

CONSENT AFTER INFORMATION

Version 1.0, 4 November 2020

**Ι. INFORMATION SHEET**

**Study title:**  [ΧΧΧΧ]

**Principal Investigator:** [XXXXXXX]

**Funding Organisation:[Name of the Funding Organisation]**

**Or The study is being conducted in the context of** [Master/PhD/Education/Course/Activity]

**Data Controller:** Aristotle University of Thessaloniki  **(AUTh)**

**Names of the coordinators of the research/scientific coordinator:** [Name CR1/SC1]

 [Name CR2/SC2] etc

 Email: xxxxx

 TeL: xxxxx

 Address: xxxxx

**Data Protection Officer (DPO):** data.protection@auth.gr

**Important Information**

You will be given information on the research conducted [a short description of the content of the study] and you will be invited to take part in the study. Your participation is voluntary.

You can talk about this study and the consent form with other people such as family/friends/or whoever you feel comfortable with. You do not have to decide right away. You can decide whether you want to take part in the study after you have thought/ discussed this.

There may be words you do not understand or some things you would like for me to explain to you in detail. You can stop anytime and ask questions.

**If applicable include the following**

**Your decision will not adversely affect the medical services or care or any relevant right conferred on you by [XXXX] in case you are entitled to any of the above mentioned.**

**Purpose: Why are we conducting this study?**

[Define the purpose of the processing of the data]

[Define that if the data will be further processed, the data subjects will be notified accordingly]

**Subject Selection: Why are we requesting your participation?**

[Brief description of the selection criteria related to participants]

**Your participation is voluntary: Do I have to do this?**

You do not have to take part in the study if you don’t want to. Even if you say “yes” now, you can change your mind later and pull out of the study at any time.

**Participation cost: What will this cost me?**

[Define weather there is any cost involved]

**Procedure: What will happen if you take part in the study?**

[Detailed description of what the participant will do and for how long]

**Data: What kind of data will be collected?**

[Detailed description of what is going to be recorded/collected and how]

[Define the period for which the personal data will be stored]

**Who will receive or to whom maybe distributed the collected personal data?**

[Define whether the data are distributed and to whom]

Personal data is intended to be transferred/not to be transferred to a third country or to an international organisation provided that in any case appropriate safeguards are taken.

Clarify that in case that personal data are transferred to third countries that are not subject to the GDPR, due to the potential absence of an adequacy decision and appropriate safeguards, the personal data provided might not to be treated according to the principles of the GDPR (EU Regulation 2016/679).

**Risks: Is this bad or dangerous for me?**

[Description of risks or explanation of why they do not exist]

**Discomfort: Will it hurt?**

[Description of possible pain that will be experienced]

**Benefits: Will this be beneficial for me?**

[Brief description of possible benefits for the participant]

**Sharing the results: Will you inform me on the conclusions?**

When the research is finished, I will be able to explain to you everything we have learned. An informational brochure will be available upon your request. Later on, we will inform other people about the research we have made and what we have found. This will be accomplished by writing articles and meeting with people that are interested in what we do.

**Right to refuse or withdraw: I can choose not to be part of this study? Can I change my mind?**

Your participation is not forced. You can stop the research at any time if you wish.

Consent is provided for [ΧΧΧΧ months/years] [the time period for which consent is given shall be in consistency with the time period that the personal data will be kept] until it is revoked by sending an e-mail to [ΧΧΧΧΧ] or by sending the application form enclosed at the end of this document to the address of the coordinator of the research/scientific. The right to withdraw consent at any time does not affect the lawfulness of the processing based on the consent given before its withdrawal.

**Data managing**

The processing of your personal data is based on consent to this processing for specific purpose. Your personal data will be codified and saved at computers in accordance with appropriate technical and organisational measures. [define in a simple and clear way these technical and organisational measures that will be taken with the view of data protection].

You have the right to request from the Head of the Research access to or rectification or erasure of your personal data or restriction of processing concerning your data or to object to processing as well as the right to data portability.[ You can choose which of these rights are feasible to be conferred on]. For any enquiry or guidance regarding your rights, you could send an email to [ΧΧΧΧΧ] or phone at [2310-XXXXXX]. Any change in your personal data will take place within 30 days of your communication with Principal Investigator.

If you have any questions about your personal data and your relevant rights or if you believe that your rights are being violated, you can contact the Data Protection Officer of the Aristotle University of Thessaloniki (data.protection@auth.gr). For additional protection you have the right to lodge a complaint with the Hellenic Data Protection Authority ([www.dpa.gr](http://www.dpa.gr)).

**If you finally decide that you would like to take part in the study you will receive a copy of this sheet.**



1. **CONSENT**

**[RESEARCH NAME]**

I the undersigned …………………………………………………………………………
[constitute the legal guardian of FULL NAME …………………………….…who is under 18 years of age],

 I declare that:

* I have been adequately and comprehensively informed by …………………………………………………………………………………………. (name and position/area of responsibility of the researcher) for the purposes of the research in which I will participate and which is part of the research project ………………………………………………………………………… ……………… (Name of the research project) related to ………….code attributed by ELKE …………………………………. (in case there is a relevant code).
* I have been adequately and comprehensively informed about the method and sources of the research financing.
* I have been adequately and comprehensively informed about what my participation in this research entails. In particular, I have been informed of all the rights and obligations I will have as a participant in the research comprising the obligation of confidentiality (if the latter is required).
* I have been adequately and comprehensively informed about any positive or directly negative, short-term or long-term consequence my participation in this research is expected to have concerning me or in relation with third parties.
* I have been adequately and comprehensively informed about how my personal data related to this research is processed and protected.
* I have been adequately and comprehensively informed about the provision and proper use of the medicines / devices / personal protective equipment /………………………………/ (fill in accordingly) that I will use during my participation in this research.

* I am aware of the fact that my participation is voluntary and that I can withdraw my participation from the research at any time for any reason and without any impact on me (as well as of the fact that the same applies to the person I represent).

* I know the Head of the research to whom I can address to withdraw my participation from this research or to notify any potential problem that might arise during my participation or after the completion of this research.

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* No pressure was exerted to me and I was given enough time to think and decide.

**I consent to participate in the above research.**

**I consent that the Participant [Full Name] for whom I constitute the Legal Guardian takes part in the above research.**

**Participant’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Legal Guardian’s signature:**

**Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **day/month/year**



**ΙΙΙ. WITHDRAWAL OF CONSENT OF THE PARTICIPANT**

**[[RESEARCH NAME]**

I the undersigned …………………………………………………………………………
[constitute the legal guardian of FULL NAME …………………………….…who is under 18 years of age],

**hereby withdraw my consent concerning my participation/the participation of my child/the participation of the person for whom I constitute the legal guardian in the research study XXXX [NAME OF THE RESEARCH STUDY], which I had given on** \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_

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| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of the participant Signature of the legal guardian  | Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ day/month/year |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Full name  |  |