**Supplementary information for study participants according to**

**General Data Protection Regulation[[1]](#footnote-1)**

**for ongoing clinical research projects (start before 25.05.2018)**

**<Study title>**

**(short title)**

EudraCT-no.:

Dear trial participant,

Due to the entry into force of the General Data Protection Regulation (GDPR) on 25 May 2018, the data protection regulations in Europe are changing. This also results in new requirements for the processing of personal data for ongoing medical research projects (hereinafter referred to as clinical studies).

If you are already a participant in a clinical trial, you have already been informed about the aspects of data protection in the respective patient information/declaration of consent and have agreed to this in writing. This includes, for example, information about the collection, storage and forwarding of your personal data and your rights in this regard. You will also receive this information as a possible new study participant as part of your investigator's informed consent interview and in the written patient information/declaration of consent for the clinical study.

The handling of your data described in the patient information / consent form for the respective clinical study continues to apply.

**In addition, you will be informed of the rights laid down in the GDPR:**

**Legal basis**

The legal basis for the processing of your personal data in clinical trials is your voluntary written consent in accordance with the GDPR and the Declaration of Helsinki (Declaration of the World Medical Association on Ethical Principles for Medical Research on Humans) and the guideline for Good Clinical Practice. In the case of clinical trials with medicinal products, the Medicines Act is also applicable and in the case of clinical trials with medical devices, the Medical Devices Act is applicable. At the same time as the GDPR the revised German Federal Data Protection Act and state data protection regulations come into force in Germany.

**Regarding your data you have the following rights**:

**Consent to the processing of personal data and right to revoke consent**

The processing of your personal data is only legal with your consent.

You have the right to revoke your consent to the processing of personal data at any time. However, the data collected up to that time may be processed by the authorities named in the patient information/declaration of consent for the respective clinical study/trial.

**Right of information**

You have the right to obtain information about the personal data concerning you that is collected, processed or, if necessary, transferred to third parties within the scope of the clinical study

**Right of correction**

You have the right to have incorrect personal data concerning you corrected.

**Right to deletion**

You have the right to delete personal data relating to you, e.g. if this data is no longer necessary for the purpose for which it was collected and there are no legal retention periods to prevent deletion.

**Right to limitation of processing**

Under certain conditions, you have the right to restrict processing, i.e. the data may only be stored, not processed. You must apply for this. Please contact your trial investigator at the trial centre.

**Right to data transferability**

You have the right to receive the personal data concerning you that you have provided to the clinical trial/trial investigator. You can thus request that this data be transmitted either to you or, as far as technically possible, to another body you have designated.

**Right of objection**

You have the right to object at any time to specific decisions or measures for the processing of your personal data. Processing does not take place afterwards unless processing is still required by law.

If you would like to make use of one of these rights, please contact **your trial investigator** at your trial centre. You also have the right to complain to the Data Protection Authority(s) if you believe that the processing of personal data concerning you is contrary to the GDPR.

**Contact data of the trial investigator:**

*Please add.*

**Contact data:**

Data Protection Officer

Address: Universitätsklinikum C. G. Carus Dresden

Datenschutzbeauftragte/r

Fetscherstraße 74

01307 Dresden, Germany

email: [DSV@uniklinikum-dresden.de](mailto:DSV@uniklinikum-dresden.de)

*For trial centres outside Dresden, if applicable: please complete the contact details of the local data protection officer here.*

1. REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [↑](#footnote-ref-1)