



STUDY FACTSHEET

This study aims to collect stool samples from healthy adult donors and prepare fecal inoculum for use and testing in human colon *in vitro* models. The **GIOTA platform team**, within the Alchemy project framework, will assess these samples using molecular biology techniques, analytical and microbiological assays. The alchemy project is a collaboration between Universidade Católica Portuguesa and the American company Amyris, currently carried out in the Centro de Biotecnologia e Química Fina (CBQF) facilities, located on the 3rd floor of the Biotechnology building, Universidade Católica Portuguesa, campus Foz do Douro and scientifically coordinated by Prof. Manuela Pintado (CBQF director).

Participation in the study is voluntary and free. Personal information will be confidential and reserved for research purposes only.

We kindly ask you to read the following consent information and fill in the consent form and questionnaire below.

We are grateful for your participation!

GIOTA platform team

Informed study consent

1. Procedure

This study aims to collect stool samples from adult and healthy donors and prepare fecal inoculum to use and test using *in vitro* models that simulate the human colon fermentation. The **BIOTA platform team**, within the Alchemy project framework, will assess these samples using molecular biology techniques, analytical analysis and microbiological assays. The alchemy project is a collaboration between Universidade Católica Portuguesa (UCP) and the American company Amyris, currently carried out in the Centro de Biotecnologia e Química Fina (CBQF) facilities, located on the 3rd floor of the Biotechnology building, Universidade Católica Portuguesa, campus Foz do Douro and scientifically coordinated by Prof. Manuela Pintado (CBQF director). Participation in the study is voluntary and free. Personal information will be confidential and reserved for research purposes only.

1.1. Procedure details

- a) A collection, preservation and transportation detailed procedure will be given and explained to each volunteer. Fecal samples will be collected by the volunteer at the Alchemy project facilities or at any other place of their choice, according to the given procedure. The sample should be delivered to the GIOTA team within 2h of collection. The volunteer must follow all the rules described in the collection, preservation and transportation procedure;
- b) The volunteer must avoid intense exercise within the 12 h previous to the donation day;
- c) The volunteer must have not taken any antibiotics within the last six month previously to the donation day.
- d) The volunteers can donate their sample(s) several times within the project's duration
- e) All samples and donors data will be treated with confidentiality. Samples will be used immediately (up to 2h of collection) or properly stored for an undefined period of time, within the Alchemy project facilities, located on the 3rd floor of the Biotechnology Building of Universidade Católica Portuguesa, Rua Diogo Botelho, 1327, 4169-005 Porto, Portugal.

2. Purpose

This study aims to collect and process fecal samples from healthy adult donors to prepare a stool slurry and use as inoculum in human colon *in vitro* models using a batch fermentation system.

3. Samples donation and data collection

- a) The decision of donating the samples and answering the questionnaire attached is voluntary, whereby, the donor is entitled to refuse without any further consequence;
- b) All samples provided, data collected and study results will be protected according to the current ethical and national and international laws, law 12-2005, 26 January and International Declaration on Human Genetic Data, 16 October 2003, respectively;
- c) Every research done will be under the supervision of the UCP Ethics committee, which will ensure that all the regulations are applied and complied with.
- d) All biological samples collected and derived products, as well as all the information given by the questionnaires will be included in a database and coded to keep the donor's anonymity.
- e) The donor's consent can be revoked at any time by fulfilling a form and with no need of further justification, either by the donor itself or by their family, in case of death or incapacity. In this case, all samples and samples derived products and data will be destroyed. However, the same does not apply to the data already processed and results already published or part of other studies.
- f) The samples can be shared with other research groups however it will obey to the same rules and will not be used for commercial end;
- g) No monetary compensation will be given to the donors and all donors will agree to volunteer free.

4. Communication and data disclosure

The data resulting from this study or studies will be published anonymously and grouped according the publication target and never individually or by name.

5. Predicted physical risks

No health or physical risks are associated to this study. At the most, the donor can experience some type of discomfort, driven by the fact that the biological samples are stool samples.

Declaration of informed consent form

Donor's full name: _____

Attributed code: _____

I, _____, with the ID number: _____, **declare** to have acknowledged the terms and conditions of this research study and voluntarily accepted to participate by donating my biological sample (stool) and filling in a questionnaire. I consent the use of my biological sample(s), exclusively for research purposes and have understood that I can withdraw my participation and authorisation at any time and ask for the destruction of my samples, with no further consequences or discrimination.

- 1) The aims of this study were explained correctly and clearly and I was given the opportunity to ask any question(s) regarding the study and/or my participation.
 Yes
 No
- 2) I was informed that my biological samples will be characterized at a microbiological and metabolic level.
 Yes
 No
- 3) I accept to participate voluntarily in this study by providing my stool sample and authorising its preservation and use for future research studies
 Yes
 No
- 4) I am aware that my participation is voluntary and free and I am willing to answer honestly to the questionnaire bellow
 Yes
 No

(Date)

(Participant's signature)

I have discussed this research study with the volunteer, using an appropriate and clear language. I have informed the volunteer about this study's nature and its potential benefits and risks and I believe the volunteer has understood correctly my explanations.

(Date)

(Researcher's signature)

This document was signed in duplicate. One signed copy will be provided to the volunteer

Questionnaire

Research Project Title - Development of an *in vitro* platform using gastrointestinal models to assess the bioactivity of new ingredients for human nutrition.

Researcher names - Nelson Mota de Carvalho, Diana Oliveira and Ana Raquel Madureira

Please read the questions carefully and answer honestly. Fill in the boxes with an X.

1. Did you read the factsheet for this study?

Yes No

2. If you asked questions, did you receive appropriate answers?

Yes No Not applicable

3. Do you understand that you are free to leave this study at any time without giving a justification?

Yes No

4. Do you agree to participate in this study?

Yes No

5. How old are you?

6. What is your height (meters) and weight (kg)?

7. Which ethnic group do you belong to (e.g. European, African, Asian, southern American, etc...)?

8. What is your gender?

Male Female Rather not answer

9. How would you define your diet (more than one option is possible)?

Omnivore Vegetarian Vegan
 High meat consumption High vegetables consumption
 High fiber consumption Low sugar consumption
 High sugar consumption High protein consumption
 High protein consumption Dairy consumption

10. If you consume dairy products, how often? (e.g. milk, cheese, yogurts, etc...)?

Every day Almost every day 2 to 3 times a week
 Rarely Never

11. Do you exercise (e.g. running, gym, sports, hiking, etc. ...)?

Every day Almost every day 2 to 3 times a week
 Rarely Never

12. Do you smoke?

Yes No

13. Do you take chronic medication (e.g. diabetes, hypertension, autoimmune diseases, etc.)?

Yes No

14. Do you suffer from any intestinal discomfort (e.g. irritable bowel syndrome, Crohn's disease, *Helicobacter pylori*, etc...)?

Yes No

15. Do you take prebiotics, probiotics or other dietary supplements that benefits the intestinal microbiota (e.g. Inulin, UL – 250 ®, Actimel®, Activia®, etc...)?

Yes No Do not known

16. In case you answered yes to the previous question, how often do you take such products?

Every day Almost every day 2 to 3 times a week
 Rarely

17. When was the last time you took antibiotics?

Last week Last month Last 3 months
 Last 6 months Last 12 months More than 12 month ago

18. When was the last time you were admitted to the hospital?

Last week Last month Last 3 month
 Last 6 month Last 12 month More than 12 month at least

The GIOTA platform appreciates your collaboration!

Any question please contact Nelson Mota de Carvalho, Mayra Saleh and/or Diana Oliveira using the contacts below.

Nelson Carvalho: ncarvalho@porto.ucp.pt

Mayra Saleh: msaleh@porto.ucp.pt

Diana Oliveira: doliveira@porto.ucp.pt