Information and consent materials for adults
Information and consent materials for adults

These materials are developed in order to provide survey centres with clear and detailed draft materials. They will be then translated and adapted by each survey centre depending on their previous experience and local circumstances, including the specific requirements of national legislation and the relevant ethics committee(s).

Notes

Each survey centre may wish to modify these drafts, depending on its experience with local ethics committees, previous cohorts, or local culture. The idea is to provide supporting materials that can be freely translated and adapted, not to stipulate exact contents or format.

Highlights mark all fields requiring specific information from survey centres.
Information on the Stance4Health study

In the near future, thanks to personalized nutrition, it will be possible to improve our health, prevent food-related diseases and understand the beneficial or negative effects of food and nutrients. The EU-funded project Stance4Health (Smart Technologies for PersonAlised Nutrition and Consumer Engagement) comes in response to this ambitious purpose and thanks to food production and mobile technologies, it will try to support food choices of specific groups of consumers (adults and children with overweight, celiac disease or food allergies) to improve and optimize the activity and composition of their intestinal flora.

Stance4Health focuses on a healthy diet that can modulate our gut microbiota (the set of bacteria and other microorganisms that inhabit our body) with the objective to promote health in the general population and in people with special needs.

The study was approved by the relevant ethical committee [insert name of committee] on [insert date]. We will ask you to fill in some questionnaires.

What we are asking you to do

As part of the study, we are asking you to agree to take part in the following:

• A short interview about your medical history;

• Questionnaires concerning your diet, education, and lifestyle (physical activity levels, sleeping and smoking habits, alcohol consumption);

This information will be needed to decide if you are eligible to participate in the study.

Are there any risks?

No. All information is kept strictly private and confidential.

Confidentiality

All data that we gain in this part of the study will be kept strictly confidential. We will not share any data with anyone except authorized researchers on the project.

In addition, all data will be kept in an anonymous form. All information about you will be identified by a random number, and will not carry your names. Names will be kept entirely separately from other data, under lock and key.

The study will be carried out only once it is approved.
Data and results derived from the study may be published and presented in an anonymized way in journals, conferences, etc as it is indicated in the current regulation (EU) 2016/679 and Directive 95/46/EC about GDPR (https://eur-lex.europa.eu/eli/reg/2016/679/oj)

Further information

This study is a project funded by European Union’s Horizon 2020 research and innovation programme under grant agreement No. 816303.

The principal investigator of your centre/ city is [to be inserted] and his/ her contact details are: [to be inserted].

If you have any questions about the study you are always welcome to get in touch with him / her. Or you can always ask the person who has given you this form, or other members of our team listed below.

You can also visit our web page: http://www.stance4health.com

Please complete the form on the next page if you agree to participate in the study. If you do agree, please remember that you may withdraw at any time and without giving a reason. You can also request that data collected at any time be deleted or marked so that it is no longer possible to trace to the individual. You also have the right to see the data we hold and to makes corrections if there are any errors – please contact us if you would like to do so.

Thank you very much for considering this request.

For questions regarding participation and timing, please contact our project assistants:

[Name and full contact details of the project assistants, plus photos of the local study team, with names and a simple description of their role underneath each photo.]

For questions regarding the ethical aspects and confidentiality of the study, please contact our principal researcher:

[Name and full contact details of the principal researcher]
Consent to participate in the Stance4Health study

Please read the following sentences, in order to be sure that you have received essential information about Stance4Health:

• I have been informed that our participation is completely voluntary. We are free to withdraw from the study at any time and without giving a reason.

Choosing not to participate or choosing to withdraw will not result in any disadvantages to me.

• I have read this form and the research study has been explained to me. I have had the opportunity to ask questions about the study. If I have more questions I know whom to ask.

I confirm my willingness to participate in the following study:

Participant eligibility

This includes questions about your medical history (Eligible participant questionnaire)

Questionnaires and reports about diet and lifestyle

This includes questions about your diet, education, physical activity, sleep, smoking and alcohol consumption.