

HORIZON 2020

**Citizen-centred EU-EHR exchange for personalised
health**

Smart4Health

Smart4Health Consent for Data Provision to Research

Information and Consent

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826117



Information

Introduction

With the MyScience App, you can choose to provide your health data for [health research](#).

[Health research](#) means all “health, medical, and biomedical research”, that aims to improve the health of citizens in everyday life, the treatment and prevention of disease by health professionals, and the understanding of disease mechanisms.

Research insights that are gained from using your [health data](#) may substantially contribute to the goals of health research.

[Health data](#) is all information related to your personal health collected in your Smart4Health account. This includes, but is not limited to, **patient data** from your electronic health/patient/medical records, if available, as well as your **self-generated fitness and health data**.

Patient data is all information about you that is recorded during a medical examination and treatment. It is stored in any of your electronic health/patient/medical records that come from previously visited health professionals or hospitals.

Self-generated fitness and health data include data from sensors, wearables and/or fitness apps (e.g., the heart rate data tracked by a smartwatch).

Providing health data for research is voluntary. If you do not wish to provide data for research, or wish to withdraw your consent later, it will not affect the medical care you receive or your ability to use your Smart4Health account.

In the following, [we](#) describe the process and considerations related to providing your data to research. Please read the information provided, the [Privacy Policy](#), and the [Terms of Use](#) carefully and take the time you need to make an informed decision. If you do not fully agree with the nature of data use, or if we have not fully answered your questions, you should not give your consent.

[We](#), the Hasso-Plattner-Institut für Digital Engineering gGmbH as part of the EU-funded [Smart4Health project](#), are responsible for the processing of your health data and provide this mobile App.

What kind of data do we ask you to provide?

When you provide your health data, we ask you for the [core set of data](#) as far as available in your Smart4Health account. You can also provide additional [optional health data](#), depending on your personal preferences, which you can define in the MyScience App.



[The core set of data](#) includes the following information:

- Clinical problems and conditions,
- Medication (medicines you are currently taking, medicines you have taken in the past, doses and dates of prescribed medicines),
- Allergies, intolerances, and adverse reactions,
- Medical discipline and health care institution associated with the provided data (type of institution, e.g., hospital or general practitioner, and part of the institution's ZIP code), as well as
- Demographic information (birthyear, gender, country of residence, part of your ZIP code).

[Optional Health Data](#) may include information such as:

- Immunizations,
- Medical devices (e.g., implants) that you have or previously had,
- History of procedures (e.g., surgeries),
- Diagnostic results (e.g., laboratory results or blood tests),
- Vital signs,
- Self-generated fitness and health data, and
- Questionnaires related to your personal health.

What happens when you provide your health data?

After confirming the provision of the core set of data and potentially selecting optional health data, we [remove or generalize personal information](#) in your data. We add a [code](#) to your data. The data is now "[pseudonymised data](#)". This code is stored only in your MyScience App. We store the pseudonymised data in the research platform.

[Remove or generalize personal information](#)

When collecting health data, information such as your name and date of birth is also collected. Such information can easily be used to identify you personally.

All **personal information** directly identifying you (name, date of birth, address, any other related information) will be **removed** from the selected data or **generalized** (e.g., *21.02.1982 → *1982) and your platform-internal identification number is replaced by a **code**.

[Code](#)

After all the information directly identifying you has been removed or generalized and replaced by a **code**, the data you are ready to provide for research are transferred to the Smart4Health research platform and stored there. The **code** is safely stored within the MyScience App on your smartphone, therefore the code linking the data to your person remains with you. With this process in place, the health data provided for health research cannot be traced back to you without exceedingly disproportionate technical effort.

[Pseudonymised data](#)

Before data is provided for research, this identifying information is either removed, or generalized. Furthermore, as a user you have a platform-internal identification number that is connected to all the data you have collected. This number is replaced by a code. The data is now "[pseudonymised data](#)". This means that the health data you provide for research is always only associated with this code, not with your real identification number or your name.

At the end of this process, you will receive a notification of the successful data provision.

Please be aware that in order for researchers to be able to use your health data for research, the **provision of a [core set of data](#) is required**.



Who can access your data for health research?

Access to the data is controlled and researchers can work with the data only on the research platform (no download of data is allowed).

Researchers from universities, research institutions and **commercial companies** can apply for data access with their health research project. The Smart4Health **Data Access Committee** reviews each research project. If it does not meet all criteria for data access, access is not granted. The data must not be used by other researchers or for other purposes than defined in the research project. Your health data will be used exclusively for scientific purposes and will not be sold.

Commercial companies

The collaboration of public research institutions and **commercial companies** is necessary for the development of new medical products, systems and procedures. Excluding commercial companies would hinder the improvement of disease prevention, treatment and care. Each request is reviewed by the Data Access Committee and access is granted only if the research contributes to medical progress and complies with National Research Ethics requirements.

Data Access Committee

The Smart4Health Data Access Committee is a body constituted of named individuals from the Smart4Health consortium. They are responsible for granting (or denying) external requestors (researchers) access to data. The decision is based on your consent, the Smart4Health Data Sharing Policy, and an ethics approval of the research project obtained and presented by the researcher. For more information on the Smart4Health Data Access Committee, its members and the Data Sharing Policy, please visit <https://smart4health.eu/dac>.

Data access is restricted to researchers from EU countries or from countries where the EU has determined that adequate data protection measures are in place. Though your data will not be sold, the provider of the Smart4Health research platform may collect a handling fee from the respective researchers, in the future.

Using data for scientific purpose includes publishing results in a form that **does not allow any conclusions about or links to your identity**.

How is your data used?

Your health data will only be used for health research. Using your data for health research means that **researchers will access your data within the Smart4Health research platform**, combine it with data provided by other users, and analyse them with tools running on the research platform to find answers to various health research questions.

The results of these analyses are exported from the research platform to be shared and discussed with others. Your health data does not leave the Smart4Health research platform without your explicit consent.

Who decides which research uses your data?

We do not offer the possibility to select the kind of research or the research fields. Research may refer to whole areas of disease (e.g., cancer, cardiovascular diseases, brain diseases) as well as to specific diseases and to changes in the genetic substance that are still partly unknown today. This means that your health data may be used for research questions that we cannot foresee today.



How can you provide additional data for research?

Whenever you have new personal health data stored in your *Smart4Health* account you can also provide this data for research using the *MyScience App*.

Alternatively, you can decide to allow the **automatic provision of future data** using the *MyScience App*. This means that data you have newly collected will be automatically provided.

This applies to all new data matching your selection.

You will receive a notification of the successful provision as a push-message or as an email according to your preferences

Does your health data leave the Smart4Health research platform?

If you have consented to this, a copy of your data is transferred from the Smart4Health research platform to **ELIXIR-LU**. For this purpose, we **anonymize** the data by removing your code. ELIXIR-LU has access criteria comparable to our access criteria.

ELIXIR-LU focuses on providing data for biomedical research that bridges between basic scientific research and clinical practice. ELIXIR-LU facilitates long-term and responsible access to research data and tools for scientists in both academia and industry. This allows the reuse of previously generated data to address new research questions.

Anonymize

During **anonymization**, the code that has been assigned to your identity will be completely removed. Further measures for your protection can be applied at any time according to regular privacy impact assessments.

Please note: Anonymized data does not count any longer as personal data, because it is not traceable to you anymore. In case you withdraw your consent to data provision, the data transferred to ELIXIR-LU cannot be deleted anymore.

At acceptance, the data can be downloaded by the researcher. The researcher's institution is responsible for and supervises the data processing.

More Details

You can choose whether or not a copy of the data you provided to the Smart4Health research platform may also be transferred to ELIXIR-LU, the publicly funded Luxembourgish national node of ELIXIR, the European infrastructure for life science information. In this case, the pseudonymized data is anonymized and copied from the Smart4Health research platform to ELIXIR-LU.

The data access request must be approved by the ELIXIR-LU Data Access Committee following the data access criteria comparable to the ones outlined in <https://smart4health.eu/dac>. The process and criteria correspond to those described before. However, in case of approval, researchers will download the data. The responsibility and supervision of the data lies with the receiving institution, which ensures a level of data security and compliance measures comparable to those established in Smart4Health.

What are the risks associated with providing your health data?

Whenever you provide data, there is a risk that private information is disclosed. Data stored in the Smart4Health research platform is separated from your name and other personal identifiers. We have implemented further adequate procedures to minimize this risk.



If your private information has been misused, you could experience harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relations or health condition.

In the case of a data breach, we will contact you within 72 hours.

[More Details](#)

The code linking your data to your identity is stored separately and securely within your MyScience App on your smartphone and therefore remains with you. Any attempt to identify you from the provided health data is prohibited by law and impracticable in practice as it would require a disproportionate amount of time, expense, and labor.

If you agree to provide pseudonymized data to the Smart4Health research platform or anonymized data to ELIXIR-LU, it is important to remember that pseudonymization and anonymization of your health data can never completely rule out the possibility of re-identification by drawing on other data sources.

Examples for misuse of private information are, e.g., taking actions on your behalf or blackmailing you with the threat to disclose health information.

In the case of a data breach, we will contact you via the MyScience app within 72 hours after we have become aware of the breach according to Article 33 and 34 of the EU GDPR.

What are the benefits for society?

Health research carried out with your data aims to understand how

- diseases develop over time,
- prevention and detection of diseases and conditions can be improved, and
- treatment and care can be improved.

This has the potential to

- reduce severity and costs of illness,
- prevent illness and improve health, and therefore
- increase the quality of life.

You can learn about research activities based on the data in the Smart4Health research platform at <https://smart4health.eu/research>.

What are the benefits for you personally?

No direct benefit to your health can be expected from providing your data for health research. However, you can also enjoy the benefits for society. Neither provision nor non-provision of data for research will impact the concrete medical treatment you may receive.

If the research leads to commercial benefits, e.g., through the development of new drugs or diagnostic procedures, you will neither have rights in the results nor receive a share in the profits.

How can you withdraw your consent?

Providing data for research is voluntary. You can withdraw your consent to provide health data for research with effect for the future at any time, without consequences for you. You can do this in whole, or in parts by changing individual statements.



Use the withdraw function in the MyScience App or [contact](#) us directly (e.g., helpdesk@smart4health.eu).

For any questions, concerns, or enquiries you can contact us directly:

Hasso-Plattner-Institut für Digital Engineering gGmbH,
Prof.-Dr.-Helmert-Str. 2-3, 14482 Potsdam, Germany
(Responsible Project Manager: Prof. Dr. Erwin Böttinger)

E-Mail: helpdesk@smart4health.eu

Website: <https://smart4health.eu>

If you withdraw, your health data will be anonymized. This anonymized data will not be used for any future research within the Smart4Health research platform. However, it has to remain accessible for a duration of 10 years to ensure that research results of completed and ongoing research projects can be reproduced.

More Details

Note that data cannot be removed from completed and ongoing projects or if anonymized data has been transmitted to ELIXIR-LU as we cannot trace it back to you.

You may also change individual parts of the declaration of consent without withdrawing it in whole. For example, you may change your consent preferences if you wish to continue to make the health data available to research but no longer have interest in being contacted for study participation.

As we explained in the section on risks, anonymization of your health data can never completely rule out the possibility of re-identification by drawing on other data sources.

How long is your consent valid?

Your consent to the provision of health data for research within the Smart4Health research platform is valid for the duration of the Smart4Health project, which will presumably end on February 28, 2023, unless you have withdrawn your consent before its end.

You can continue to provide your health data after the end of the project by signing a re-consent form. If you do not re-consent, your health data that has been stored based on this consent will be anonymized, by erasing the code that has been assigned to you. As in the case of withdrawing your consent, this anonymized data will not be used for any future research. It will remain accessible for a duration of 10 years for completed and ongoing research projects to ensure that research results can be reproduced.

The optional provision of health data to ELIXIR-LU is unaffected by the project end. Anonymized health data that was already provided to ELIXIR-LU remains on their premises. This anonymized data cannot be traced back to you and therefore cannot be deleted upon your request. It remains available to be used for research.

Right of withdrawal

I voluntarily consent to provide my data for research. I may withdraw my consent in whole or in part in the MyScience App or by contacting HPI at any time, without giving reasons and without any consequences for me.



Upon withdrawal, the data stored on the basis of this consent will not be used for future research. It will be deleted (anonymized). Data from already performed analyses cannot be removed.

How can you reach us?

For any questions, concerns, or enquiries you can contact us directly:

Hasso-Plattner-Institut für Digital Engineering gGmbH,
Prof.-Dr.-Helmert-Str. 2-3, 14482 Potsdam, Germany
(Responsible Project Manager: Prof. Dr. Erwin Böttinger)

E-Mail: helpdesk@smart4health.eu

Website: <https://smart4health.eu>

May we contact you?

You can consent to be contacted by us with

- general updates to the research platform,
- general information based on the data you provided for research (e.g., aggregated research results, number of projects using your data), and
- invitations to participate in research studies outside the Smart4Health project, which are related to the data you provided.

You can change your preference also later in the App.

[More Details](#)

If you have agreed to be contacted, researchers may submit a request to the [Smart4Health Data Access Committee](#). After approval, you receive the contacting message in the App. Neither researcher nor Committee ever know your identity.

Even if you are being contacted for a study on a specific condition, this does not mean that you have this condition, but only that your profile fits into the study design, e.g., as member of the control group.

If you decide to participate in studies outside of the research platform, you are redirected to an external website or software that is not under the responsibility of the data controller.



General Consent

- **I consent to the processing and use of my health data for health research** exclusively as described in the information sheet, with separate storage of my name and other directly identifying data (pseudonymization).
- **I consent to the scientific analysis and use of my coded health data by researchers associated with** universities, research institutes or commercial companies on the premises of the Smart4Health research platform.
- I understand that I will receive no compensation for providing data for research and that I have no rights in the result of the research.
- I agree to the [Terms of Use](#) and [Privacy Policy](#).

☐ **Yes**, I consent

☐ **No**, I do not consent

Option to automatically provide future data

I agree that health data from my selected categories is **automatically processed to be provided to the Smart4Health research platform when it is newly uploaded to my personal Smart4Health account**. I understand that this always applies to the **core set of data** (demographics, institution, medication, allergies and intolerances, clinical conditions). Apart from that, **I can decide in my user preferences which optional health data is uploaded automatically**. Details have been provided before.

☐ **Yes**, I consent

☐ **No**, I do not consent

Option to transmit my health data to ELIXIR-LU in anonymized form

I consent that a **copy of my health data is transferred from the Smart4Health research platform to the European Research Infrastructure ELIXIR-LU in anonymized form**. Details have been provided before.

☐ **Yes**, I consent

☐ **No**, I do not consent

Options to be contacted

I agree that I may be contacted by Smart4Health in order to receive

- general updates to the research platform,
- general information based on the data you provided for research (e.g., aggregated research results, number of projects using your data), and
- invitations to participate in research studies outside the Smart4Health project, which are related to the data you provided.

☐ **Yes**, I consent

☐ **No**, I do not consent

