**Patient information for adolescents**

(14 to 17 years)

Participation in the Chronic Angioedema Registry (CARE)

Dear Patient,

You are being treated by your doctor because you have recurrent swelling of your skin. The medical term for this is "recurrent angioedema" or "chronic angioedema".

Although recurrent angioedema is very common, we still know too little about the frequency, duration, causes, treatment response, and many other related aspects of the different subtypes of angioedema. Therefore, we are planning a worldwide registry study to collect and compare data from exactly these topics from many affected people.

Your doctor would like to ask you if you would like to participate in this registry study. The more patients participate in the registry, the more we will learn about recurrent angioedema, the difficulties it causes for patients, and the treatment options.

**Aims of the study**

The aim of the registry study is to improve the understanding of the clinical picture of recurrent swelling. The results from the angioedema registry will be scientifically evaluated and help to improve patient care.

**Procedure of the registry study**

For your participation in the angioedema registry, it is necessary that you receive clarification via this patient information sheet and a written, dated, and signed approval is necessary (declaration of consent).

If you agree, data on your medical history will be documented when you are first admitted to the registry, e.g. time of first occurrence of swelling, further afflictions, medications taken, factors triggering the swelling, previous diagnostics (and their results), and therapies used (and their effect and tolerability). During the course of the study, further data e.g., on the course of your recurrent angioedema as well as on further diagnostics and therapy, will be entered into the registry at intervals of several months.

This registry study has no influence on your treatment by your doctor. No additional examinations or additional appointments with us will be required as a result of your participation. The only difference is that you may be asked by your doctor to fill out questionnaires.

It is important that you know that your data will be protected. No personal data such as surname, first name, date of birth or address are recorded in the register. In other words, it is not possible to draw any direct conclusions about you as a person in the register. The entry of your data in the register is pseudonymized. This means that only the entering doctor and his / her staff can bring connection to the registry entry and your data.

**Duration of the study**

The course of your recurrent angioedema will be documented in the registry for as long as your doctor finds it necessary and you agree to it. The registry runs without a time limit i.e., there is no end date foreseen so far.

**Possible risks of the study**

There are no risks for you, because only data about your swellings and your treatment are documented.

**Circumstances that may lead to discontinuation of the study**

* Withdrawal of your approval to participate.
* Termination of your participation by your doctor.
* Termination of the registry study by the Urticaria Network e.V. (UNEV).

**Possible benefit for the participant or the general public**

There is no direct benefit for you through your participation. Due to the expected gain of knowledge from the registry database over time could result in a better understanding of the different forms of recurrent angioedema and improved care for those affected.

**Voluntariness of participation**

It is your free decision whether you want to participate in this registry study or not. In any case, your decision will not have any disadvantages for you or influence your further medical treatment. You have the opportunity to withdraw your approval at any time during the study without giving reasons. In this case, no further data will be documented for the study. You can also say at any time that you do not want your data to be further processed. At your request, your data can be removed from the register at any time.

**Insurance**

Since this project is an observational study and no medications are being tested, patient insurance is not required.

**Is there an expense allowance?**

There is no compensation for expenses for the participation in this study. No additional expenses are required for participants, as all examinations are routine clinical practice and there are no additional costs to the participant.

**Financing of the project**

This study is a scientific research project, which is partly financed by the Urtikaria Network e.V. (UNEV), Schönhauser Allee 163, 10435 Berlin.

**Data protection**

* The legal basis for data processing is your voluntary approval (Art. 6, No. 1, letter c), DSGVO).
* The person responsible for data processing is: to be filled in by the center.

The data will be treated confidentially at all times. The data will be forwarded in pseudonymized form to the initiator of the study Charité - Universitätsmedizin Berlin - Institute for Allergy Research or to bodies commissioned by him for the purpose of scientific evaluation. Only the responsible employees in the respective study center have access to the personal data.

Pseudonymization means that the personal data, such as the name and date of birth, can no longer be assigned to a specific person without consulting a list. The personal data is replaced by a number and / or letter code; the date of birth is limited to the year of birth. A list is stored in the study center, on which the names are assigned to the number and / or letter codes. This list is kept separately at the study center and is subject to technical and organizational measures there to ensure that the personal data cannot be assigned to you by unauthorized persons.

The data collected in the course of this study will be kept in the registry database for at least 10 years after completion of this study in accordance with the legal requirements.

Competent employees of the initiator of the study or companies commissioned by him for the purpose of scientific evaluation who are bound to secrecy may, even after all relevant data have already been transmitted, inspect the treatment records available at the study center in order to check the data transmission. For more details, please refer to the data protection (see “declaration of consent form”). With your signature, you release your doctors from the medical confidentiality obligation for this purpose.

**Are there risks associated with data processing?**

There are confidentiality risks associated with any collection, storage, use and transmission of data (e.g., the possibility of identifying the person concerned). These risks cannot be completely eliminated and increase the more data can be linked. The initiator of the study assures you that it will do everything possible according to the state of the art to protect your privacy and will only pass on data to bodies that can demonstrate a suitable data protection concept. Medical risks are not associated with data processing.

The data may also be transferred to countries outside the internal EU area. In these countries, there may be a lower level of data protection. With your agreement, you agree that the data may also be transferred to these countries. [To be filled in/corrected by the center]

The initiator of the study will make every effort to ensure an appropriate level of data protection. **Please note: The data will only be passed on in pseudonymized form.** The code (the pseudonym) can only be decrypted within the EU at the study centers in order to assign the pseudonymized data to you (see above).

**Can I recall my declaration of consent?**

You can recall your declaration of consent in writing or verbally at any time without giving reasons and without any disadvantage to you. If you recall your agreement, no further data will be collected. However, the data processing that took place until the recall of your declaration of consent remains lawful.

**What other rights do I have in relation to data protection?**

You have the right to request information from the person responsible about your personal data stored (including the free provision of a copy of the data). You can also request the correction of inaccurate data and, if necessary, a transfer of the data you have provided and the restriction of its processing.

As a rule, please contact the study center, because only the study center can fully access your data or provide corresponding information due to the pseudonymization process. The initiator of the study can only help to a very limited extent.

If you have any concerns about data processing and compliance with data protection requirements, you can also contact the following data protection officers:

To be filled in by the center

You have a right to complain to any data protection supervisory authority. You can find a list of supervisory authorities in Germany under following link:

https://www.bfdi.bund.de/DE/Infothek/Anschriften\_Links/anschriften\_links-node.html

**Your right to ask questions**

As a study participant, you have the right to ask your doctor questions at any time about all matters relating to this study.

1. The responsible data manager is the person who decides on the purposes and means of data processing (Art. 4, No. 7, DSGVO). This is in any case the initiator of the study, so that this person and the contact details of his data protection officer must be named. Depending on the study design - an additional responsibility of the local study center is also possible.

2. According to Art. 13, No. 1, letter f), GDPR, information must be provided not only about the intention to transfer the data to a non-EU country, but also about the existence or absence of an adequacy decision. Likewise, information must be provided about what suitable and adequate safeguards exist within the meaning of Art. 46, 47, GDPR, how a copy of them can be obtained and where they are available.

3. This information is also required under Art. 13, No. 1, letter f), GDPR .

4. Here, only the contact details are required in each case, but not also the names of the ones giving data. Accordingly, a generic e-mail address is also enough.