

Patient Information

TraumaRegister DGU®

Dear Patient,

We would like to ask for your participation in the TraumaRegister.

This register ensures and documents the high quality of treatment of seriously injured patients. It contributes towards further improving medical care, e.g. by carrying out particularly successful therapies in hospitals. The TraumaRegister provides information on medical advances and paves the way for new approaches in the area of accident prevention.

Most German hospitals with trauma surgery departments (currently around 650) participate in the TraumaRegister that is managed by the Akademie der Unfallchirurgie (Academy of Trauma Surgery). A doctor or hospital employee enters the respective information about the injury and the treatment of the affected persons into a database without mentioning the patient's name and address.

Your participation in the TraumaRegister is voluntary, and you will not experience any disadvantages if you decline. The register is concerned solely with collecting data and you will not have to undergo any additional examinations.

This Patient Information provides you with a detailed explanation of the register and its objectives and contains all the Data Protection Information of relevance to you.

Goals of the TraumaRegister

Treating patients with severe or extremely severe injuries represents a particular challenge for trauma surgery. Despite the generally high level of care for severely injured persons, there are still differences in quality. The aim of the TraumaRegister is to make these differences measurable and to optimise the quality of treatment at all participating hospitals. At the same time, an extensive dataset also allows research into scientific interrelationships, and offers the possibility of regularly carrying out critical examinations of established treatment procedures and identifying new treatment approaches.

Managing the register

The TraumaRegister is managed by the Akademie der Unfallchirurgie GmbH (AUC) on behalf of the Deutsche Gesellschaft für Unfallchirurgie e.V. (German Trauma Society).

Procedure and scope of data collection

The register is concerned solely with collecting data, and you will not have to undergo any additional examinations.

All hospitals participating in the register use the existing medical documentation that was carried out as part of your treatment and extract a scientifically formulated data set from it. This data set

contains health data and information about your accident, for example. The doctor treating you holds the complete data set in readiness so that it can be viewed. You can also access the data entry form at any time on the internet at:

www.traumaregister-dgu.de/de/registerstruktur/erhebungsboegen.html

The hospital treating you enters the data into a digital data mask of the TraumaRegister and forwards it to the register database. The entry in the register is made by your doctor or an employee of the trauma surgery department.

The data is transferred to the register using a freely assigned patient ID (so-called pseudonym) without your name and without your date of birth. Only the hospital treating you is able to assign the pseudonym to your person; the required assignment list remains at your hospital and will not be passed on.

Benefits and risks of participation

You will be making an important contribution to improving the quality of care, existing treatment methods and research into new approaches if you agree to participate in the register.

As the register is merely concerned with the transfer of data, you do not incur any medical risks.

How is the data used?

The medical data entered into the Trauma Register by your hospital is combined with the data of other patients from the same hospital over a period of 12 months and statistically processed in a report for the hospital for quality assurance purposes. With this report, the participating hospital is shown the quality of its own care in comparison with the summarised results of all other hospitals participating in the TraumaRegister.

Extracts from the entire register are made available to research groups at the participating hospitals for concrete research purposes and specific scientific evaluations in the field of trauma surgery. The research groups work exclusively with anonymised data, i.e. patient data, that have been statistically summarised in accordance with the actual research question before being passed on, so that they are free of any individualising characteristics. The pseudonyms are also never passed on to third parties.

The research results and other scientific findings from the TraumaRegister are made known to the professional public, in particular in the form of publications and other published materials and can therefore be deployed again in patient care.

All publications are always anonymised, and no reference is ever made to concrete, individual persons.

Optional: Contact for assessing quality of life

The treatment data is unable to chart questions regarding the progress of healing and the quality of life after discharge from hospital. However, a patient's long-term condition after treatment is frequently of decisive importance for assessing the success of the treatment. To determine interactions between the long-term outcome of treatment and the preceding medical care, it is particularly important for us to be able to contact you at a later date.

We therefore ask you to give your consent for us to contact you at a later date. If we contact you, your doctor will inform you about the further questions and separately ask you to give your consent. As the register does not contain any identifying data, the only way you can be contacted is through your hospital.

Voluntary participation and withdrawal of consent

Your participation in the TraumaRegister is voluntary. You will not experience any disadvantages if you decline. You are free to revoke your consent at any time without experiencing any disadvantages. In this case, your data will be deleted from the register and the pseudonym assigned to you will be removed in the hospital.

Please send your revocation to your hospital or to the AUC. You will find the contact details in the Data Protection Information at the end of this information sheet.

Further questions

If you have further questions, please contact at any time the doctor treating you, the hospital treating you or the AUC.

AUC – Akademie der Unfallchirurgie GmbH

Emil-Riedel-Str. 5

80538 Munich

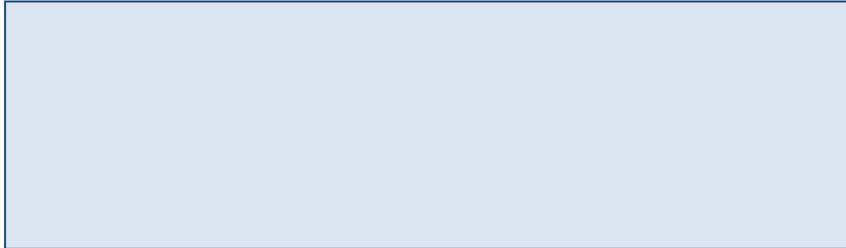
Tel.: +49 (0)221 8882 3910

E-mail: support-tr@auc-online.de

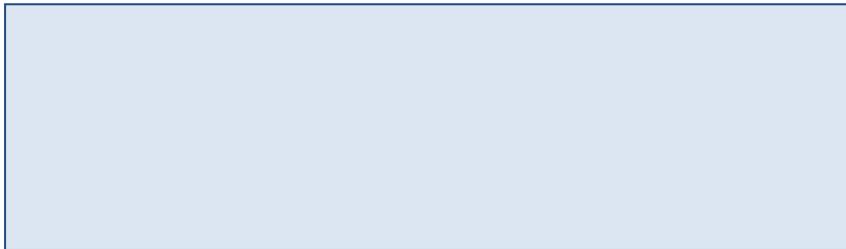
For more information on the TraumaRegister, see www.traumaregister-dgu.de

Data Protection Information of your hospital

We require your consent before we can pseudonymise and transmit your data for the TraumaRegister project. This consent is voluntary and will not have any consequences for your treatment. Legal basis for this is Art. 6 (1) lit. a in conjunction with Art. 9 (2) lit. a GDPR (General Data Protection Regulation). Responsible body for processing the data is:

A large rectangular area that has been redacted with a light blue background, obscuring the name of the responsible body for processing the data.

You can reach the data protection officer at:

A large rectangular area that has been redacted with a light blue background, obscuring the contact details of the data protection officer.

With your consent, your data – including information about your age and gender, information about your accident as well as data concerning the course of treatment in hospital – will be assigned a pseudonym and subsequently transferred to the TraumaRegister at AUC – Akademie der Unfallchirurgie GmbH. Instead of your name, the hospital treating you will freely select a sequence of digits (or pseudonym) which only the hospital can afterwards assign to your name. The pseudonym is stored in the hospital. The data for the register belongs to the so-called special category of personal data because it contains information about your health.

By pseudonymising the data, assurance is made that your data **cannot be directly assigned to your person, whether by the AUC or by third parties**. Data such as your name, address or date of birth is not transferred to the register. Only the hospital treating you has access to directly identifiable data. The pseudonyms are stored at the hospital for a maximum of 3 years or until revoked by you.

The data is transferred for quality assurance and research purposes.

Your rights as data subject

You can obtain information about the personal data stored about you at any time. You have the right to freely revoke your consent at any time with effect for the future and to have the personal data stored in the register corrected or deleted or the processing of aforesaid restricted. You also have the right to receive your data in a machine-readable format for the purposes of transmission. If you revoke your consent, your hospital will delete the pseudonym assigned to you.

To exercise your rights, please use the aforementioned contact details of your hospital.

If you believe that the applicable law is being violated as a result of the processing of your data, you have the right to lodge a complaint at a supervisory authority.

Data Protection Information of AUC – Akademie der Unfallchirurgie

Your consent is required for us to store and evaluate your data in the TraumaRegister. This consent is voluntary and will not have any consequences for your treatment. The legal basis for storing and using aforesaid data is Art. 6 (1) lit. a in conjunction with Art. 9 (2) lit. a GDPR (General Data Protection Regulation). Responsible body for processing the data is:

AUC – Akademie der Unfallchirurgie GmbH

Emil-Riedel-Str. 5

80538 Munich

Tel.: +49 (0)221 8882 3910

E-mail: support-tr@auc-online.de

You can reach the data protection officer at:

AUC – Akademie der Unfallchirurgie GmbH

Emil-Riedel-Str. 5

80538 Munich

Tel.: +49 (0)89 5404 81123

E-mail: datenschutz@auc-online.de

With your consent, your data – including information about your age and gender, information about your accident and data concerning the course of treatment – will be stored in the register and evaluated there. The data belongs to the so-called special category of personal data because it contains information about your health.

Your data will be pseudonymised by your hospital before being transmitted to us, thereby ensuring that **neither the AUC nor third parties can assign this information directly to your person**. Data such as your name, address or date of birth are not stored in the register; only your hospital knows this data.

Only the hospital treating you and the register office of the AUC – Akademie der Unfallchirurgie, as well as its authorised representatives, all of whom are bound to secrecy, are granted access to the data in the register. Your data will not be passed on to third parties.

The data will be processed for the purposes of quality assurance in the hospital treating you and for research purposes. Research in this context includes the statistical evaluation of accumulated register data as well as the publication of findings in the field of trauma surgery. Evaluations and publications of research results are always based on data that has been previously condensed and thus anonymised. A patient's individual data sets are never released from the register.

We store and use your data until revoked by you. Furthermore, your data will be deleted by us immediately as soon as they are no longer required for upcoming research projects.

Your rights as data subject

You can obtain information about the personal data stored about you at any time. You have the right to freely revoke your consent at any time with effect for the future and to have the personal data stored in the register corrected or deleted or the processing of aforesaid restricted. You also have the

right to receive your data in a machine-readable format for the purposes of transmission. If you revoke your consent, we will delete your data from the register database.

To exercise your rights towards us, you can contact the hospital treating you at any time which will forward your concern to us without revealing your identity.

You can also contact us directly with proof of your identity, and the necessary assignment to your data for the purposes of fulfilling your rights will be arranged by us with your hospital. To do this, you must release your doctor from his duty of confidentiality.

If you believe that the applicable law is being violated as a result of the processing of your data, you have the right to lodge a complaint at a supervisory authority.

Please note that we cannot identify you directly from the data in the register and that your rights may be restricted by Art. 11 (2) GDPR.

Declaration of consent under data protection law

for participation in the TraumaRegister

Name: _____

First name: _____

Date of birth: _____

Representative: _____

I have read and understood the Patient Information and the Privacy Policy of the TraumaRegister. I had the opportunity to ask questions and have understood the explanation about the importance of my participation. I have understood my rights as a data subject.

I am aware that my participation is voluntary and that it will not have any consequences for my treatment and that the TraumaRegister is a pure documentation project. I am aware that I can freely revoke my consent to participate at any time with effect for the future without this resulting in any disadvantages for me.

I was given a copy of the Patient Information and consent form.

I consent to allow my hospital to pseudonymise my data in the context of the TraumaRegister, to store the pseudonym and transmit my data to the AUC without direct reference to my person.

I consent to allow the data to be stored and processed there by the AUC for purposes of quality assurance and research in the field of trauma surgery until revoked.

I consent to allow **data concerning my health** to be transmitted, stored and used in the context of the TraumaRegister as set out in the Patient Information and the **Data Protection Information**.

Optional: I also consent to being contacted at a later date

Place, date

Signature of patient/representative

Place, date

Signature of employee