

Appendices: Informed Consent Materials and GDPR



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Informed Consent Form

Title of research project: Food Acceptance Study (FAST) [or include title in national language]

I confirm that: (please initial next to each statement to show you agree)

I have obtained written and oral information about the research project and I am informed about the aim, methods, benefits and risks of participating in the study.	
I have read and have understood the information sheet [version number] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
I understand that taking part in the study involves completing a screening visit plus 6 clinical investigation days during which I will need to consume foods, provide blood [urine, and faeces] samples and fill in questionnaires.	
I understand that I will not be able to donate blood for the duration of my participation in the study.	
I understand that my participation is voluntary and that I am free to stop taking part and can withdraw from the study prior to anonymization of the data (1 st March 2023) without giving any reason and without my rights being affected.	
I understand that I can ask for access to the data I provide and I can request the destruction of that data at any time prior to anonymization of the data [add date]. I understand that after anonymization of the data, I will no longer be able to request access to or withdrawal of the data I provide.	

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I understand that the data, including any identifiable data I provide will be held securely and in line with data protection requirements at [add institution].	
I understand that pseudo-anonymised data (including my participant number) will be sent to other partners within the larger EU project for testing and analysis.	
I understand that pseudo-anonymised data may also be shared with other researchers who are not working on this study for future research purposes in the public interest.	
I understand that fully anonymised data (after destruction of the ID-log) will be made available to the public (open access). As a result other external organisations or researchers will be also able to access these anonymised data for future research purposes.	
I understand that my anonymised data will be retained indefinitely on password-protected computers at [add institution].	
I consent to participate in the above study.	
[Remove if not applicable] I consent that my biological material will be stored in a research biobank at the [enter University].	
I have received a copy of this informed consent form as well as a copy of the Participant Information Sheet ([version number]) and a copy of the General Data Protection Regulation information sheet ([version number]).	

Participant name: _____

Date: _____ Signature: _____

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In case new information that has substantial influence on your health emerges from the research project, you will be informed. If you would prefer **not** to be informed about such information please mark it here _____ (insert X).

Consent from the study staff that provided the oral information:

I declare, that the participant has received both written and oral information about the research project.

I declare to the best of my knowledge and belief that the participant has received sufficient information to decide to participate in the research project.

Study staff name: _____

Date: _____ Signature: _____

National project identification: [include e.g. ethical approval number from ethical committee and date of approval]



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General Data Protection Regulation (GDPR) information for study participants

What data will be collected, how will they be used and who will see them?

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In relation to your participation in the Food Acceptance Study (FAST), a range of data will be collected from you. This document explains how your data will be used.

1. Which data will be collected and how?

The data collected includes information about health and personal data e.g. name, [civil registration number if relevant, include name/type], contact information, gender and ethnicity and biological material (i.e. blood[,urine and faeces]). The data is registered in a personal participant folder and/or in an electronic database.

Data and biological material that is sent from the intervention site to other laboratories or researchers will contain a participant number but never your name or any other personal identifying data.

The investigators and other data processors will ensure that the information collected about you is not accessed by unauthorized persons and that your identity is protected when the results of the study are published. The online questionnaire delivery platform collecting body sensations and other measures will only use basic cookies to enable the proper functioning of the program. No marketing or other tracking cookies will be used.

2. How will my data be stored?

The investigators and the data manager will take all necessary security precautions to ensure that any identifying information about you is kept confidential and stored securely in accordance with local law [include name/references] and EU Regulation.

You will be assigned a unique ID number which your data will be identified by throughout the study. All electronic forms of data will be protected with a password which can only be accessed by the researchers. All data recorded on paper will be locked in study-specific storage cabinets accessible only to the researchers on the project.

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3. How long will my data be stored for?

Pseudo-anonymised data (including your participant ID) will be stored for up to 5 years. At that point, the participant ID-log will be destroyed and the pseudo-anonymised data will become fully anonymised data.

Fully anonymised data (not including your participant ID) after completion of the study will be retained indefinitely in an open-access repository (see point 7. *Will my data be archived for use in other research projects in the future* below).

Your biological samples (i.e. blood[, urine and faeces]) will be stored temporarily at the intervention site in freezers at either -20 or -80°C and later sent to other specialist laboratories for analysis. Once the biological material has been analysed for results related to this study, it will be destroyed by the laboratory. Destruction will happen at the latest by [2025] (five years after the study has ended).

[A research biobank contains biological material that is stored for future related research. If you wish to donate any excess of your biological material from this study to the research biobank of the [add university or other identifying name]), you must state it separately below. The donation is completely voluntary and does not affect your participation in this study. Samples in the biobank of the [university name] consist of a small amount (e.g. 5 ml blood [amend as suitable]), and are stored at [include name of intervention site] in freezers at -80 ° C for a maximum of 15 years after the study has ended. In order to conduct new analyses of your biological material from this biobank in a new study, the national ethical committee must first approve the study. You can always contact the intervention site and ask to have your samples in the biobank destroyed, unless the samples have been totally anonymised beforehand, which means that no one, nor the principal investigator, can longer assign the material to you. Sample full anonymization will take place alongside full anonymisation of all other data, after 5 years from study termination at the latest.]

4. What measures are in place to protect the security and confidentiality of my data?

The site-principal investigator will store an identifier (ID)-log (“key”) that associates your participant number with your personal information. This ID-log

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is stored at the intervention site separately from data and biological material in a locked room. Only a few relevant persons from the study staff have access to the ID-log including national and international authorities controlling clinical research projects e.g. the local ethical committee [and if relevant, include other local authorities]. The ID-log will be used to identify you in case it is relevant. The ID-log will be stored at the intervention site as long as it is relevant to have your contact information and for ethical and legal considerations related to the conduct of the study. The ID-log will be stored for a maximum of 5 years after the study has ended.

5. How will my data be used?

The data collected will be securely forwarded to a project data hub at the University of Navarra (Spain) and subsequently used for analysis.

In case you withdraw from the study, the data already collected from you may be used and included in the analyses if the researchers find it important for the quality of the study. Already collected data from you will therefore only be processed if it is fair and important for the study. However, you may request that your data are destroyed and no further use is made of them. Please note, it will not be possible to withdraw your data after the results have been processed (this may be approximately 3 months after the study has ended, or by the 1st of March 2023).

The results of the study, regardless of whether they are positive, negative or inconclusive, will be written-up and submitted for publication after the end of the study e.g. as a publication in a journal, a summary of the test results on the Internet or at www.clinicaltrials.gov. Published results do not contain any information that can identify you.

6. Who will have access to my data?

Your pseudo-anonymised data (including your participant number) will be securely sent to other partners within the larger EU project e.g. the University of Navarra (Spain) and the University of Surrey (UK) for analysis and your pseudo-anonymised biological material will be sent to partner laboratories, e.g. Bioiatriki S.A. (Athens, Greece) for testing and analysis. Data and biological material are

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only sent from the intervention site to other laboratories with your participant number and never your name or other personal identifying data.

Pseudo-anonymised data may also be shared with other researchers who are not working on this study for future research purposes in the public interest.

After full anonymisation (destruction of the participant ID-log) the data collected in this study will be made available to the public (open access) by depositing it in an open access repository or other related archive. As a result, other external organisations or researchers will be also able to apply to access these fully anonymised data.

7. Will my data be archived for use in other research projects in the future?

Yes. We will make the fully anonymised data available to other organisations or researchers by depositing it in an open access repository or other archive. It is important that you understand that your data will be completely anonymised for these purposes, therefore there will be no way that you can be identified.

8. How will my data be destroyed?

The ID-log for all data will be stored for a maximum of 5 years after the study has ended. After that point, the ID-log will be destroyed and all data will be fully anonymized. After full anonymisation data will be available to the public (open access).

Any excess biological material will be destroyed by the handling laboratories after the analyses have been completed [keep/remove: unless you have chosen to donate some to a biobank in your local country. If this is the case, biobank material will be destroyed after 15 years following the termination of the study (i.e. by 2035)].

I confirm that I have read and agree to the above information about the handling, processing and storage of my personal information in this study

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as well as data sharing procedures between external partners within this larger EU project and other external organisations.

[Please, consider if you want to donate excess material for the biobank:

Yes, I want to donate potential excess biological material from me to a biobank.

No, I do not want to donate potential excess biological material from me to a biobank.]

Participant's signature:

Date
Signature

Name

Researcher's signature:

Date
Signature

Name