Additional information for clinical trial participants according to the General Data Protection Regulation (GDPR)[1]

CLINICAL TRIAL TITLE

EudraCT-No.: .....
Protocol Code: .....

Madam/Sir,

This information is provided to you as a potential future participant in the above-mentioned clinical trial and is part of your informed consent interview with the investigating physician. You will receive it in written form in addition to the "Informed Consent to Participate in a Clinical Trial" document.

The conditions for processing your data are described in your informed consent to participate in the clinical trial.

This document informs you about your rights under the GDPR:

Legal title
The legal basis for the processing of your personal data is your voluntarily signed informed consent to participate in the clinical trial, in accordance with the Declaration of Helsinki (Declaration of Ethical Principles for Medical Research Involving Human Subjects) and the regulations of good clinical practice. In the case of clinical trials, Act No 378/2007 Coll. on Medicinal Products, as amended, and Act No 110/20019 Coll. on the Processing of Personal Data, as amended, also apply.

You have the following rights in relation to your personal data:

Consent to the processing of personal data and the right to withdraw this consent
The processing of your personal data is only permitted with your consent. You have the right to withdraw your consent to the processing of your personal data at any time. However, data collected up to that time may already be processed by the competent authorities specified in the patient's informed consent to participate in the clinical trial.

Right of access to personal data
You have the right to be informed about the collection and processing of your personal data and, where applicable, the transfer of data to third parties.

Right to repair
You have the right to request the correction of incorrect personal data.

Right to erasure
You have the right to request the deletion of your personal data, for example, if the data is no longer necessary for the purposes for which it was collected and if there are no legal time limits for its retention.

Right to restriction of processing
Under certain conditions, you have the right to request the restriction of the processing of your personal data. In this case, your data may only be stored but not further processed. You must

[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)

request this. If you wish to exercise this right, please contact the investigating doctor at the centre where the clinical trial is taking place.

Right to data portability
You have the right to obtain the personal data that you have provided to the investigating doctor or centre where the clinical trial is taking place. You may request that this data be transferred to you or, if technically possible, to a third party of your choice.

Right to object
You have the right to object to the processing of your personal data at any time. The sponsor of the clinical trial will stop the processing immediately if further processing is not required by law.

If you would like to exercise any of these rights, please contact the **investigating physician** at the centre where the clinical trial is taking place. You also have the right to lodge a complaint with the Data Protection Authority if you believe that the processing of personal data relating to you is in breach of the GDPR or Act No. 110/2019 Coll. on the processing of personal data.

Contact the examining physician:

Contact details can be found on page 1 of the informed consent form.

Contact details for the Data Protection Officer.:

Data Protection Officer / Contracting Authority
Address: Masaryk University
Data Protection Officer
Arna Novák 1/1
602 00 Brno
email: poverenec@muni.cz
phone: 549 49 1030

Data Protection Officer / Centre
Address: …….
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email:
phone: