

Definitions of Withdrawal Types and Protocol Violations in the DZHK

Notification to the Trusted Third Party (TTP):

Complete Withdrawal: The study participant fully withdraw their informed consent(s). The consequences and implications are specific to the study and the type of consent.

Partial Withdrawal – Contact Blocking: The study participant no longer wishes to be contacted, meaning that primary data and biosamples can no longer be collected. Already collected data will be retained and may continue to be used for the purpose previously consented to by the participant. Secondary data may still be collected if the participant has agreed to it.

Partial Withdrawal – Secondary Data Use DZHK: The study participant wishes to continue regular participation in the study but withdraws consent for the secondary use of data by the DZHK. The release of data for research purposes outside the study by the DZHK will be blocked.

Erroneous Entry: The person was mistakenly entered into secuTrial®. However, they never signed a consent declaration for this study, so all data and, if applicable, biosamples and image/biosignal data associated with this pseudonym will be deleted.

Notification to the Responsible Study Personnel:

Study Termination / Lost-To-Follow-Up: The study participant, for example, no longer wishes to attend study visits, no longer wants to take the medication, or is unreachable. The consent remains valid. For further information, please contact the study coordination or study management.

Erroneous Inclusion (Study Exclusion / Screening Failure): The erroneous inclusion is identified by the study center. After the person has been entered into secuTrial®, it becomes apparent that an exclusion criterion is present and/or an inclusion criterion is not met. The consent remains valid. For further steps, please contact the study coordination or study management.

Erstellt:	Fiedler-Lacombe, Lizon Léonie - 27.10.2025	ID: 86596
Inhaltlich geprüft:	Naumann, Pia - 29.10.2025	Version: 003/11.2025
Formal geprüft:	Ruback, Alexander - 30.10.2025	Gültig bis: 03.11.2027
Freigegeben:	Dittmann, Kathleen - 03.11.2025	Seite 1 von 2



**Reporting of an exclusion of study, a contact blocking or a withdrawal to the
Trusted Third Party (TTP)**

Before reporting an exclusion from study, a contact blocking or a withdrawal to the TTP, please consult the process with the central study coordination/management respectively with the project management, the sponsor or the monitoring of the study.

Afterwards, please send the completed and signed form to the Trusted Third Party (TTP) by e-mail.

Process	
Study	
Study centre	
Study centre staff recording the process	
Last name	First name
Date	Signature
study participant concerned	
pheno pseudonym	

<input type="checkbox"/>	I hereby confirm that the process reported to the Trusted Third Party on this form has been validated by the central study coordination/management respectively by the project management, the sponsor or the monitoring of the study.
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comments
