

Information and Consent to the Use of Image Data in a Data Donation

Based on the recommendation of the German Working Group of Medical Institutional Review Boards
(Version 2.0, according to the decision of 10th of June 2016)

Name and contact details (address, telephone number) **of the entity collecting the data, including the data controller:**

Medical Data Donors e.V., Apfelstr. 2, 91054 Erlangen, project-medicaldatadonors@lists.fau.de

Title of the study:

Medical Image Data for the Future of Medical Image Processing

Name and contact details of the responsible study coordinator: Andreas Maier, Apfelstr. 2, 91054 Erlangen

Participant Information

Dear participant!

We thank you very much for taking the time to read this consent information. Please consider carefully if you would like to participate in the study "Medical Image Data for the Future of Medical Image Processing" and wish to provide data to the researchers involved. Your participation is voluntary and requires your written consent. If you do not agree or revoke your consent later, you will not suffer any disadvantages. Of course, with revocation, all your data will be deleted. If you have any questions that are important to your decision or that arise during your participation in the study, please contact us at project-medicaldatadonors@lists.fau.de.

The study of human image data and the analysis of the data obtained or derived from it have become an important tool of medical research. For example, we now know that, for example, radiological findings play an important role in the treatment of diseases. That's why we ask our participants, and therefore you too, if they are willing to provide us with certain images and data for research. The images and data should be collected in a so-called image database and linked with related medical data. This image database is operated by Medical Data Donors e.V., an association that supports research in medical image processing. Its members are universities, universities of applied sciences, university hospitals and non-university research institutions. As of 1 September 2017, these included scientists and researchers from

- Friedrich-Alexander-University Erlangen-Nuremberg
- University of Heidelberg
- Technical University Munich
- University Hospital Basel
- German Cancer-Research Center

Medical Data Donors e.V. is charitable and does not pursue commercial purposes.

In the following, we will inform you about the objectives of the image database, the procedures, and the measures taken to protect your personal data so that you can form your own opinion and make a decision on this basis.

Your data will be used exclusively in cooperation with Medical Data Donors e.V. Each time your data is used, Medical Data Donors e.V. will be informed and the usage will be coordinated. Beforehand, researchers at their own institution must obtain a positive vote from their institutional review board. This ensures that your data is used for meaningful and ethically sound research purposes.

You will receive a transaction number (TAN) for the donation that will allow you to access your data. This will also allow you to delete the data or to find out about research projects in which your data was used.

1. What are the objectives of the image database?

The image database serves to promote medical research. For this purpose, the collected image and related data should be stored for a long time and be available for research to improve the prevention, detection, and treatment of diseases. The purpose of this research is not to diagnose you or other individuals or to prove disease-triggering predispositions. Rather, biomedical correlations are to be determined in the comparative study of larger groups of people. In particular, we are interested in making the creation of medical findings faster, easier, and safer. For this purpose, we want to use methods of machine learning to automatically detect organs and other important structures in the human body and to assist in their assessment. This is to provide the physician in charge with a second opinion, which was created on purely objective grounds.

2. What kind of image and related data is involved?

The data are medical images taken during the course of your current hospitalization / medical visit for the purpose of examination or treatment. So, you donate data that has already helped you and can now improve the medical diagnostics in a second use. In addition to the images, the collected data includes selected information about yourself: age, gender, and the diagnostic code for your illness (the so-called ICD Code).

3. How are the image and related data used?

The image and related data provided by you are provided solely for medical research and teaching. They are to be used in the interest of a broad benefit to the general public for many different medical research purposes. At the time of writing this information, not all future medical research goals can be described. These may relate to certain disease areas (for example, cancer, cardiovascular diseases, diseases of the brain) as well as to currently unknown diseases and genetic defects. So, it may be that your data is also used for medical research questions that we cannot anticipate today. **In particular, we would like to have your image data analyzed by third parties via the Internet. For this purpose, the data will be shown anonymously to these third parties for a specific purpose.** For example, we would ask where the liver is shown on the image. Based on this information we can develop automatic programs that are able to find and accurately measure the liver.

The image and related data are to be stored indefinitely and made available for medical research and teaching. Every five years, it is checked whether the data still corresponds to the state-of-the-art in imaging. Should the data no longer correspond to this (for example because of too low resolution), the image data together with linked data will be deleted. Furthermore, you can also withdraw the usage consent at any time via our website. Then, the data will be deleted and no longer be available to the scientists.

For logistical reasons it is not possible for the image database to make individual restrictions (for example, exclusion of certain research or teaching). If you do not fully agree with the type and duration of use described, you should not give your consent.

It is intended that results and lessons learned from your data will also be provided to you. Therefore, we commit all participating scientists to publish in the so-called open access format. If you wish, we will inform you about these results.

4. What are the risks associated with your donation?

a. Health risks

Since we only want to use image data for the image database, which is created within the diagnostic or therapeutic measures intended for you, the donation is not associated with any additional health risk for you.

b. Further risks

Any collection, storage and transmission of data in research projects involves confidentiality risks (such as the ability to identify you), particularly with regard to information about your illness. These risks cannot be completely ruled out and will increase if you publish (for example, on Facebook) medical image data on the Internet yourself. Under point 7 "Who has access to your images and data?", we will explain in more detail how your privacy is protected.

5. What benefit does it give you personally?

Personally, you cannot expect any immediate benefit or benefit from donating your samples and data to your health. Their evaluation is solely for research or teaching purposes and not to draw conclusions about your health.

In rare cases, research on image data of individuals may reveal changes that may affect the health of that person or their offspring. However, individual research results are generally not sufficiently safe and meaningful enough to be used clinically. Therefore, no individual research results are reported back to patients.

We are pleased to inform you about the general progress of the study "Medical Image Data for the Future of Medical Image Processing" on our website <http://www.medicaldatadonors.org>.

6. What benefits does it have for our society?

Medical-scientific research and teaching aim to improve our understanding of the pathogenesis and diagnosis and, on this basis, to develop new treatment approaches. Information about the activities of the image database can be found at <http://www.medicaldatadonors.org>.

7. Who has access to your images and data and how are they protected?

a. All data directly identifying your person (name, date of birth, address, etc.) will be replaced (pseudonymised) with an identification code immediately after arrival of the image material. Thereafter, the record is re-encoded and stored again. This double coding excludes an identification of your person by unauthorized persons according to today's knowledge as far as possible. Only in this form, the image and related data are available for research and teaching.

b. The data that immediately identifies you remains with Medical Data Donors e.V., where they are stored separately from the medical data. The data can therefore not be assigned to an individual without the participation of Medical Data Donors e.V. Such assignment will only be made in order to contact you again if you have agreed to this (**see point 9 below**). **A transfer of the data identifying your person does not take place.**

c. The coded data can be forwarded to universities, research institutes, and research companies, possibly also outside the EU, for more specific medical research purposes on a contractual basis under EU data protection law. Data that has been released to scientists and researchers may only be used for the purpose of the research and may not be passed on by the recipient for other purposes.

d. The prerequisite for using the data for a specific medical research project is that the research project has been evaluated by scientists and an institutional review board.

e. Scientific publications of results are exclusively anonymous, i.e. in a form that does not allow any conclusions about your person.

8. Do you or the image database gain a financial advantage from the use of your image materials and data?

You will not receive any financial compensation for the transfer of your data. Should a commercial benefit be obtained from the results of the research or teaching, one day outside of Medical Data Donors e.V., you will not be financially compensated.

By transferring the image and related data to Medical Data Donors e.V., you authorize Medical Data Donors e.V. to use your data.

The organization uses your data exclusively for scientific purposes. The data is not sold. However, the association may charge a fee for the provision of the data by the users.

9. Will you contact me again?

To collect further historical data, it may be useful to contact you at a later date to request additional information and / or images from you. In addition, such contact can be used, e.g., to inform you about the latest research results from your data.

If this is desired, you can use your TAN, which you receive during your donation, on our website <http://www.medicaldatadonors.org> and register there. With the TAN you can also delete your data from the database again.

10. What does your right of withdrawal include?

You may withdraw your consent to the use of your data at any time without stating reasons and without adverse consequences for you. The data is then deleted from all servers on which it is located and is no longer available for further research.

For the deletion, please use the TAN you received during the donation on our website <http://www.medicaldatadonors.org>.

11. Where can I get more information?

If anything is unclear to you, please ask your medical examiner before giving your consent. You can also contact us for further information at a later date. Our contact details can be found on our website <http://www.medicaldatadonors.org>.

CONSENT FORM

Last Name: _____
First Name: _____
Maiden Name (if applicable): _____
Date of Birth (DD.MM.YYYY): _____
Address: _____
ZIP-Code, City, State, Country: _____
ICD Codes (ask your physician): _____

Please read the following text carefully and sign the consent form at the bottom of this page.

I consent to my data being given to Medical Data Donors e.V. as described in the informational document and used for medical research and educational purposes. I agree that the purposes of the scientific and medical research and teaching for which my data will be used will not be limited, but remain under supervision of the involved institutional review boards and Medical Data Donors e.V. and in compliance with the EU Data Protection Regulation.

I transfer the right to use the data to Medical Data Donors e.V.

For the purpose of tracking your data or revoking your consent, please register on our website <http://www.medicaldatadonors.org>.

(signature)

Data Protection Consent

I agree that Medical Data Donors e.V. as described in the information document

- collects and stores personal data, in particular information about my health, from me,
- and makes the data available anonymous and double-coded for medical research and teaching projects.

My data may be used indefinitely for medical research and teaching projects.

They may be disclosed anonymously to universities, universities of applied sciences, university hospitals, non-university research and teaching institutions and private supporters of research projects via the Internet for the purposes of medical research and teaching, subject to any revocation. This also includes the transfer for research projects abroad in compliance with the EU General Data Protection Regulation and with the participation of the Data Protection Officer of Medical Data Donors e.V.

I have received the study information for this declaration of consent. I was given a copy of the document to stay with me. I have read and understood both documents. This provided me with sufficient information about the purpose and course of the study, the chances and risks of my participation, the use and eventual transfer of my data and images, and the rights and obligations arising from my participation.

I had enough time for my decision. I have been informed that I can withdraw my consent to Medical Data Donors e.V. at any time without giving reasons. Upon revocation, the collected data will be deleted in all places where it was stored. Derived data from already performed analyzes cannot be removed anymore.

I have received a copy of the participant information and consent form. The original remains with Medical Data Donors e.V.

Name of participant in block letters

Place, date (to be entered by the participant), signature of the participant