Here's what you need to do as study staff if...

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

...a patient no longer wishes to be contacted or to participate.

Study staff

End of study

- Patient no longer wants study medication/intervention; study is no longer feasible (relocation, death...).

- In the eCRF in secuTrial: fill out end of study form
- The Trusted Third Party does not have to be informed

Data and biosamples: remain
Further data collection: possible
Further contact: possible

Patient

Exclusion from study

- Patient no longer meets inclusion criteria according to study protocol or has an exclusion criterion.

- Form withdrawal/exclusion from study, select process exclusion from study and send it via Upload-Ticket to the Trusted Third Party
- In the eCRF in secuTrial: fill out end of study form and document reason for exclusion

Data and biosamples: remain
Further data collection: not possible
Further contact: possible

Contact blocking

- Patient no longer wishes to be contacted.

- Form withdrawal/exclusion from study, select process contact blocking and send it via Upload-Ticket to the Trusted Third party
- In the eCRF in secuTrial: Fill out end of study form

Data and biosamples: remain
Further data collection: not possible
Further contact: not possible

Complete withdrawal

- Patient withdraws consent completely.

- Form withdrawal/exclusion from study, select process complete withdrawal and send it via Upload-Ticket to the Trusted Third Party
- In the eCRF in secuTrial: Fill out end of study form

Data and biosamples: Deletion/destruction possible (only upon request)
Further data collection: not possible
Further contact: not possible

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1 If there are any questions or uncertainties please contact the principal investigator.

2 Timely documentation of already created visits possible.

3 Is dependent on consent or other legal bases (e.g., CTR, MDR).

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