was given to the participant. [Delivery date].

This document contains confidential information and is kept on file

Name of researcher/ individual obtaining the consent.

Researcher's/individual's signature.

Date.



Video Recording of Research and Clinical Trials

Information on the processing of participants' personal data and provision of Consent

The University of Thessaly (hereinafter “the University”) attaches great importance to the lawful and secure processing of your personal data, which is carried out in compliance with the fundamental principles of personal data protection imposed by Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons concerning the processing of personal data and on the free movement of such data (General Data Protection Regulation – GDPR), namely the principles of lawfulness, fairness and transparency of processing, purpose limitation, data minimization, accuracy, storage limitation, integrity and confidentiality, and, finally, accountability.

1. Data Controller

The University is the Data Controller of the personal data processed within the framework of the following purpose:

Our address is Argonafton and Filellinon Streets, P.C. 382 21, Volos, Contact Tel.: 30 2421074000, and you may contact the University’s Data Protection Officer (DPO), which is the company Priority Quality Consultants S.A, at the email: dpo@uth.gr

2. Purpose and Data Processing

The University would like to process your personal image and audio data, for the purpose of more effective processing and optimization of research results, within the framework of conducting research studies and clinical trials carried out for

.....

4. Legal Basis for Processing

With regard to the personal data processed by the University within the framework of the above-mentioned purpose, the legal basis for such processing is your consent. Failure to provide your consent, or withdrawal of it at a later stage, shall not entail any adverse consequences for you.

In the event that you withdraw your consent, the lawfulness of the processing based on consent prior to its withdrawal shall not be affected. However, from the moment the consent is withdrawn, any processing of your image and audio data shall cease

5. Access to personal data-recipients

Access to your personal data collected within the framework of the above-mentioned purpose is granted to the University personnel authorised to handle this procedure, who have received the appropriate training regarding the secure processing of your personal data.

In addition, recipients of your data include the participating attending physician, external



laboratories (e.g. at other universities in Europe or other specialized laboratories), collaborating Research Centers / Public Hospitals in Europe (e.g. in France for a Biochemistry laboratory), and doctoral candidates (who are not members of the research team).

Finally, recipients of your data include cooperating companies (data processors) that have undertaken the support of our information systems and applications. These data processors have been informed in advance and committed to maintaining the confidentiality of the data, are aware of and follow our instructions regarding the processing of personal data, and take all appropriate measures for their protection.

6. Transfers outside the EEA (European Economic Area)

Your personal data collected within the framework of this purpose are transferred outside the European Economic Area, specifically to universities in the United States of America and to Microsoft's data storage infrastructure, also located in the United States.

Regarding transfers to universities in the United States, such transfers are carried out based on standard approved contractual clauses on data protection.

Regarding the transfer of personal data to the data storage infrastructure in the United States, this is carried out based on an adequacy decision, and specifically where the recipient entity is part of the EU-US Privacy Shield framework for the secure transfer of data.

7. Retention period of your personal data

Your personal data is retained only for the reasonable period required by the nature of data processing and only for as long as necessary to achieve its purpose, unless there is a contrary legal obligation requiring their further retention.

8. Security of your data

We have implemented appropriate organizational and technical measures to ensure the security and protection of your data against any form of accidental or unlawful processing. It is noted that our specially authorised personnel, who process your personal data, have received appropriate training, guidance, and information.

These measures are reviewed and modified at regular intervals, or whenever necessary, in accordance with new requirements and technological developments

9. Your rights and how to exercise them

As a data subject you have the following rights:

- Right of access to personal data
- Right to rectification of inaccurate personal data
- Right to erasure / right to be forgotten
- Right of data portability
- Right to restriction of processing



- Right to withdraw your consent
- Right to object to the processing of your data

In the event that: (a) you believe that any of your requests has not been adequately and lawfully satisfied, or (b) you consider that your right to the protection of personal data is being violated by any processing we carry out, you have the right to lodge a complaint with the Hellenic Data Protection Authority (address 1-3 Kifisias Str., P.C. 115 23, Athens, Tel. 210. 6475600, e-mail: contact@dpa.gr).

If you wish to obtain further information regarding the processing of your personal data or to exercise any of the above rights, you may contact the University's Data Protection Officer at the email address: dpo@uth.gr, or send a letter to the postal address indicated above (Argonafton & Fillelinon, P.C. 382 21, Volos), marking it "For the attention of the Data Protection Officer," with a description of your request. We will ensure that it is reviewed and responded to as soon as possible.

We will respond to your request within one (1) month of its receipt, and this service will not entail any cost to you. This period may be extended by an additional two (2) months due to the complexity or number of requests. In such cases, you will be informed of the extension and the reasons for it as soon as possible and no later than one month after receipt of the request.

In cases where the request is considered manifestly unfounded, excessive, or repetitive, the University may either refuse to process it or request the payment of a reasonable fee to cover the administrative costs of providing the information or carrying out the requested action.

CONSENT FORM FOR VIDEO RECORDING

I, the undersigned,of....., having been informed about the processing of my personal data (image and audio):

☐ **I give** my consent for the processing of my data exclusively for the above-mentioned purpose of processing, namely the more effective processing and optimization of the research results.

☐ **I do not give** my consent for the processing of my data exclusively for the above-mentioned purpose of processing.

Date:

Name:.....

Signature:

Conducting Research Studies and Clinical Trials Information on the Processing of Participants' Personal Data

The University of Thessaly (hereinafter “the University”) attaches great importance to the lawful and secure processing of your personal data, which is carried out in compliance with the fundamental principles of personal data protection imposed by Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons concerning the processing of personal data and on the free movement of such data (General Data Protection Regulation – GDPR), namely the principles of lawfulness, fairness and transparency of processing, purpose limitation, data minimization, accuracy, storage limitation, integrity and confidentiality, and, finally, accountability.

1. Data Controller

The University is the Data Controller of the personal data processed within the framework of the following purpose:

Our address is Argonafton and Filellinon Streets, P.C. 382 21, Volos, Contact Tel.: 30 2421074000, and you may contact the University’s Data Protection Officer (DPO), which is the company Priority Quality Consultants S.A, at the email: dpo@uth.gr

2. Purpose of Processing

The University processes personal data within the scope of managing the research/clinical trial it conducts for and in which you are participating.

3. Personal data subject to processing

Within the scope of the above purpose, the following personal data is subject to processing:

1. Basic personal details (e.g., name of the treating physician, name of the patient, patient ID/code/barcode, address, telephone number, age, gender, registration number, information related to physical condition/activity, data concerning dietary habits, etc.)
2. Biometric data (e.g., biological material / urine or blood sample / sample code etc.)
3. Health data (e.g., medical history, medication, physician’s certificate for participation in the research, data related to drug use or smoking etc.)
4. Unique identifiers (e.g., Identity Card Number)
5. Data related to sexual orientation



6. Genetic Data (DNA)

7. Image data (e.g., photos, videos)

8. Sound data

9. Anthropometric data (e.g., weight, height)

Your personal data listed above are collected either directly from you or from the respective parties involved in the process, such as the Principal Investigator Person/Professor, the attending physician, the collaborating hospital or clinic, external laboratories, cooperating Research Centers, public hospitals in Europe, students participating in the research/trial, as well as your accompanying person. Finally, your data are collected from the REDCAP online research platform and other clinical trial databases/applications, in cases where they have already been entered by other entities.

4. Legal Basis for Processing

With regard to the personal data processed by the University within the scope of managing the research/clinical trial we conduct and in which you participate, ~~with the exception of~~ except for special categories of data (health, biometric and genetic, anthropometric data, as well as data concerning sexual orientation), the legal basis for their processing is that it is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the University.

With regard to special categories of personal data that we process, the legal basis for such processing is that it is necessary for scientific/historical research or statistical purposes, as well as for archiving purposes in the public interest pursued by the University

5. Access to personal data-recipients

Access to your personal data collected within the scope of the above purpose is granted to the authorised University personnel responsible for handling this procedure, who have received appropriate training regarding the secure processing of personal data.

In addition, recipients of your data include the participating attending physician, external laboratories (e.g., at other universities in Europe or other specialized laboratories), collaborating Research Centers / Public Hospitals in Europe (e.g., in France for a Biochemistry laboratory), and doctoral candidates (who are not members of the research team).

Finally, recipients of your data also include cooperating companies (data processors) that support our information systems and applications, external laboratories, other external collaborators (e.g., statistical analysts), as well as the cooperating company responsible for the development and maintenance of the clinical trial application. These data processors have been informed in advance and committed to maintaining data confidentiality, are aware of and follow our instructions regarding the processing of personal data, and take all appropriate measures to protect them.

6. Transfers outside the EEA (European Economic Area)

Your personal data collected within the framework of the present purpose are transferred outside the European Economic Area, specifically to universities in the United States of America and to Microsoft's data storage infrastructure, also located in the United States.

Regarding transfers to universities in the United States, such transfers are carried out on the basis of standard contractual clauses approved for data protection.

Regarding the transfer of personal data to data storage infrastructure in the United States, this is carried out on the basis of an adequacy decision, and specifically where the entity to which the data are transferred is part of the EU–US Privacy Shield framework for the secure transfer of data.

7. Retention period of your personal data

Your personal data are retained only for the reasonable period required by the nature of the data processing and only for as long as necessary to achieve the purpose of such processing, unless there is a contrary legal obligation requiring their further retention.

8. Security of your data

We are committed to ensuring that appropriate organizational and technical measures have been implemented for the security and protection of your data against any form of accidental or unlawful processing. It is noted that our specially authorised personnel, who process your personal data, have received appropriate training, guidance, and instructions.

The measures we implement are reviewed and amended at regular intervals, or whenever necessary, in response to new requirements and technological developments.

9. Your rights and how to exercise them

- Right of access to personal data
- Right to rectification of inaccurate personal data
- Right to erasure / right to be forgotten
- Right of data portability
- Right to restriction of processing
- Right to object to the processing of your data

In the event that: (a) you believe that any of your requests has not been adequately and lawfully satisfied, or (b) you consider that your right to the protection of personal data is being violated by any processing we carry out, you have the right to lodge a complaint with the Hellenic Data Protection Authority (address 1-3 Kifisias Str., P.C. 115 23, Athens, Tel. 210. 6475600, e-mail: contact@dpa.gr).

If you wish to obtain further information regarding the processing of your personal data or to exercise any of the above rights, you may contact the University's Data Protection Officer at the email address: dpo@uth.gr, or send a letter to the postal address indicated above (Argonafton & Fillelinon, P.C. 382 21, Volos), marking it "For the attention of the Data Protection Officer," with a description of your request. We will ensure that it is reviewed and responded to as soon



as possible.

We will respond to your request within one (1) month of its receipt, and this service will not entail any cost to you. This period may be extended by an additional two (2) months due to the complexity or number of requests. In such cases, you will be informed of the extension and the reasons for it as soon as possible and no later than one month after receipt of the request.

In cases where the request is considered manifestly unfounded, excessive, or repetitive, the University may either refuse to process it or request the payment of a reasonable fee to cover the administrative costs of providing the information or carrying out the requested action.

I was informed about my personal data processing.

Date:.....

Name:

Signature:.....