**Patient information parents / legal guardians/ legal caregivers**

**(Version 1.0, 15.09.2023)**

Participation in the Chronic Angioedema Registry (CARE)

Dear Parents / legal Guardians / legal Caregivers,

Your child has recurrent swellings (“chronic or recurrent angioedema”), which can occur on different parts of the body. Although this symptom is very common, and it is clear that many different clinical pictures can be the cause, we still know too little about the exact epidemiology (e.g., frequency, duration of swellings, swelling progression), underlying causes, further afflictions, trigger factors, burden, treatment responses, and costs associated with various forms of angioedema.

Therefore, data shall be collected on exactly these topics within the framework of this angioedema registry. The data shall not only be collected in Germany, but also in other European and non-European countries, and will be scientifically evaluated during the process. This patient information serves to ask you whether your child would like to participate in this registry project. Please read the following information carefully and contact the attending doctor if you have any uncertainties or additional questions.

**Aims of the study**

The aim of the present registry study is to improve data on the various forms of recurring swelling (angioedema), including the subject area epidemiology (e.g., frequency, duration of swellings, swelling progression), underlying causes, further afflictions, trigger factors, burden, treatment responses, and cost of illness, and thus to improve the overall understanding of recurring angioedema and its subtypes. The results from the registry shall be published and will help to improve the care of future affected patients.

**Procedure of the registry study**

As a prerequisite for your child's participation in the angioedema registry it is necessary that you receive clarification via this patient information sheet (as well as an age-appropriate patient information for your child) and the presence of your written, dated, and signed approval as well as your child's agreement are necessary (declarations of consent).

If the declarations of consent are available, data on your child's medical history will be documented at the time of initial inclusion in the registry, including time of onset, further afflictions, medications taken, triggers of the angioedema, previous diagnostics (and their results), therapies used (and their effects and tolerability). During the course of the study, further data e.g., on the course of the recurrent angioedema, diagnostics and therapy, will be entered into the registry at intervals of several months.

This registry study does not affect your child's treatment. The treatment of the recurrent angioedema and the implementation of the therapy will be determined solely by the treating doctor. No additional tests or additional clinic appointments will be required as a result of participation. Only the usual examinations, performed as part of the routine clinical management of your child's condition, will be performed. The only deviation from routine is that you or your child may be asked by their doctor to complete questionnaires (e.g., regarding quality of life limitations or costs incurred as a result of the recurrent angioedema).

It is important that no personal data, such as surname, first name, date of birth or address are recorded in the disease register. The entry of data in the register is pseudonymized. This means that only the entering doctor and his / her staff can bring connection to the registry entry of your child. The doctors entering the data are asked to record the circumstance of register entry and the pseudonym assigned to your child in the regular patient documentation i.e., in the patient file.

**Duration of the study**

The course of your child's recurrent angioedema will be documented in the registry for as long as the attending doctor deems necessary and for as long as you and your child approve this. The entire CARE registry runs without a time limit i.e., there is no end date for the registry so far.

**Possible risks of the study**

There are no risks to your child beyond routine treatment, as this study only documents data from routine treatment. No additional examinations will be performed that pose a risk to you.

Circumstances that may lead to termination of the study

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

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

There is no immediate benefit to you or your child of your child's participation as a result. The expected increase in knowledge from the registry database over time could result in a better understanding of the various forms of recurrent angioedema and improved care for those affected.

**Voluntariness of participation**

It is the free decision of you and your child whether it wishes to participate in this registry study or not. In any case, your or your child's decision will not result in any disadvantages for your child or influence further medical treatment. Both you and your child 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. Both you and your child can object to the further processing of the data already obtained at any time and request their deletion or destruction.

**Insurance**

Since this project is an observational study and it is not a drug trial, patient insurance is not required.

**Is there a compensation for expenses?**

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 of Allergology 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 code 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 codes and / or letter codes. This list is kept separately at the study center where it is subject to technical and organizational measures to ensure that the personal data cannot be assigned to your child by any unauthorized persons.

The data collected in the course of this study will be kept in the registry database for at least 10 years after the completion of this study, in accordance with the legal requirements. Responsible employees of the initiator of the study or companies commissioned by the initiator for the purpose of scientific evaluation, may inspect the treatment records available at the study center, even after all relevant data have been transmitted, 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 any 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 completely be eliminated and increase the more data can be brought to connection. The initiator of the study assures you that he will do everything possible according to the state of the art to protect your child's privacy and that he will only pass on data to bodies that can demonstrate an appropriate data protection concept. Medical risks are not associated with the data processing.

The data may also be transferred to countries outside the internal EU area e.g., the United States of America or Brazil. In these countries, there may be a lower level of data protection. With your approval, you agree that the data may also be transferred to these countries. 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 decoded within the EU at the study centers in order to assign the pseudonymized data to your child (see above).

**Can I revoke my approval?**

Both you and your child can revoke your approval (declaration of consent) in writing or verbally at any time without giving reasons and without any disadvantage for your child. If you or your child revoke your declaration of consent, no further data will be collected. However, the data processing that took place until the revocation remains lawful.

**What other rights do I, respectively my child have with regard to data protection?**

You have the right to request information from the responsible data manager about the personal data stored from your child (including the provision of a copy of the data free of charge). Likewise, you can request the correction of inaccurate data and if necessary a transfer of the data provided by your child and the restriction of their processing.

As a rule, please contact the study center, because only the study center can fully access your child's data or provide corresponding information due to the pseudonymization process. Against this background, 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 may also contact the following data protection officers:

To be completed by the center

You have a right to complain to any data protection supervisory authority. You can find a list of the 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 participant in the study, you and your child have the right to ask your doctor questions about all matters relating to this study at any time.

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 sufficient.