



Data security information according to Art. 13 GDPR in connection with the "Food & You DE" study

1. Processing activities

This information relates to the processing of personal data in connection with participation in the "Food & You DE" study. The study is being conducted by the ZIEL - Institute for Food & Health of the Technical University of Munich, hereinafter also referred to as TUM, in cooperation with the Digital Epidemiology Lab of the Ecole Polytechnique Fédérale de Lausanne, hereinafter also referred to as EPFL. The project partners TUM and EPFL are working closely together to carry out the study. Participation in the study is voluntary and open to anyone who registers for it. Participants will be recruited from the general public. All interested persons can register for the study, provided they meet the inclusion criteria and do not meet the exclusion criteria (e.g., diabetes, pregnancy, minority). The number of participants is limited to a maximum of 200.

When participating in the study, the test persons receive a package with the necessary study material at their postal address. Various online questionnaires will ask them about nutrition-related topics, their state of health and demographic characteristics. The participants are also asked to record anthropometric data (body weight, height, waist and hip circumference) on their own under supervision. These data are then entered into the corresponding online forms. The interviews and surveys will be scheduled before, during and after the 14-day main conduction phase and will take place exclusively online (via the website https://www.foodandyou.org).

During the main conduction phase (14 consecutive days per person), the participants record their diet with the app MyFoodRepo. MyFoodRepo was developed by the Digital Epidemiology Lab at EPFL and allows users to easily document their food consumption. The app uses either the barcode or a photo taken by the user. An image recognition algorithm records what the individual has consumed. Any ambiguities are clarified and corrected by a trained annotator. While logging, subjects will use a Flash Glucose Monitor FreeStyle Libre sensor and the FreeLink smartphone app from Abbott Diabetes Care to continuously measure their glucose levels for 14 days. The glucose readings are stored every 15 minutes. At least every 8 hours, the user must scan the sensor with a smartphone to transfer the data to it. Six of the 14 main study days require the consumption of standardized breakfast meals. These breakfast meals include either white bread, white bread with butter or a glucose solution. Alternative dietary protocols for probands with gluten/dairy intolerances are available. Apart from these standard meals, participants can go about their normal (nutritional) daily lives.

Subjects will also be asked to collect and submit a stool sample. Required materials and detailed instructions are included in the study package.

- 2. Accountability for the processing of your data
- 2.1 Name and contact details of the data controllers
- 2.1.1 Technical University of Munich (TUM)

Performing body: ZIEL - Institute for Food & Health

Prof. Dr. Kurt Gedrich

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E-Mail: kgedrich@tum.de

Internet: https://www.ziel.tum.de/ziel/phn/

2.1.2 Ecole Polytechnique Fédérale de Lausanne (EPFL)

Performing body: Digital Epidemiology Lab, EPFL, Campus Biotech

Prof. Dr. Marcel Salathé und Dr. Harris Héritier

9 Chemin des Mines

1202 Geneva (Switzerland) Telephone: +41 21 695 51 45 E-Mail: harris.heritier@epfl.ch

Internet: https://www.digitalepidemiologylab.org

2.2 Joint processing and accountability pursuant to Art. 45 GDPR

The processing of your personal data and health data takes place at both project partners. The EPFL is subject to the Swiss legal foundation for data protection (Swiss Federal Act on Data Protection (FADP)), which is similar to the GDPR and provides an adequate level of protection (Art. 45 GDPR).

2.3 Joint accountability pursuant to Art. 26 GDPR

EPFL and TUM are working closely together on the Food & You DE study. This also applies to the processing of your personal data. The project partners have jointly defined the responsibilities for processing this data in the individual process stages. They are therefore jointly responsible for the protection of your personal data within the process sections described below (Art. 26 GDPR). The joint responsibility applies to the entire duration of the Food & You DE study and thus extends to the recruitment of participants, the collection of data from the participants, the evaluation of the collected data and the preparation of the results reports and personal results.

2.4 Agreement of the project partners

Within the framework of their joint responsibility under data protection law, the project partners have agreed upon their respective obligations under the GDPR. This concerns in particular the exercise of the data subject rights and the compliance with the information obligations according to Art. 13 and 14 of the GDPR.

Due to the fact that during the implementation of the Food & You DE study, personal data are processed in different process sections and systems operated either by TUM and/or EPFL, this agreement is necessary.





No.	Processing stage	Compliance with data pro-
NO.	r rocessing stage	tection obligations
1	Provision of the website (https://www.foodandyou.org), the infra- structure and the associated server;	EPFL
	Encryption of personal data, in particular:	
	Full nameAddress (street, street number, city, postcode)	
	 Profile data for the use of the study website (e-mail, username, password) 	
2	Type of consent form Recruitment and selection of participants including potential contact	TUM
	(if proband initiates contact prior to registration)	TOW
3	Pseudonymization of the participants (automated)	TUM, EPFL
	Access to the German subject directory	TUM
4	Provision and storage of the questionnaires and measurements to be completed	EPFL
	Access to completed questionnaires and measurements	TUM
	Access to completed questionnaires and measurements (pseudon-ymized)	EPFL
5	Storage of physical activity data by external service providers (e.g., Google LLC.; Fitbit Inc.; Apple Inc.), if applicable.	EPFL
	Access to the physical activity data Access to physical activity data (pseudonymized)	TUM EPFL
6	Provision of the mobile app MyFoodRepo and the underlying server for logging of the nutrition, including storage of the data.	EPFL
7	Validation of the recorded dietary inputs	TUM
8	Mailing of the study material (sample tubes, glucose sensor) to the study participants	TUM
9	Collection and storage of stool samples in pseudonymized form	TUM
10	Collection and storage of microbiome data by analytical laboratory	TUM
	Access to the data on the study website Access to microbiome data in database (pseudonymized)	TUM EPFL
11	Collection and storage of blood glucose data (continuous measurement over 14 days) by external service provider (Abbott Labs; LibreLink App) after independent upload of the blood glucose file by study participants.	TUM, EPFL
	Access to blood glucose data on study website Access to blood glucose data in database (pseudonymized)	TUM EPFL
12	Withdrawal of TUM's access rights to the study website after completion of the study	EPFL
12	Provision of a pseudonymized and/or partially encrypted complete data set for the TUM after completion of the study.	EPFL





13 Analysis of the partially encrypted and/or pseudonymized total data set TUM, EPFL

2.5 Importance of shared accountability for data subjects

Even if there is joint responsibility, the project partners fulfil the data protection obligations according to their respective responsibilities for the individual processing stages as follows:

- TUM shall make the information required under Articles 13 and 14 of the GDPR available
 to data subjects free of charge in a precise, transparent, comprehensible, and easily accessible form in clear and simple language. EPFL shall provide all the necessary information for this purpose.
- The project partners shall inform each other without delay of the legal positions asserted by data subjects. They shall provide each other with all information necessary to respond to requests for information.
- Regardless of the responsibilities for the respective processing section, you can assert
 the rights to which you are entitled under the GDPR against any project partner. For organizational reasons, however, we ask you to contact TUM, if possible, with regard to data
 protection rights. A response will usually be sent to you by the office where the rights were
 asserted.

2.6 Reuse of data

According to Art. 6 of the GDPR (Recital 50 of the GDPR), further processing of the data and biological samples in the sense of citizen science is intended for an indeterminate period of time for other research projects. If the data subject has given his/her consent, the personal data may be further processed regardless of the compatibility of the purposes mentioned here. In any case, the project partners shall ensure that the principles laid down in the GDPR are applied and, in particular, that the data subjects are informed about the further use and about their rights, including the right to object in the consent form. The project partners are obliged to guarantee the pseudonymization or encryption of data subjects' data (Art. 6(4) GDPR(e)). This also includes deleting or permanently encrypting (Art. 11(1) GDPR) all personal data from the dataset that are not necessary for further processing in another research project, so that identification is made impossible or nearly impossible. In the first case, Articles 15 to 20 of the GDPR can no longer apply (Article 11(2) of the GDPR), as the individual data subject is no longer identifiable, and the individual data set can no longer be traced back to the data subject.

3. Data protection officers

3.1 Data Protection Officer of the Technical University of Munich

Technical University of Munich

Data Protection Officer

Prof. Dr. Uwe Baumgarten

Data Protection Office

Boltzmannstr. 3, 85748 Garching n. Munich E-Mail: beauftragter@datenschutz.tum.de

3.2 Data Protection Officer of the École Polytechnique Fédérale de Lausanne

Dr. Chiara Tanteri





Data protection Officer, Legal Affairs EPFL P-SG AJ BS 248 (Bâtiment BS) Station 4 CH-1015 Lausanne

E-Mail: chiara.tanteri@epfl.ch

Website: https://www.epfl.ch/about/presidency/presidents-team/legal-affairs/

4. Purposes and legal bases of data processing

The purpose of the data processing is to record, evaluate and analyze individual variations in postprandial (after food intake) blood glucose concentration, while factoring in various parameters such as dietary habits, anthropometry, lifestyle, physical activity and sleep, as well as the composition of the microbiome. This is done using the citizen science approach. Citizen science refers to the process of conducting research with the help of, or entirely by, interested volunteers. In this way, it makes people more familiar with scientific processes and enables the population to participate in the generation of scientifically sound statements.

Based on the study results, the objective is to contribute to the development of an algorithm (which is being developed by EPFL) for the prediction of the postprandial glucose reaction. This can later be used as a simple and effective tool for the personalization of nutrition, as well as a medical screening measure. In addition, the citizen science approach will be used to evaluate the benefits and challenges of scientific research with a (cross-border) digital citizen science cohort and to test its scalability.

The data and results will be published in a summarized form, both in conjunction with the existing EPFL cohorts and on a stand-alone basis. The release of research results in publications or at conferences will only take place in summarized, pseudonymized, anonymized or coded form. This means that it is not possible to draw inferences about individual data subjects at any time. Under no circumstances will data be published that would allow the identification of individual persons.

The legal basis for the collection, transmission, storage and processing of your personal data in this context is your consent pursuant to Art. 6 (1) a and Art. 9 (2) a GDPR.

This consent can be revoked at any time without giving reasons and for the future

- either via the website https://www.foodandyou.org (settings or contact form)
- o or by e-mail (support-de@foodandyou.org).

The lawfulness of the processing of your personal data based on your consent until your revocation is not affected by the revocation. If still possible according to Art. 11(2) GDPR, the deletion of the collected data and the destruction of the biological material can be requested in case of revocation. If explicit consent is given at the time of revocation, the data can be further used pseudonymized (without attribution of the person).

5. Categories of personal data

5.1 Data request before participant recruitment

The following inclusion and exclusion criteria relating to your person will be requested on the website https://www.foodandyou.org prior to registration for participation:





5.1.1 Inclusion criteria:

- o Are you 18 years or older?
- Do you have a postal address in Germany?
- Do you have a smartphone, at least version iOS 10/Android 5 with NFC?
- Do you have sufficient knowledge of German or English to read and understand the instructions?
- o Are you competent and willing to give informed consent?

5.1.2 Exclusion criteria:

- Are you currently pregnant?
- o Are you currently breastfeeding?
- o Are you a dialysis patient?
- o Are you taking chronic immunosuppressive medication?
- Do you have any skin diseases, including contact dermatitis?
- Are you seriously ill?
- Are you currently taking antibiotics, or have you taken antibiotics in the last three months?
- Do you have or have you had any chronically active inflammatory or neoplastic diseases in the last three years?
- Do you have any chronic gastrointestinal disease, including inflammatory bowel disease and coeliac disease?
- Do you have an active neuropsychiatric disorder?
- Have you had a myocardial infarction or cerebrovascular accident in the last six months?
- Have you been diagnosed with diabetes mellitus type I or type II?
- o Do you have a BMI below 18.5?

The respective criteria are queried on the website and either confirmed or denied by clicking on them. If the selection criteria are met, you will be forwarded to registration. If the criteria are not met, no data will be stored.

5.2 Registration for study participation

When registering for study participation on the website, the following data will be collected and processed:





5.2.1 Registration data: E-mail address, username (to be chosen by the user), password (to be chosen by the user)

5.2.2 Declaration of consent

5.3 During study participation

- **5.3.1** Base data: Date of birth/age, gender, nationality, telephone number, country of birth, nationality(ies), ethnicity(ies), information on the place of residence for sending the study material.
- 5.3.2 **Anthropometric data:** Body height, body weight, hip circumference, waist circumference

5.3.3 Demographic data:

- Information on current living situation: marital status, housing situation, income, occupation/employment, household.
- o Information on educational qualifications and occupational training

5.3.4 Health-related data

- o Information on smoking status
- o Information on diet
- o Information on the use of food supplements
- Information on the use of medication
- Information on hunger status
- Information on general health status
- Information on medical conditions
- Information on medical interventions and therapies
- Information on bowel movements
- Information on physical and nutritional history
- Information on stress and sleep

5.3.5 Women-specific data

- Information on contraception
- Information on the menstrual cycle
- Information on pregnancy and breastfeeding
- Information on illnesses

5.3.6 Physical activity and sleep data

- Information on daily physical activity
- Information on sporting performance
- Information on sleeping hours





5.3.7 Blood glucose readings continuously over 14 days

5.3.8 Microbiome data: stool sample including analysis result of bacterial DNA (no human DNA)

5.3.9 Photo-based digital food log over 14 days

- Information on the type and quantity of food
- Information on times and frequency of food intake
- Information on the nutrient composition (incl. water)

5.3.10 Logging of physical activity and sleep over 14 days

5.3.11 Contact:

- o Information on individual contacts and email correspondence (if applicable).
- o Complaint requests and ambiguities
- Reasons for failure and refusal

6. Recipients of personal data

The project partners are the primary recipients of personal data of the study participants. The following additional recipients are involved in the performance of the project:

Analysis laboratory (pseudonymized): Core Facility Microbiome (part of ZIEL – Institute for Food & Health (TUM))

Other recipients of personal data are:

- EPFL server for storing the databases and websites: AWS Europe; Amazon Web Services, Inc., 410 Terry Avenue North, Seattle WA 98109, United States; Server location: Frankfurt, Germany
- TUM NAS server: RBG Rechnerbetriebsgruppe Mathematik und Informatik, Boltzmannstr. 3, 85748 Garching near Munich, Germany
- Nutrition data (pseudonymized): MyFoodRepo (a product of EPFL (cf. 2.1.2)).
 Server: AWS Europe; Amazon Web Services, Inc, 410 Terry Avenue North, Seattle WA 98109, United States; Server location: Frankfurt, Germany.
- Glucose data (pseudonymized): Abbott GmbH, Abbott Diabetes Care, Max-Planck-Ring 2, 65205 Wiesbaden, Germany

The TUM carries out the microbiome analyses internally in the institute's own Core Facility Microbiome laboratory. The TUM collects the stool samples of the participants, analyses the bacterial ribosomal DNA using next-generation sequencing and bioinformatic analysis. Your results and personal microbiome data are then made available to you on the website https://www.foodandyou.org in your subject profile. Only you have access to your results by logging in with your account data on the website.

Your personal data and health data are protected by pseudonymization in accordance with Art. 4 No. 5 GDPR. Your most sensitive data that could potentially lead to your identification (in particular first name, surname, address, telephone number, e-mail address and user account data on the website) are further secured and stored in encrypted form. This means that this data is not





directly accessible. Only authorized personnel of the EPFL have access to the decryption data. The decryption data are stored separately and securely.

7. Storage of personal data

Your personal data that we collect and process in the course of conducting the Food & You DE study will be stored as follows:

7.1 Registration data

Your information on inclusion and exclusion criteria as well as the registration data (cf. sections 5.3.1 to 5.3.5) will be stored exclusively on the servers used by the project partners. If you decide not to participate in the study, this data will be deleted immediately.

7.2 Data from questionnaires

The data you provide in the questionnaires (see sections 5.3.1 to 5.3.5) will initially be stored exclusively on the website server and then transferred to the EPFL databases. If you decide not to participate in the study, all data collected so far will be deleted immediately or, after your consent, will be used in a pseudonymized form.

To ensure your data confidentiality, your data will be encrypted. This means that your sensitive data are not directly linked to your identifiable data (name, e-mail, address, date of birth, etc.), but are provided with code numbers (pseudonymization). In addition, your personal or sensitive data (e-mail, password, username, type of consent form and address, as well as first and last name) are stored in encrypted form. Access to the decryption keys is reserved for authorized personnel only.

7.3 Glucose data

Your data collected during the 14-day continuous glucose measurement (see section 5.3.7) will initially be stored exclusively with the service provider (Abbott GmbH) via the FreeStyle LibreLink app. When using the app, you are not obliged to enter correct personal data. The linking of your glucose data with that of your study participation is carried out via your e-mail address (the e-mail address used for https://www.foodandyou.org and FreeStyle LibreLink must be the same). At the end of the data collection period, you will be asked to upload the glucose data to the website https://www.foodandyou.org, to be linked to your dataset. You can request the service provider (Abbott GmbH) to delete your customer account and your data at any time (see Abbott GmbH privacy policy). The glucose data will then be analyzed by TUM and EPFL, processed using your nutritional data (see section 7.5) and the personal results report will be made available to you on the website. If you decide not to participate in the study, all data collected so far will be deleted immediately or, after your consent, will be used in a pseudonymized form.

7.4 Stool samples

The stool samples are likewise pseudonymized (identification only by means of tube ID), stored exclusively at the TUM and then transferred to the analytical laboratory mentioned under point 6 for analysis. The stool samples can be stored at room temperature, as the samples are mixed with preservation liquid. The storage rooms for the sample material are only accessible to selected TUM staff by key. The pseudonymized analysis results are then transmitted to the TUM and EPFL and stored there. Once your individual microbiome profile has been created, it will be made available on the website https://www.foodandyou.org only for you in your subject profile. If you decide





not to participate in the study, all previously collected biological data will be deleted immediately or, after your consent, will be used in pseudonymized form. The biological material, i.e., the bacterial DNA extracted from the stool sample, will be permanently destroyed. No analyses of the human genome will be carried out.

7.5 Dietary protocol

During the study, you will be asked to record your diet using the MyFoodRepo app. MyFoodRepo is an app developed by EPFL (see 2.1.2) that uses the open-source database "The Open Food Repo" (https://www.foodrepo.org) to record the food intake of packaged foods and a machine learning algorithm to determine the intake of non-packaged foods by automatically detecting the content of photos. Where necessary, you will be asked to validate or correct the interpretation of the photos or add information to ensure an accurate assessment of food intake. The MyFoodRepo app provides food composition estimates, i.e., the estimated energy value in kilojoules and kilocalories, and the main nutrients (protein, carbohydrates, fiber, fat) for each photo. The app can be used completely anonymously. As part of the study, you will be asked to register with your study ID when using the app. In this way, your dietary data is recorded in pseudonymized form and can subsequently be linked to the rest of your data set. The nutritional data will then be analyzed by TUM and EPFL, processed using your glucose data (cf. section 7.3) and the results report will be made available to you on the website. If you decide not to participate in the study, all data collected so far will be deleted immediately or, after your consent, will be used in a pseudonymized form. You can request MyFoodRepo to delete your customer account and your data at any time (see MyFoodRepo privacy policy).

7.6 Physical activity

To determine your physical activity, select one of the four possible systems:

- Logging via the website: You can enter your physical activities directly on the foodandyou.org website. The physical activity data will be linked to your existing data set and analyzed by TUM and EPFL. If you decide not to participate in the study, all data collected so far will be deleted immediately or, after your consent, will be used in a pseudonymized form.
- 2) Logging via the smartphone health app (Google Fit or Apple HealthKit): This method of recording your physical activity asks you to keep your smartphone with you at all times and/or enter each activity into the app. At the end of the collection period, you will be asked to upload the data to the foodandyou.org website, where it will be linked to your existing data set. The physical activity data will then be analyzed by TUM and EPFL. For more information on data protection or to delete your collected data via your chosen app, please contact the service provider directly (i.e., Google LLC, Apple Inc.).
- 3) Logging via a fitness tracker (e.g., FitBit, Garmin, etc.): This method of recording physical activity asks you to keep your fitness tracker with you at all times and/or enter each activity into the corresponding app. At the end of the survey period, you will be asked to upload the data to the foodandyou.org website, where it will be linked to your existing record. The physical activity data will then be analyzed by TUM and EPFL. For more information on data protection or deletion of your collected data via your chosen service provider, please contact the service provider directly (e.g., FitBit, Garmin, etc.).
- 4) Sharing your Google Fit account: With this type of physical activity tracking, you can give us access to your health data via Google Fit. This allows us to collect your data directly





and without further involvement. You will be asked to carry your smartphone or Google Fit connected fitness tracker with you at all times and/or enter each activity into the app. The physical activity data will then be linked and analyzed by TUM and EPFL with your existing record. For more information on data protection or deletion of your collected data via Google Fit, please contact the service provider (i.e., Google LLC) directly.

7.7 Declaration of consent

Your declaration of consent is recorded on the website https://www.foodandyou.org and then stored by both project partners. The type of consent form is stored in the study database in encrypted form. The consent form also includes the reuse of your data. In the interest of citizen science, your collected data and biological samples will then be made available to the public for an unspecified period of time and will also be reused for other research projects. For example, your data may be used in future research projects or sent for analysis in other research projects in Germany, Switzerland or other countries. However, this only applies insofar as standards and requirements are met there that are at least equivalent to the German or Swiss standards and requirements. All legal provisions on data protection must be complied with in any case.

We assure you that the data collected here will only be used for further research purposes if an ethics committee has also deliberated on the new project and raised no objections.

We will only transfer personal data to third parties if this is permitted by law and you have given your consent.

7.8 Contact

The contact requests are recorded by the project partners and stored for a short period of time. Deletion takes place at the end of the project and by 31.12.2023 at the latest. Reasons for dropout and refusal are logged and stored anonymously. Complaint requests and issues of ambiguity are anonymously recorded as internal improvement approaches.

8. Your rights

a) Data subject rights

Insofar as we process your personal data, you as the data subject have the following rights:

- If your personal data is processed, you have the right to obtain information about the data stored about you (Art. 15 GDPR).
- If inaccurate personal data is processed, you have the right to rectification (Art. 16 GDPR).
- If the legal requirements are met, you can request erasure or restriction of processing (Art. 17 and 18 DSGVO).
- If you have consented to the processing and the data processing is carried out with the help of automated procedures, you may have a right to data portability (Art. 20 GDPR).
- You have the right to object at any time to the processing of personal data concerning you on grounds relating to your particular situation (Article 21 of the GDPR).

To enforce your rights as a data subject, please contact primarily for organizational reasons

the project coordination of the project partners by e-mail to support-de@foodandyou.org;





• or use the contact form on the foodandyou.org website.

Irrespective of this, you can assert the rights to which you are entitled under the GDPR against any project partner.

To ensure the protection of your data and your privacy, for the reuse of your data in other research projects, all personal data that are not relevant for the realization will be deleted from the data set or permanently encrypted (Art. 11(1) GDPR), so that identification is made impossible or almost impossible. In the first case, Articles 15 to 20 of the GDPR can no longer apply (Article 11(2) of the GDPR), as you are no longer identifiable as a person and your data set can no longer be traced back to you.

b) Right of appeal to the supervisory authority

There is also a right of appeal to the Bavarian State Commissioner for Data Protection.

Bavarian State Commissioner for Data Protection Postal address: PO Box 22 12 19, 80502 Munich Address: Wagmüllerstraße 18, 80538 Munich

Tel.: +49 89 212672-0 Fax: +49 89 212672-50

E-Mail: poststelle@datenschutz-bayern.de

9. Withdrawal from the study

If you wish to withdraw from the study before it is completed, you can do so at any time without giving a reason. To do so, you can withdraw from the study on the website in your study profile under Settings. Alternatively, you can contact:

- the project coordination of the project partners by e-mail to support-de@foodandyou.org;
- or the contact form on the website https://www.foodandyou.org.

Factors leading to drop-out are as follows:

- Withdrawal of your given declaration of consent and/or expression of the wish to terminate participation before completion.
- o If you are not able to follow the instructions of the study procedure.
- o If you develop an allergic reaction to the FreeStyle Libre sensor.

The study coordinators can remove you from the study at any time if one or more of the above factors occur (or for any other legitimate reason).

In case of withdrawal, after your explicit consent, the already collected health-related and biological data will be pseudonymized. You will be asked to upload the glucose measurement data (if already available) and the physical activity data (if available). The biological material, i.e., the bacterial DNA extracted from the stool sample, will be permanently destroyed.