FFinStatReas	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). **Reason Participant's Participation in the Study Has Ended** provide pertinent details in COMMENTS **Required done jts** ***Note: If participant is requesting to withdraw, make the appropriate selection based on whether the participant has formally withdrawn consent in writing.*** Participant not eligible Participant requests to withdraw - did not withdraw consent in writing – *detail in COMMENTS.* Participant requests to withdraw - participant formally withdrew consent in writing (Please fax letter to the Jaeb Center 1-888-795-2857) – *detail in COMMENTS.* Lost to follow up - *detail efforts to contact participant in COMMENTS.* Site withdraws participant – *detail in COMMENTS.* Death
PtWithdrawReas	*If 'Subject formally withdrew consent in writing' or 'Subject requests to withdraw (not in writing)' then reason for participant withdrawing is required, else null done jts -RR* *If not 'Death,' Date of Death and Cause of Death must be null done jts* *If FFinalStatusReas = 'Death' then there must exist a record in tbl[Protocol]AdvEvent for the participant where AEOutcome = 'Fatal'; else show message: "Please complete an adverse event form indicating the fatal event prior to completing the patient final status form." Done jts* *If 'Death' and either Date or cause of death is missing—show warning message that these are missing and ask for verification that they are to be left missing and indicate that they can be completed later as edits done jts* 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:**
DeathDt **DeathDs**	[Adverse event Changed doctor Does not want study treatment Finances Moved Other treatment requested Poor health Poor outcome

Travel difficulty

Unknown

Visit too lengthy]

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

If <u>*Death*</u>**, complete the following:**

Date of Death ___/___/___

Cause of Death _____