



Attention - DO NOT enter patient data on this form if the header does not contain *preprinted* HALT PKD ID number, clinical center ID, and visit number.

Participant ID: \_\_\_\_\_ *haltid* Clinical Center: \_\_\_\_\_ *clinic* Date of Visit \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
*dvm dvd dvy*

visit:

Missing Data Codes: A-Participant Refused B-Reading Not Possible C-Institutional Error

### MAJOR PROTOCOL VIOLATION FORM

Form # 29

This form is to be completed by designated personnel whenever a major protocol violation occurs. Note that it is not necessary to complete this form when minor protocol deviations occur. Refer to the Manual of Procedures for a definition of major protocol violations and minor deviations.

1. Date of the violation: \_\_\_\_ / \_\_\_\_ / \_\_\_\_  
*pvd pvm pvy*

*pvpt* Enrollment of an ineligible participant *pvptc* \_\_\_\_\_

*pverl* Failure to enter enrollment form within 3 business days of the start of drug washout *pverlc* \_\_\_\_\_

*pvrads* Randomization of an ineligible participant *pvradc* \_\_\_\_\_

*pvschn* Failure to collect all screening tests *pvschn* \_\_\_\_\_

*pvmv* Missed visit/safety lab during titration period (through F5) *pvmvc* \_\_\_\_\_

*pvrpt* Serious Adverse Event not reported in a timely fashion *pvrptc* \_\_\_\_\_

*pvdsc* Participant was misdosed *pvdsc* \_\_\_\_\_

*pvmec* Non-participant took study medication *pvmec* \_\_\_\_\_

*pvard* Open-label drugs given out of order *pvardc* \_\_\_\_\_

*pvmri* Failure to collect MRI/MRA/LVM *pvmric* \_\_\_\_\_

*pvcrc* Failure to collect central creatinine *pvcrc* \_\_\_\_\_

*pvcrcd* Failure to re-check creatinine doubling within two weeks *pvcrcd* \_\_\_\_\_

*pvald* Failure to collect 24 HOUR urine sample (aldosterone) *pvaldc* \_\_\_\_\_

*pvcnf* Breach of Confidentiality *pvcnfc* \_\_\_\_\_

*pvlw* Participant lost to follow up *pvlwc* \_\_\_\_\_

*pvoth* Other *pvothc* \_\_\_\_\_



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*visit:*

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2. Is the participant eligible to continue on study? *pvelg* 1  Yes 2  No 3  N/A

3. Comments *pvcmt* \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\*\*\*\*\*

HALT PKD staff member completing this form: \_\_\_\_\_ *cmidnum* Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
Month *cdm* Day *cdd* Year *cdy*

HALT PKD investigator reviewing this form: \_\_\_\_\_ (signature required) Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
Month Day Year

Data Entry Status: Please check to indicate that the above information has been entered

Primary Entered by: \_\_\_\_\_ *deidnum* Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
*dem* Month *ded* Day *dey* Year