

TASK DOCUMENTATION

[Post-Randomization Final Status Form]

Patient ID: **PtID**

Complete this form to report a change in a participant's status to inactive prior to the completion of the protocol. Please contact the Jaeb Center before dropping a participant (except for death).

HPostRandFinalStatReas

Reason participant's participation in the Study has ended (provide pertinent details in COMMENTS):

Note: If participant is requesting to withdraw, make the appropriate selection based on whether the participant has formally withdrawn consent in writing.

Participant requests to withdraw - did not withdraw consent in writing

Participant requests to withdraw - participant formally withdrew consent in writing

Lost to follow up - *detail efforts to contact participant in COMMENTS*

Site withdraws participant – *indicate reason in COMMENTS*

Death

If Death, Adverse Event Form indicating the fatal event must be completed prior to submitting the final status form.

If Participant requests to withdraw, complete the following and provide additional details in comments:

Reason for participant withdrawal:

[Adverse event

Changed doctor

Does not want study treatment

Visit too lengthy

Finances

Moved

Other treatment requested

Poor health

Poor outcome

Travel difficulty

Unknown]

**** If reason is not listed please contact the coordinating center**

If Death, complete the following:

PtWithdrawReas

DeathDt

Date of Death: ____/____/____