

**INFORMED, CLARIFIED AND FREE CONSENT  
For Clinical Research**

<b>Study</b>	<b>Envelhecimento na população portuguesa, um estudo piloto</b> <b>Mapa da Idade</b>
<b>Sponsor</b>	<b>Fundação GIMM – Gulbenkian Institute for Molecular Medicine</b>
<b>Principal Investigator</b>	<b>Pedro Sousa-Víctor</b>
<b>Research Center</b>	<b>Fundação GIMM – Gulbenkian Institute for Molecular Medicine</b>
<b>Responsible Ethics Committee</b>	<b>Comissão de Ética do Centro Académico de Medicina de Lisboa – CAML (Ref. 358/25)</b>
<b>Date of approval by the ethics committee</b>	<b>08/01/2026</b>

**Introduction**

Volunteers aged 40 to 80, inclusive, are invited to participate in this study on aging.

To help you make an informed decision about participating in this study, this document describes its purpose, procedures, potential benefits and risks, and the personal data that will be collected and may be used during the study and after its completion. Your participation may contribute to improving our understanding of aging and the development of a biological clock tailored to the Portuguese population.

Please read this information carefully and take as much time as you need. After reading this document, understanding the study, and having no questions about it, you should decide whether or not to participate. If, during the study, you have questions or need help filling out the documents, please contact the research team.

If you wish to participate, you will be asked to select the relevant “I Authorize” options (according to the consents you wish to give).

**Who is the study sponsor, who is responsible for conducting the study, and who approved it?**

This research study is sponsored by the GIMM Foundation – Gulbenkian Institute for Molecular Medicine, based in Lisbon at the Faculty of Medicine of the University of Lisbon (“Sponsor”). The study is led by Dr. Pedro Sousa-Víctor, as Principal Investigator, and the rest of the research team.

This study is also being conducted in partnership with Joaquim Chaves Saúde, which will be contracted by the GIMM Foundation to perform clinical laboratory analyses for this study.

This study has been reviewed and approved by the Ethics Committee of the Lisbon Academic Medical Center.

**What type of study is this?**

This study is an observational study whose main objective is to assess whether the algorithm developed by an international team, known as the LinAge2 Biological Clock, can calculate the biological age of 120 Portuguese individuals between the ages of 40 and 80, examining how different characteristics of the population influence this calculation. The relationship between this biological age and other aspects of the participants’ health, such as telomere length and markers of gut function, will also be analyzed.

The LinAge2 Biological Clock is an algorithm (mathematical model) that has already been applied in studies of the U.S. population and allows for the calculation of an individual’s biological age. Biological age may differ from chronological age. Chronological age is the time that has passed since a person’s



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birth, while biological age indicates the actual state of health and aging of their body, which may differ from chronological age. The difference between chronological age and biological age, calculated using mathematical models, can be used as a measure of healthy or unhealthy aging.

Telomeres are the ends of chromosomes and act as protectors of genetic material. They can be compared to the plastic tips that prevent shoelaces from fraying. Over time, and with each cell division that occurs throughout a person's life, telomeres become shorter. They are, therefore, a measure of cellular aging.

Intestinal permeability refers to the ability of the intestinal wall to control what is absorbed into the bloodstream. Normally, this wall acts as a barrier that allows water and nutrients to pass through while preventing toxins or unwanted substances from entering the bloodstream. When this barrier is weakened or damaged, excessive "leakage" can occur, allowing toxins and foreign particles to cross into the bloodstream, which can cause inflammation and associated health problems. It is also a measure of the human body's aging process.

### **Why are you invited to participate, and how can you express your interest?**

Approximately 120 volunteers will be able to participate in this pilot study. You are invited to participate because you meet the eligibility criteria, namely: being between 40 and 80 years of age, inclusive.

The informational session we are holding today is intended to explain what the study entails and what participation involves for those who wish to join the study.

If, at the end of the session, you are interested in participating in the study, you will be asked to register on our scheduling platform so that we can contact you regarding the study and schedule your first visit. Today, you will take this form home so that you have time to read it carefully and, if you wish, discuss it with your family. Registering on the platform does not mean you are already a participant. It is simply an expression of interest in having a participant recruitment visit scheduled for you.

### **What will happen if you agree to participate in this study?**

On the day and time of your appointment, you should go to the location you selected.

During this visit, you will be asked if you have any questions or concerns regarding this informational document that you would like clarified before agreeing to participate in the study and before the samples are collected. You may decide not to participate at any time.

If you wish to participate, you will need to complete and sign this Informed Consent Form, and then proceed with the collection of your anthropometric measurements (weight, height, waist circumference, blood pressure, and handgrip strength) and biological samples (blood and urine).

You must come on an empty stomach for the clinical laboratory tests. For this reason, after completing the data collection procedures, you will be served breakfast,

During breakfast, or if you prefer, immediately afterward, you will also be asked to complete a health and lifestyle questionnaire.

### **What are my obligations if I decide to participate in this study?**

If you decide to participate in this study, you will need to perform the activities listed above. As a participant, you have no other obligations during the course of the study.

### **What are the risks of participating in the study?**

This study only collects information, so it is unlikely that there are any risks associated with it. Your lifestyle will not be affected by your decision to participate or not in the study. Anthropometric measurements and blood and urine samples may cause the normal discomfort associated with these clinical tests or the risks inherent in them. Any injury you may experience while participating in this study will not be considered an injury resulting from the research.

**Is there any benefit to participating in the study?**

This study is being conducted solely for academic research purposes, that is, not for commercial purposes. There is no guarantee that you will derive any direct benefit from participating in this study. The direct benefit is for the advancement of medical science.

**What alternatives do I have if I decide not to participate in this study?**

This study is being conducted solely for research purposes. You may choose not to participate in this study.

**Will I receive any payment if I decide to participate in this study?**

Your participation in this study will not be paid. Likewise, you will not incur any expenses related to your participation in this study; all such expenses will be covered by the GIMM Foundation.

**What happens if I change my mind about participating?**

If you agree to participate in the study and later change your mind, you may withdraw at any time, without giving a reason, by sending an email to [info@gimm.pt](mailto:info@gimm.pt). Any healthcare (treatment and medical care) to which you are entitled will not be affected. From that point on, you will no longer be able to participate in the study, and no further samples or new information will be collected from you.

**Can I find out the results of the study?**

The clinical study report containing the results of this study will be made available to any participant who requests a copy. Before this report is provided, additional measures will be taken to protect your information. Scientific publications by the Sponsor will be available on the website [www.care.gimm.pt/](http://www.care.gimm.pt/).

**INFORMATION ABOUT THE PROCESSING OF YOUR PERSONAL DATA**

The GIMM Foundation – Gulbenkian Institute for Molecular Medicine, located at Av. Professor Egas Moniz, 1649-026 Lisbon, telephone: (351) 217 999 411, and email: [info@gimm.pt](mailto:info@gimm.pt), acting as the sponsor of this study, is the data controller responsible for processing your personal data in connection with the study. The contact information for the Data Protection Officer of the GIMM Foundation is: [dpo@gimm.pt](mailto:dpo@gimm.pt).

Your personal data will be processed based on your explicit consent for the purposes of conducting scientific research, communication within the scope of the study, and compliance with applicable legal and regulatory obligations and requirements. For the above purposes, your personal data may be processed by the researchers and members of the study team, by the Sponsor, by the study auditor/monitor, and, if necessary, by administrative authorities and the Ethics Committee.

During the study, the following personal data about you will be collected: date of birth; data regarding nationality, sociodemographic profile, and socioeconomic status; health data, including medical history, dietary habits, alcohol consumption, smoking habits, test and examination results, and clinical evaluation. All personal data is recorded in a pseudonymized form, that is, using an identification code instead of your name, and all data and samples collected about you will be protected using this code. Only the research team will control the code key.

Because the purpose of the study is to evaluate this data, if you do not agree to provide your personal data, you will not be able to participate in this clinical study.

The data will be stored at the GIMM Foundation for the period necessary to fulfill the purposes described in this informed consent, only until the publication of the results (scientific articles), which

may be up to 10 years after the end of the study.

Regarding the biological samples, participants will be asked to provide separate informed consent, which explains the purpose of the GIMM-Biobank and allows them to choose whether they also wish to authorize the use of their samples for future studies. Participation is voluntary, and confidentiality in the handling of samples is guaranteed.

If you have given consent for the future storage of samples in the GIMM-Biobank, they will be stored for 20 years.

Regarding all your personal data, you have the following rights:

- You have the right to withdraw your consent to the processing of your personal data at any time. If you do so, you will no longer be able to participate in the study. Your personal data that has already been collected up to that point may need to be retained and used solely to ensure the scientific integrity of the study, without prejudice to compliance with legal obligations to which the entities involved in the study are bound.
- You have the right to access your personal data, as well as other information regarding the processing of your data. *[Find out how at: <https://www.cnpd.pt/cidadaos/direitos/direito-de-acesso-aos-dados/>]*
- You have the right to correct and update your personal data.
- You have the right to restrict the processing of your personal data under certain legally prescribed circumstances (for example, if the information is inaccurate). *[Learn how at: <https://www.cnpd.pt/cidadaos/direitos/direito-a-limitacao-do-tratamento/>]*
- You have the right to receive the personal data you have provided to us in a structured, commonly used, and machine-readable format, and to have your data transmitted directly to another entity of your choice, whenever technically possible. *[Learn how at: <https://www.cnpd.pt/cidadaos/direitos/direito-de-portabilidade/>]*
- You have the right to object to the processing of your personal data at any time, in accordance with the law. *[Learn how at: <https://www.cnpd.pt/cidadaos/direitos/direito-de-oposicao/>]*
- You have the right to request that your personal data be erased under the existing legal conditions and limitations. *[Learn how at: <https://www.cnpd.pt/cidadaos/direitos/direito-ao-apagamento-dos-dados/>]*
- You have the right to file a complaint with the National Data Protection Commission *[Learn how at: <https://www.cnpd.pt/cidadaos/participacoes/geral/>].*

To exercise your rights with GIMM or to clarify any questions, please send an email to: [dpo@gimm.pt](mailto:dpo@gimm.pt).

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The data resulting from this study, once anonymized, may be used in other scientific research projects.

**PROFESSIONAL DECLARATION**

I confirm that I have explained the procedures involved in the study to the person listed below in a clear and understandable manner.

I answered all the questions asked of me and ensured that there was sufficient time for reflection before deciding.

I explained the voluntary nature of participation, the right to refuse or withdraw consent, and the possibility of requesting to interrupt or even withdraw from participation should they feel the need or desire to do so, without this resulting in any detriment to their clinical care.

I informed them that the privacy of the personal data collected is ensured through pseudonymization, guaranteed by the assignment of a code whose decryption key is restricted to the Principal Investigator of the project or whoever they designate to assist them or act in their place, and that the confidentiality and protection of personal data are safeguarded in accordance with the General Data Protection Regulation (GDPR).

LEGIBLE NAME:
SIGNATURE:
DATE:

**TO THE INDIVIDUAL/REPRESENTATIVE**

Please read the entire contents of this document carefully. Do not hesitate to ask for more information if anything is unclear

Please verify that all information is correct.

**PARTICIPANT IDENTIFICATION**

NAME:
DATE OF BIRTH:
ADDRESS:
TYPE OF IDENTIFICATION DOCUMENT:
IDENTIFICATION DOCUMENT NUMBER:
EXPIRATION DATE:

**IF YOU ARE NOT SUBMITTING THE ENTRY YOURSELF DUE TO DISABILITY**

NAME OF REPRESENTATIVE:
TYPE OF IDENTIFICATION DOCUMENT:
IDENTIFICATION DOCUMENT NUMBER:
EXPIRATION DATE:
TYPE OF REPRESENTATION:

**DECLARATION BY THE CONSENTING PARTY**

I declare:

- That I am aware of the voluntary nature of participation in this study and have understood its objectives.
- That I have been given sufficient time to reflect on this proposal, the opportunity to ask all questions regarding the matter, and that I have received clear answers to all of them; that I have been assured that there will be no prejudice to my healthcare rights if I refuse to participate or revoke the consent previously provided.

- I have read and understood the information provided regarding the processing of my personal data, and I understand that participation in this study requires the processing of such data, as explained above.\
- I understand that I may withdraw my consent to participate in the study and to the processing of my personal data at any time, and that this will not affect my medical care or my legal rights.

**I intend to participate in the study “Aging in the Portuguese Population, a Pilot Study” and, to that end, I authorize the collection of personal information (date of birth, clinical information, and lifestyle information), the collection of anthropometric measurements (weight, height, waist circumference, blood pressure, and handgrip strength) and biological samples (blood and urine) for use in accordance with the informed consent forms.**

**I authorize the corresponding processing of personal data so that it may be used for this study, under the terms described above.**

**If, during the study “Aging in the Portuguese Population, a Pilot Study,” factors with potential relevance to my health are identified, I wish to be informed of them by a qualified healthcare professional and authorize such contact.**

Name	Date	Signature
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