



# As study staff, here's what you need to do if...

...you are aware of reasons that speak against a further active participation in the study.

Study staff

## Erroneous Entry



The patient was mistakenly entered into the productive system of secuTrial®. The patient never signed a consent declaration and is not participating in the study.

- ▶ Select on the TTP form\*: **Erroneous Entry** via uploadticket to the Trusted Third Party.

- ✗ **Clinical data, biosignal and image data, biosamples:** Deletion and, if necessary, disposal
- ✗ **Further data collection:** not possible
- ✗ **Further contact:** not possible

## Lost-to-follow-up



The patient no longer wishes to attend study visits, no longer wants to take the medication, or is unreachable. The patient does not reject further contact. The consent(s) remain(s) valid.

- ▶ For further information, please contact the study coordination/study management.

- ✓ **Data and biosamples:** remain
- ✓ **Further data collection:** possible
- ✓ **Further contact:** possible

## Erroneous Inclusion (Study Exclusion/Screening Failure)



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(s) remain(s) valid.

- ▶ For further information, please contact the study coordination/study management.

- ✓ **Data and biosamples:** remain
- ✗ **Further data collection:** not possible
- ✓ **Further contact:** possible

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# As study staff, here's what you need to do if...

...a patient would no longer be contacted or participate.

Patient

## Complete withdrawal



Patient fully withdraws their informed consent(s).

- ▶ Select on the TTP form\*: **Complete withdrawal** via uploadticket to the Trusted Third Party.

- ❗ **Data and biosamples:** specific to the study and consent
- ❗ **Further data collection:** specific to the study and consent
- ❌ **Further contact:** not possible

## Contact Blocking



The patient no longer wishes to be contacted and is thus no longer participating in the study. The consent(s) remain(s) valid.

- ▶ Select on the TTP form\*: **Partial Withdrawal - Contact Blocking** via uploadticket to the Trusted Third Party.

- ✅ **Data and biosamples:** remain
- ❗ **Further data collection\*\*:** Only possible for the timely documentation of previously created visits
- ❌ **Further contact:** not possible

## Withdrawal DZHK Heart Bank



Secondary Data Use



DZHK biobanking

The patient wishes to continue regular participation in the study but withdraws consent either for the secondary use of data (for research purposes outside the study, including DZHK biobanking) or for the separate consent regarding the DZHK biosample resource. The other consent(s) remain(s) valid.

- ▶ Select on the TTP form\*: **Partial Withdrawal - Secondary Data Use or Partial Withdrawal - separate consent for DZHK biosample resource** via uploadticket to the Trusted Third Party.

- ❌ **Data and biosamples:** Data Blocking for Secondary Use and/or disposal of DZHK biobanking
- ✅ **Further data collection:** possible for the study
- ✅ **Further contact:** possible for the study

Here's what to do

These are the consequences

