Information on the handling of data collected in a study:

Within the **DECADE- Deciphering the CACNA1E developmental and epileptic encephalopathy study**, your personal data[1] will be collected and processed.

Your data will be documented and archived pseudonymously[2] in a protected electronic database, to which only authorized employees including doctoral students bound to professional and data secrecy have access. In order to verify the correct transfer of treatment data from your medical record to the encrypted study database, authorized persons are allowed to view personal medical data related to the study. All staff members involved are subject to the obligation of confidentiality.
The obtained video data files will be saved on an encrypted file server. Blurring of faces is not plannend. Due to this a re-identification of participants cannot be excluded. If you provide your sepreate consent videos can be subject to publication in scientific literature. Here re-identification can be excluded to a high degree as these videos will be subject to blurring of the face.

The legal basis for processing is Article 6 (1) (a) and Article 9 (2) (a) of the General Data Protection Regulation (DSGVO) in conjunction with your consent.
For the collection, storage, use and disclosure of your data, your express consent is required by signing the data protection consent form.
The research results from the study will be published in anonymized form in scientific journals or in scientific databases. The pseudonymized data will be processed on survey forms and electronic data carriers.
Pseudonymized data obtained in this study may, with your consent, be transferred to international databases on rare epilepsies (including Epi25, ILAE Genomics, Treat-ION/EpiReg, EpiCare) to build larger patient cohorts and gain further knowledge. In the context of this transfer, the data protection standards and deletion times applicable to the database apply, which may differ from the deletion times specified here. Video recordings are not subject to this transfer, so that re-identification can be excluded to a high degree.

The data is stored for 25 years after completion or discontinuation of the study for use in follow-up studies and for longer follow-up. They will be protected against unauthorized access and will be deleted as soon as they are no longer needed for the purpose of data processing in the study, at the latest after 25 years.

With your consent, the collected pseudonymized data can also be transferred to international pharmaceutical companies with the aim of developing specific therapies for the disease studied. The video recordings obtained are not the subject of this transfer, so that a re-identification can be excluded to a high degree.

The information obtained in the course of this study may also be transferred for scientific purposes to cooperation partners outside the scope of the European General Data Protection Regulation (GDPR), i.e. also to countries with a lower level of data protection (this also applies to the USA). In these countries, there may be restrictions on the enforcement of your rights (e.g. data disclosure); government authorities may also have access to your (pseudonymized) data. If your data is transferred to countries with a lower level of data protection, the controller will take all necessary measures to ensure the level of data protection. Your data will only be transferred if you expressly consent to the proposed data transfer.

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

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[1] **personal data:** Name, date of birth, address, previous findings, study-related findings including imaging procedures, results of study-related genetic tests, etc.

[2] **pseudonymized** means that your personal data (name, date of birth, etc.) are encrypted and can only be assigned to your person with the help of an identification list that is only accessible to the authorized study personnel who are subject to the duty of confidentiality

You can also request information about your stored data at any time and demand that we provide you with a free copy, and you have the right to have incorrect data corrected.
You can also request at any time that your data be deleted or made anonymous so that a reference to your person can no longer be made.

These rights are restricted in accordance with Section 13 of the State Data Protection Act (Landesdatenschutzgesetz, LDSG) and Section 27 of the Federal Data Protection Act (Bundesdatenschutzgesetz, BDSG), respectively, to the extent that these rights are likely to make it impossible or seriously impair the realization of the respective research purposes and the restriction is necessary for the fulfillment of the respective research purposes. Furthermore, the right to information does not exist if the data is required for scientific research purposes and the provision of information would require a disproportionate effort.

The responsible party for data processing pursuant to Art. 4 (7) DSGVO is the University Hospital Tübingen, legally responsible institution under public law of the University of Tübingen, Geissweg 3, 72076 Tübingen, Tel.: 07071 29-0, service@med.uni-tuebingen.de. The person responsible for data processing in this study is the study director Prof. Dr. med. Holger Lerche. If you have any questions regarding the use or processing of your data, please contact her/him.

If you have any concerns or complaints regarding data protection or wish to exercise your rights under Art. 15ff. DSGVO, you can contact the following person: University Hospital Tübingen, Data Protection Officer, Geissweg 3, 72076 Tübingen, Tel.: 07071 29-87667, e-mail: Datenschutz@med.uni-tuebingen.de. You also have the right to complain to the competent supervisory authority for data protection (State Commissioner for Data Protection and Freedom of Information in Baden-Württemberg, P.O. Box 10 29 32, 70025 Stuttgart, Tel.: 0711 / 61 55 41 - 716, Mail: Poststelle@lfdi.bwl.de).

Declaration of consent to the handling of data collected in a study:

I declare that I agree to the collection and processing of data and their encrypted (pseudonymized) transfer taking place within the scope of the study.
I agree that authorized persons may inspect my personal medical record for the purpose of reviewing the data and release the attending physician from his medical confidentiality obligation in this respect.
I am aware that the results of this study will be published in medical journals, but in anonymous form, so that a direct link to my person cannot be established.
I have been informed that I can request information about my stored data and the correction of incorrect data at any time.
I know that I can demand at any time, for example when withdrawing from participation in the study, that my data collected up to that point be deleted or anonymized immediately.
I declare that I have been adequately informed about the collection and processing of my data collected in this study and my rights.
I consent to the use of the data collected in this study in the manner described above. For the inspection of authorized persons, I release my treating physicians and the study team from the duty of confidentiality to the extent necessary.

I consent to video recordings for the purpose of monitoring disease progress. I am aware the complete pseudonymization of this data is not possible.
Yes □ No □

I consent to the publication of these videos in scientific journals without the mentioning of my name.
Yes □ No □

I also expressly consent to my personal data being transmitted in encrypted form (pseudonymized) to cooperation partners in countries with a possibly lower level of data protection.
Yes □ No □

I consent to my data being shared with pharmaceutical industry partners as part of further research.
Yes □ No □

I expressly consent that the study team may contact me even after the end of the study to ask whether I agree that the data collected in the course of the study may also be used and processed for specific future research projects of the clinic or institute.
Yes □ No □

I agree that data from other treating physicians (general practitioner, specialists) may be collected as part of the study. I hereby release these doctors from their legal duty of confidentiality.
Yes □ No □

I consent that my pseudonymized data may be transferred to international databases for further analysis.
Yes □ No □

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Place, date	Signature of legal representative For persons not capable of giving consent	Signature of patient

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Name of legal representative