UNIVERSITÀ DEGLI STUDI DI FIRENZE
DIPARTIMENTO DI MEDICINA SPERIMENTALE E CLINICA

UNITÀ DI RICERCA IN MEDICINA DELL'INVECCHIAMENTO

AZIENDA OSPEDALIERO - UNIVERSITARIA CAREGGI
FIRENZE
DAI MEDICO GERIATRICO

SOD GERIATRIA – UNITÀ DI TERAPIA INTENSIVA GERIATRICA

Direttore: Prof. Andrea Ungar

Direzione: Largo Brambilla, 3
50134 Firenze

Unità di Terapia Intensiva Geriatrica 055-7949429
Ambulatori 055-7949579 / 055-7949558

April 19, 2021

Microbiota-Inflammation-Brain Axis in Heart Failure: New Food, biomarkerS and Artificial Intelligence Approach for the Prevention of undeRnutrition in Older (AMBROSIA)

Dear Sir/Madam,

The information contained in this information sheet is detailed and may appear VERY COMPLEX.
We kindly ask you to agree to participate in the study ONLY after having carefully read this information sheet and having had a THOROUGH DISCUSSION with the study physician, who will dedicate the NECESSARY TIME to help you fully understand what is being proposed.

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WRITTEN INFORMATION FOR THE PATIENT
Version 1 – April 19, 2021

Study Title:
"Ambrosia" food strategy for preventing undernutrition and assessment of new biomarkers in older heart failure and atrial fibrillation patients.
AMBROSIA: "Microbiota-Inflammation-Brain axis in heart failure: new food, BiomarkerS and AI Approach for the prevention of undeRnutrition in Older Heart Failure and Atrial Fibrillation Patients"

Protocol code, version and date:
Version 1 – April 19, 2021
EudraCT number: Not applicable

Study Sponsor:
Prof. Amedeo Amedei
Department of Experimental and Clinical Medicine
Laboratory of Immunology and Microbiome
University of Florence
amedeo.amedei@unifi.it
+39 055 2758330

Principal Investigator:
Prof. Stefano Fumagalli
Geriatrics Unit – UTIG, Careggi University Hospital
Department of Experimental and Clinical Medicine, University of Florence
+39 055 7949429
stefano.fumagalli@unifi.it

Dear Madam / Sir,

You have been invited to take part in a clinical study, and this document is intended to inform you about the nature of the study, its objectives, what your participation will involve, as well as your rights and responsibilities.

Please read this written information carefully before deciding whether to participate in the study. You will have all the time you need to consider your decision.

You are also free to ask any questions you may have and to raise any concerns that have not been clearly and fully addressed.

If, after reading and understanding all the information provided, you decide to participate in the clinical study, you will be asked to sign and personally date the attached Informed Consent form.

Your personal data will be processed as described in the specific privacy notice regarding the processing of

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personal data, in compliance with Regulation (EU) 2016/679 – the General Data Protection Regulation (GDPR) – and Italian Legislative Decree of 30 June 2003, the Personal Data Protection Code, which implements the GDPR into national law. This privacy notice and the related request for consent to data processing will be provided to you separately.

1. Purpose of the Study

The aim of the study is to assess the effects of a chocolate bar enriched with probiotics and proteins on the nutritional status of older patients with atrial fibrillation and/or heart failure.

2. Study Characteristics

This is a parallel-group study conducted at this facility, which will enroll 120 patients with atrial fibrillation, heart failure, or both conditions.

"Parallel-group" means that one group of patients will receive the chocolate bar, while another group will receive standard care without the bar and will serve as the control group.

This is an **open-label** study, meaning that both you and the study physician will know in advance which group you are assigned to (intervention or control).

The total duration of the study is 36 months, but your individual participation will last only **6 months**.

As specified in the attached privacy notice, the study also involves other institutions, brought together in a **consortium**:

No.	Paese	Nome	Affiliazione
1	Palma de Mallorca, Spain	Gwendolyn Barceló-Coblijn	IdISBa, Foundation Health Research Institute of the Balearic Islands, Lipids in Human Pathology group

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			Edificio S, Hospital Universitario Son Espases,
2	Camerino, Italy	Maria Cristina Verdenelli	Synbiotec Srl,
3	Dublin Ireland	Marco Garcia-Vaquero	Section of Food adn Nutrition, School of Agriculture and Food Science, University College Dublin
4	Newcastle upon Tyne United Kingdom	Iain Brownlee	Northumbria University, NB144, Northumberland Building, Northumbria University
5	Göttingen, Germany	Thomas Lingner	Genevention GmbH, R&D

3. What Your Participation in the Study Involves

If you decide to take part in the study, please note that, after evaluating your eligibility and completing all standard medical and instrumental assessments (regardless of your participation in this research), the study will include:

- The completion of questionnaires to assess your physical and psychological condition
- A blood sample
- The collection of stool, urine, and saliva samples for gut microbiome analysis

If you are selected for the experimental group, you will be provided with a **chocolate bar enriched with probiotics and proteins**, to be consumed **once daily**, **15 minutes before breakfast**, for a period of **6 months**.

At the 6-month follow-up visit, the same assessments (questionnaires, blood test, biological sample collection) will be repeated.

Samples will initially be processed at the Laboratory of Immunology and Microbiome, Prof. Amedeo Amedei, Department of Experimental and Clinical Medicine, University of Florence. Specifically:

- Bacterial DNA will be extracted from stool and saliva
- Serum will be separated from blood
- Fecal water will be extracted from stool samples for **metabolomic analysis**, i.e., the analysis of human

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and microbial components eliminated from the body

Some serum samples will be sent to **Dr. Gwendolyn Barceló-Coblijn**, IdISBa – Foundation Health Research Institute of the Balearic Islands, Lipids in Human Pathology Group, Son Espases University Hospital, Palma de Mallorca, Spain.
Fecal water will be sent to **Prof. Iain Brownlee**, Northumbria University, Newcastle upon Tyne, UK, for further analysis.

All residual biological samples will be stored for 10 years at Prof. Amedei's lab and may be used for studies directly related to the present research.

4. Assessments You Will Undergo During the Study

You will be required to visit our center at baseline and again 6 months later. Baseline clinical procedures will be the same as standard care:

- Clinical visit for heart failure monitoring
- Clinical visit and electrical cardioversion for atrial fibrillation, if needed
- Comprehensive geriatric assessment in all cases

The chocolate bar, to be taken **once daily**, contains **probiotics** (lactobacilli similar to those found in yogurt), **proteins**, **fiber**, and **coenzyme Q10**. These substances are widely used in daily practice. The novelty lies in their **combination** in a single, convenient bar.

Blood tests will include standard clinical markers plus specific markers of **low-grade chronic inflammation**, related to aging and chronic disease development. Stool samples will be used to analyze gut microbiota. All tests and clinical assessments will be repeated at the follow-up visit to evaluate the effects of the intervention compared to the control group

5. Potential Benefits of Participating

Although not guaranteed, the intake of the bar is expected to help restore gut microbiota balance, improve nutrient absorption, and reduce the risk of undernutrition. This is due to the action of proteins and coenzyme Q10.
In elderly cardiac patients, **metabolic disturbances** are common and may contribute to **muscle loss** and the development of **frailty**. This study may help us better understand the relationship between cardiovascular disease, physical function decline, and frailty.

6. Potential Risks of Participation

Participating in a study always involves potential risks or inconveniences. However, since the nutritional components used are common and well-known, **no serious or foreseeable adverse events** are expected.

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In rare cases, **temporary intestinal bloating** may occur.
The only significant risk is potential **allergic reactions** to specific components.

For any concerns about risks, you should consult with the study physicians.
It is important that you inform the study physician immediately of any changes in your health, regardless of whether you believe they are related to the supplement.

If any medical issue arises as a result of the study, **you will receive appropriate medical care**.

6.1 Prohibited Medications

There are no medications strictly prohibited during the study. However, due to the nature of the assessments, it is recommended to avoid regular use of:

- Non-steroidal anti-inflammatory drugs (NSAIDs)
- Corticosteroids or other immunosuppressants
- Antibiotics

6.2 Risks Related to Unexpected Findings

The procedures in this study are not expected to reveal findings unrelated to the study purpose (i.e., incidental findings).

7. What Happens in Case of Study-Related Injury?

The sponsor has taken out insurance coverage with **HDI Global SE**, in accordance with the Ministerial Decree of July 14, 2009. This policy covers **damages caused to participants** during the study, including those resulting from negligence, error, or accident.

Coverage includes:

- Maximum of **€7,500,000 per patient**
- Maximum of **€1,000,000 per protocol**

Coverage is valid for injuries occurring during the trial period, provided the damage appears within **24 months** of the study end and the claim is submitted within **36 months**.

You retain the right to seek compensation directly from those responsible for any harm.
Signing this consent form **does not waive any of your legal rights**.

If you have a personal insurance policy, you are advised to consult your provider to ensure that participation will

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not affect your coverage.

Exclusions from insurance coverage include:

- Unauthorized studies or deviations from approved protocols
- Damages unrelated to the trial
- Damages to pregnant women or fetuses if no prevention measures are described in the protocol
- Claims based on the product's lack of effectiveness
- Claims related to non-compliant equipment or chemicals
- Claims involving HIV-related immunodeficiency or diagnostic errors
- Damages from invasive or surgical procedures (excluding standard injections or blood draws)

Coronavirus and Pandemic Exclusion:
The policy excludes all damages, injuries, losses, or disruptions directly or indirectly caused by:

- Any Coronavirus (e.g., COVID-19, SARS, MERS-CoV)
- Any Filovirus (e.g., Ebola, Marburg)
- Any epidemic or pandemic declared or not
- Any mutation, variation, or threat thereof

8. Possible Alternatives

This study is designed to **enhance standard clinical care** by testing a new combination of nutritional supplements and evaluating their effects.
If you choose not to participate, you will continue to receive **optimal care**, based on current clinical guidelines.

9. What Happens If You Decide Not to Participate

Your participation is **entirely voluntary**. You are free to decline or withdraw at any time without giving a reason, simply by notifying the study physician, **Prof. Stefano Fumagalli** (055 7949429, stefano.fumagalli@unifi.it).
In such cases, no further data will be collected, and you may request the deletion of any previously collected data.

Your current and future medical care will not be affected by your decision. Your doctors will continue to treat you with the same level of care and attention.

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Your participation may also be discontinued if:

- The physician deems the treatment ineffective
- You experience adverse effects

In such cases, you will be informed immediately and alternative treatments will be discussed.

10. End-of-Study Procedures

At the end of the study, **no special patient procedures** are planned beyond standard clinical practice.

11. Consent to Inform Your General Practitioner

To best protect your health, you will be asked to inform your general practitioner about your participation in this study.
Their involvement is important to **prevent potential interactions** between study supplements and medications they may prescribe.

12. Information About Study Results

If you wish, **you may receive a summary of the general study results**, as well as results specific to your participation.
Study-related websites will **not include any personal identifiers**, only general summaries of procedures and outcomes. These will be publicly accessible.

If any results are available only in English, you may ask the study physician for assistance in reviewing them.

13. Additional Information

There are **no costs to you** for participating in the study. You will **not receive any financial compensation** for your participation.
The study site will receive funding from the **Joint Programming Initiative "A Healthy Diet for a Healthy Life" (JPI HDHL) 2020: "PREVNUT"** for data collection and study management.

The study protocol has been approved by the **Ethics Committee** on [insert date].
The Committee has confirmed compliance with **EU Good Clinical Practice (GCP)** and the ethical principles outlined in the **Declaration of Helsinki**.

If you wish to report any concern about the study, you may contact the **Ethics Committee** or the **Hospital Medical Directorate**.

For any questions about the study, your participation, potential harm, or your rights as a participant, please contact:
Prof. Stefano Fumagalli – 055 7949429 – stefano.fumagalli@unifi.it

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_____	___/___/_____	_____	_____
Full name of the physician who provided the information	**Date**	**Time**	**Signature of the physician**

INFORMED CONSENT FORM
FOR PARTICIPATION IN THE STUDY
Version 1 – April 19, 2021

Study Title:
"Ambrosia" food strategy for preventing undernutrition and assessment of new biomarkers in older heart failure and atrial fibrillation patients.
AMBROSIA: *Microbiota-Inflammation-Brain axis in heart failure: new food, BiomarkerS and AI Approach for the prevention of undeRnutrition in Older Heart Failure and Atrial Fibrillation Patients*

Protocol Code, Version and Date:
Version 1 – April 19, 2021

Study Sponsor:
Prof. Amedeo Amedei
Department of Experimental and Clinical Medicine
Laboratory of Immunology and Microbiome
University of Florence
amedeo.amedei@unifi.it – +39 055 2758330

Principal Investigator:
Prof. Stefano Fumagalli
Geriatrics Unit – UTIG, Careggi University Hospital and University of Florence
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INFORMED CONSENT FORM

I, the undersigned
Name: _____ Date of Birth: ___ / ___ / _____
Place of residence: _____ Street: _____
Phone: _____ Address (if different from residence): _____

DECLARE THAT

- I have received from Dr./Prof. _____ full and clear explanations regarding the request to participate in the above-mentioned research, as outlined in the information sheet, which forms part of this consent document. I received a copy of the information sheet on (date): ___ / ___ / _____ at (time): _____;
- I have read the patient information sheet related to this study, understand that participation is entirely voluntary, and agree to follow the instructions provided by the study physician;
- The nature, purpose, procedures, expected benefits, possible risks and discomforts, and alternatives to participating in this clinical study have been clearly explained to me and I have understood them;
- I have had the opportunity to ask questions and have received satisfactory answers;
- I have had sufficient time to consider whether or not to participate;
- I have not been subject to any undue pressure in being asked to give consent;
- I have been clearly informed that I am free to choose not to participate or to withdraw from the study at any time, without having to provide a reason and without incurring any penalty. Such a decision will not affect my relationship with my healthcare providers or the facility where I receive care;
- I understand the importance of (and my responsibility for) informing my general practitioner about this study. If I choose not to do so, I release both my general practitioner and the study investigators from any liability for harm that may result from potential incompatibility between the study product(s) and other medical treatments;
- I understand that I have the right to request a dated and signed copy of this informed consent form.

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THEREFORE, I DECLARE THAT I:

☐ wish ☐ DO NOT wish
to participate in the study

☐ wish ☐ DO NOT wish
to be informed of the results of this research by the study physician

☐ wish ☐ DO NOT wish
to be informed of the study results by the study physician, including any unexpected findings that may arise from the procedures performed

☐ wish ☐ DO NOT wish
to inform my general practitioner of my participation in the study

_____	___/___/_____	_____	_____
Full name of the patient (adult or mature minor)	**Date**	**Time**	**Signature**
_____	___/___/_____	_____	_____
Full name of legal representative (if applicable)	**Date**	**Time**	**Signature**

If the patient or legal representative is unable to read:

I have participated in the entire informed consent discussion. I certify that the contents of the consent form and all other written materials have been clearly explained and apparently understood by the patient or their legally authorized representative. Informed consent was freely given by the patient or their legal representative.

_____	___/___/_____	_____	_____
Full name of impartial witness	**Date**	**Time**	**Signature**

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INFORMATION ON THE PROCESSING OF PERSONAL DATA

Pursuant to EU General Data Protection Regulation (GDPR) 2016/679

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AMBROSIA: *Microbiota-Inflammation-Brain axis in heart failure: new food, BiomarkerS and AI Approach for the prevention of undeRnutrition in Older Heart Failure and Atrial Fibrillation Patients*

Protocol Code, Version and Date:
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Study Sponsor:
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Department of Experimental and Clinical Medicine
Laboratory of Immunology and Microbiome
University of Florence

Principal Investigator:
Prof. Stefano Fumagalli
Geriatrics Unit – UTIG, Careggi University Hospital and University of Florence
stefano.fumagalli@unifi.it

1. Premise

It is important to recall the following:

- Personal data means any information capable of identifying – directly or indirectly (i.e., also through additional information) – a natural person, the so-called data subject (hereinafter, any reference to the data subject refers to the participant in the study; the terms "data subject" and "participant" are used interchangeably for the purposes of this document);

- Personal data processing refers to any operation carried out on personal data;

- The data controller is the entity (including public bodies) that uses personal data for its own purposes (i.e., for a practical goal or activity), determining the means (i.e., technical and organizational modalities) of such processing.

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For data processing to be lawful, it must comply with specific conditions, legal bases, and purposes set forth and permitted by current legislation. The main legal references concerning personal data protection are:

- **EU Regulation 2016/679** on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (hereinafter: **General Regulation** or **GDPR**);

- **Italian Legislative Decree no. 196 of June 30, 2003**, Personal Data Protection Code, as amended to comply with EU Regulation 2016/679 (hereinafter: **Code**).

Providing information about data processing (also referred to as a privacy notice) is both a right of the data subject and an obligation of the data controller. In short, whether authorized by law or by the data subject's consent, the controller must inform the data subject beforehand about the purposes of processing, its legal basis, the types of data involved, retention periods, modalities, etc., in accordance with Articles 13 and 14 of the General Regulation.

This notice refers to both **Article 13** (personal data collected from the data subject) and **Article 14** (data not obtained directly from the data subject), as the data is collected by the Clinical Trial Center and shared with other controllers who do not have direct contact with the data subject.

2. Purpose and Legal Basis of Processing

The purpose of data processing refers to the practical aim pursued. However, for the processing to be lawful, this is not sufficient. The legal basis refers to a legal condition which, when met, makes the purpose (and the related processing) lawful for a certain category of controllers.

This processing is carried out **for scientific study and research purposes**.

The primary legal basis is **Article 9(2)(j) of the General Regulation** (“processing is necessary for... scientific research purposes”) and, at national level, **Article 110 of the Code** (“Research in the medical, biomedical and epidemiological field”), according to the limitation clause in Article 9(4) GDPR. Since Article 110 of the Code usually requires **the data subject's consent** for research purposes, consent under **Article 9(2)(a)** GDPR is also a legal basis.

Regarding obligations to document the research process and the oversight role of supervisory bodies, these are grounded in specific laws, and the corresponding legal basis is **Article 9(2)(g) GDPR** (“processing is necessary for reasons of substantial public interest”).

3. Controllers, Processors, and Authorized Personnel

The **data controllers** are all entities affiliated with the **Ambrosia Consortium** that, in their respective roles, share the research protocol and have accepted the purposes and modalities of data processing necessary for its implementation.

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Persons who carry out the processing under the authority of the data controller are defined as **authorized personnel**. According to Article 2-quaterdecies of the Code, the data controller may assign specific tasks and functions to natural persons working under their authority. The following are the entities and persons involved in the study:

- **Clinical Trial Center**: Careggi University Hospital (AOU Careggi – Geriatrics Unit – UTIG), referred to as the "Clinical Trial Center", with **Prof. Stefano Fumagalli** as the Principal Investigator;
- **Promoting Center**: University of Florence (Department of Immunology and Microbiome), referred to as "UNIFI" or "Promoting Center", with **Prof. Amedeo Amedei**;
- **Foundation Health Research Institute of the Balearic Islands**, Palma de Mallorca, Spain – Dr. **Gwendolyn Barceló-Coblijn**;
- **Synbiotec Srl**, Camerino, Italy – Prof. **Maria Cristina Verdenelli**;
- **Department of Agriculture, Food and the Marine (DAFM)** – School of Agriculture and Food Science, University College Dublin – Dr. **Marco Garcia-Vaquero**;
- **Northumbria University**, Newcastle upon Tyne, UK – Prof. **Iain Brownlee**;
- **Genevention GmbH**, Göttingen, Germany – Dr. **Thomas Lingner**.

If an external subject processes data on behalf of a controller (e.g., IT services), this requires a **data processing agreement** under **Article 28 GDPR**, and the subject becomes a **data processor**. A list of processors can be requested using the contact details of the Clinical Trial Center found at the end of this notice.

4. Types of Data Processed

This study involves processing the following personal data categories:

- **Special categories of personal data** under Article 9(1) GDPR, particularly health-related data including clinical, functional, psychological, and laboratory test results.

5. Processing Methods

Providing personal data is **essential** to participate in the study. Refusal to provide such data will exclude participation.

Authorized personnel from AOU Careggi may access **identifying data**, whereas authorized personnel from other data controllers will only access **pseudonymized data**.

Pseudonymization means replacing direct identifiers (e.g., names) with codes, and securely storing the re-identification key separately. For example, a tax code, although encoded, is not pseudonymized under this

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SOD GERIATRIA – UNITÀ DI TERAPIA INTENSIVA GERIATRICA

Direttore: Prof. Andrea Ungar

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definition and cannot be used.

The pseudonymization process is carried out by AOU Careggi, which maintains a **direct relationship with participants**. It will record, process, and store personal data and biological samples with the associated code. Only AOU Careggi can re-identify participants.

The code will be used in all communications with other data controllers instead of the participant's name.

Only the Clinical Trial Center has access to the **original clinical documentation and the decoding key**. All other parties receive only **pseudonymized data**.

The legal basis for data communication among controllers is **the participant's consent**.

Data (pseudonymized) may be transferred to the **United Kingdom**, a third country not under EU law. However, the Clinical Trial Center and the Promoting Center ensure adequate safeguards based on **EU Commission Implementing Decision (EU) 2021/1773**.

Participation implies that the **Ethics Committee** and **National/International Health Authorities** may access the original clinical data for compliance and monitoring, regardless of consent.

A third party affiliated with UNIFI will perform **study monitoring** to ensure data quality. These subjects may access identifying data based on legal grounds and independently of participant consent.

Health data will **not be disclosed**. Study results will be made public using **aggregated, anonymous data** (data that cannot be traced back to an individual).

Both the Clinical Trial Center and Promoting Center will apply appropriate **technical and organizational measures** to protect personal data, dignity, and confidentiality.

Processing will be carried out using **paper and digital tools**. The main study **database**, which stores the pseudonymized data, is located at the **University College Dublin**.

6. Data Retention

Personal data will be stored for **ten (10) years** after the conclusion of the study.

Biological samples collected during the study (linked to pseudonymized data) will be stored for **ten (10) years** at the Laboratory of the Department of Experimental and Clinical Medicine at UNIFI.

Data and samples may be used for **related studies** (i.e., studies that directly follow from the present one). In such cases, a new data processing notice will be published on the official AOUC and UNIFI websites.

Outside these cases, **all personal data will be deleted** after the retention period.

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7. Exercise of Rights

The data subject has the right to:

- Access their personal data;
- Request correction, supplementation, or, where applicable, deletion (with some exceptions);
- Request restriction of processing (under Article 18 GDPR);
- Object to data processing.

A participant may **withdraw from the study at any time**. No further data will be collected after withdrawal.

A participant may also request deletion of previously collected data. However, this right may be **limited** if data retention is legally required or if deletion would **compromise the scientific integrity** of the study.

Requests to exercise these rights can be submitted to the **Data Protection Officer (DPO) of AOU Careggi** or the **Principal Investigator**, using the contact details below.

If the data subject believes their rights are violated, they may **file a complaint with the Italian Data Protection Authority** (Garante) under **Article 77 GDPR** or seek legal redress under **Article 79 GDPR**.

8. Contact Details

Data Protection Officer (DPO): Paolo Tagliaferri
Tel: +39 055 7979067 | Mobile: +39 366 6823917
Email: rpd@aou-careggi.toscana.it

Principal Investigator: Prof. Stefano Fumagalli
Email: stefano.fumagalli@unifi.it

Supervisory Authority:
Garante per la Protezione dei Dati Personali
Website: www.garanteprivacy.it
Email: garante@gpdp.it
Phone: +39 06 696771

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DECLARATION OF CONSENT TO THE PROCESSING OF PERSONAL DATA

pursuant to the EU General Data Protection Regulation 2016/679 and Italian Legislative Decree 196/2003
Version 1 dated April 19, 2021

Study title:
"Ambrosia" food strategy for preventing undernutrition and assessment of new biomarkers in older heart failure and atrial fibrillation patients.
AMBROSIA: "Microbiota-Inflammation-Brain axis in heart failure: new food, BiomarkerS and AI Approach for the prevention of undeRnutrition in Older Heart Failure and Atrial Fibrillation Patients"
Protocol code, version and date: Version 1 – April 19, 2021
Study Sponsor: Prof. Amedeo Amedei
Department of Experimental and Clinical Medicine
Laboratory of Immunology and Microbiome
University of Florence
amedeo.amedei@unifi.it
+39 0552758330
Principal Investigator: Prof. Stefano Fumagalli
Geriatrics Unit – UTIG, AOU Careggi and University of Florence
stefano.fumagalli@unifi.it
+39 0557949429

I, the undersigned _____
born on ___ / ___ / _____ resident in _____ street/square _____
Phone number _____
domicile (if different from residence) _____

- **DECLARE**
  that I understand and explicitly accept that my personal data will be processed for this study in the manner described in detail in the Information on the processing of personal data in accordance with the General Regulation and the Code;
- that I understand and explicitly accept that my pseudonymized personal data may be transferred to a recipient in a country outside the European Union (United Kingdom), where the General Data Protection Regulation does not apply;
- that I understand and explicitly accept that if I withdraw my consent to participate in the study, no further personal data about me will be collected;
- that I understand and explicitly accept that even after withdrawing my consent, the pseudonymized personal data previously collected may still be stored and processed solely for the purpose of meeting any legal obligations or to the extent that such data are essential for the conduct of this study and the achievement of its objectives;
- that I understand and explicitly accept that for any questions regarding the protection of personal data processed for this study, I can contact the Data Protection Officer of the Trial Center, whose contact information is indicated in the information notice.

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I therefore declare to

give my consent, pursuant to Art. 110 of the Code and Art. 9(2)(a) of the General Regulation, to the processing of my personal data for the purposes and in the manner described in the information sheet, which is part of this consent, and of which a copy was provided to me on the date: ___ / ___ / _____.

_____	___/___/_____	_____	_____
Full name of patient	**Date**	**Time**	**Signature**

_____	___/___/_____	_____	_____
Full name of legal representative	**Date**	**Time**	**Signature**

If the patient, or the recognized legal representative, is unable to read:

I have participated in the entire informed consent discussion for data processing. I certify that the information in the consent form or any other written information was explained thoroughly and was apparently understood by the patient or the recognized legal representative of the patient. Informed consent was freely given by the patient or the recognized legal representative.

_____	___/___/_____	_____	_____
Full name of impartial witness	**Date**	**Time**	**Signature**