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Participant ID:_____ *haltid* **Clinical Center***:* _____ *clinic* **Date of Report**____/____/_____
visit: month *dvm* day *dvd* year *dvy*

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

SERIOUS ADVERSE EVENT REPORT FORM *rptif* ___ Initial Report ___Follow-up Report # ___*followup* Form # 13

This form is to be entered within 24 hours of study personnel becoming aware of a SAE. Refer to instructions for form completion and Manual of Procedures for event codes, terminology, and reporting guidelines. A hard copy of this form is to be completed and signed by the Investigator prior to submitting this report to the DCC.

I. SERIOUS ADVERSE EVENT (EVENT #1) *Note: PI must determine #7, 8, 9, 10 and 14 below.*

1. **Event Code** _____*ncateg* **Event Term** _____ *nspecc* **Severity Grade:** ___ *ngrade*

2. **Onset Date:** __ __/__ __ /__ __ __ *eom eod eoy* **Onset Time:** ____:____ (24h) *eoh eon* **Pregnant?** *preg* 2 ☐ **N/A** 0 ☐ **No**
1 ☐ **Yes, #weeks** _____ *pregwk*

3. **End Date:** __ __/__ __/__ __ __ *eem eed eey* **End Time:** ____:____ (24h) *eeh een*

4. **Outcome of Event:** *evtoutc*
2 ☐ **Ongoing** 1 ☐ **Recovered** 3 ☐ **Sequelae** *(describe in #15)* 4 ☐ **Fatal** *(complete #6, 1)* 5 ☐ **Unknown**

5. **When did PCC personnel learn of the event?** **Date:** __ __/__ __/__ __ __ *plm pld ply* **Time:** ____:____ (24h) *plh pln*

6. **Reason the event is serious:** *(Check all that apply)*

☐ **Resulting in Death:** *resa (Enter Death Notification From 31 within 2 weeks)* **Autopsy:** *autopsy* 1 ☐ **Yes** 0 ☐ **No**

Date of Death: __ __/__ __/__ __ __ *ddm ddd ddy* **Cause of Death:** _____ *causedeath*

☐ **Hospitalization – any initial or prolonged stay in hospital/health care facility** *resb (Enter Hospitalization Form 30 within 2 weeks)*

☐ **Life-threatening - the patient is at substantial risk of dying at the time of the event, or continued use of a study medication [5] or study procedure [6] would result in the patient's death. Included in this definition are potassium levels of >6.5 mEq/L, and doubling of baseline serum creatinine within 12 weeks of beginning study medications.** *resc*

☐ **Resulting in persistent or significant disability/incapacity** *resd*

☐ **Exceeding the nature, severity or frequency described in the protocol** *rese (If event is related to study drug, it is "unexpected")*

☐ **Congenital anomaly/birth defect of offspring** *resf*

☐ **Abuse of or dependency on study medication** *resg*

☐ **Any other important medical event, including new cancer diagnosis, which may jeopardize the participant, or may require intervention to prevent permanent impairment/damage or other outcome listed above** *resh (describe in #15 below)*

7. **Is the event <u>related to study participation?</u>** *evtrsp*
1 ☐ **Definitely** 2 ☐ **Probably** 3 ☐ **Possibly** 4 ☐ **Unlikely** 5 ☐ **Not Related** 6 ☐ **Unknown**

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Participant ID:_____ *haltid* **Clinical Center***:* _____ *clinic* **Date of Report**____/____/_____
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SERIOUS ADVERSE EVENT REPORT FORM *rptif* ___ Initial Report ___Follow-up Report # ___*followup* **Form # 13**

8. **Is the event <u>related to blood pressure medication?</u>** *evtrbpm*

1 ☐ **Definitely** 2 ☐ **Probably** 3 ☐ **Possibly** 4 ☐ **Unlikely** 5 ☐ **Not Related** 6 ☐ **Unknown**

9. **Is the event <u>related to masked medication?</u>** *evtmkm*

1 ☐ **Definitely** 2 ☐ **Probably** 3 ☐ **Possibly** 4 ☐ **Unlikely** 5 ☐ **Not Related** 6 ☐ **Unknown**

10. **If the event is related to study drug** *(see #8-9),* **is it considered <u>unexpected?</u>** *evtunex*

1 ☐ **Yes** 0 ☐ **No** 2 ☐ **Unknown** 3 ☐ **N/A** (unrelated)

11. **Setting in which the event occurred:** *evtset*

1 ☐ **Hospital** 2 ☐ **Outpatient** 3 ☐ **At Home** 4 ☐ **Nursing Home** 5 ☐ **Not Reported**

12. **Therapy for event:** *evtthr* 1 ☐ **Yes** *(specify drug and non-drug therapy in #15 below)* 0 ☐ **No**

13. **Action taken with masked medication due to this event:** *evtammt*

1 ☐ **Continued** 5 ☐ **Protocol Completed**
2 ☐ **Reduced** 6 ☐ **Discontinue & Reintroduce**
3 ☐ **Discontinued** 7 ☐ **Not Applicable**
4 ☐ **Increased**

14. **In the PI's opinion, is the event related to ADPKD?** *evtrpkd*

1 ☐ **Yes** 0 ☐ **No** 2 ☐ **Unknown**

15. **Description:** *descrip*

_____

_____

_____

_____

_____

_____

Drug & Non-drug Therapies to treat event *therapy*	Formulation *formul*	Strength *strength*	Daily Dose *dose*	Route *route*	Onset Date *onsm onsd onsy*	Onset Time *onsh onsn*	End Date *endm endd endy*	End Time *endh endn*	Related to Event? *relate*
									1 ☐ Yes 0 ☐ No
									1 ☐ Yes 0 ☐ No
									1 ☐ Yes 0 ☐ No

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SERIOUS ADVERSE EVENT REPORT FORM *rptif* ___ Initial Report ___Follow-up Report # ___*followup* **Form # 13**

II. **ASSOCIATED ADVERSE EVENT (EVENT # _____)** ***Note: PI must determine #20 and #21.***
Use as many copies of pages 3 and 4 as there are associated adverse events.

16. **Event Code** _____*ncateg* **Event Term** _____ *nspecc* **Severity Grade:** _____ *ngrade*

17. **Onset Date:** __ __/__ __ /__ __ __ (*eom eod eoy*) **Onset Time:** ____:____ (24h) (*eoh een*)

18. **End Date:** __ __/__ __/__ __ __ (*eem eed eey*) **End Time:** ____:____ (24h) (*eeh een*)

19. **Outcome of Event:** *evtoutc*

2 ☐ **Ongoing** 1 ☐ **Resolved** 3 ☐ **Sequelae** *(describe in #25)* 4 ☐ **Fatal** 5 ☐ **Unknown**

20. **Was the event serious?** *serious* 1 ☐ **Yes** *(If Yes, check reasons for seriousness)* 0 ☐ **No** *(If No, skip to #21)*

☐ **Resulting in Death** *resa*

☐ **Hospitalization – any initial or prolonged stay in hospital/health care facility** *resb*

☐ **Life-threatening – the patient is at substantial risk of dying at the time of the event or continued use of a study medication [5] or study procedure [6] would result in the patient's death. Included in this definition are potassium levels of >6.5 mEq/L, and doubling of baseline serum creatinine within 12 weeks of beginning study medications.** *resc*

☐ **Resulting in persistent or significant disability/incapacity** *resd*

☐ **Exceeding the nature, severity or frequency described in the protocol** *rese (If event is related to study drug, it is "unexpected")*

☐ **Congenital anomaly/birth defect of offspring** *resf*

☐ **Abuse of or dependency on study medication** *resg*

☐ **Any other important medical event, including new cancer diagnosis, which may jeopardize the participant, or may require intervention to prevent permanent impairment/damage or other outcome listed above** *resh (describe in #15 below)*

A. **Is the event <u>related to study participation</u>?** *evtrsp*

1 ☐ **Definitely** 2 ☐ **Probably** 3 ☐ **Possibly** 4 ☐ **Unlikely** 5 ☐ **Not Related** 6 ☐ **Unknown**

B. **Is the event <u>related to pressure medication?</u>** *evtrbpm*

1 ☐ **Definitely** 2 ☐ **Probably** 3 ☐ **Possibly** 4 ☐ **Unlikely** 5 ☐ **Not Related** 6 ☐ **Unknown**

C. **If the event is related to study drug** *(see #20B and #21),* **is it <u>unexpected?</u>** *evtunex*

1 ☐ **Yes** 0 ☐ **No** 2 ☐ **Unknown** 3 ☐ **N/A** (unrelated)

D. **In the PI's opinion, is the event related to ADPKD?** *evtrpkd*

1 ☐ **Yes** 0 ☐ **No** 2 ☐ **Unknown**

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SERIOUS ADVERSE EVENT REPORT FORM *rptif* ___ Initial Report ___Follow-up Report # ___*followup* **Form # 13**

21. Is the event related to masked medication? *evtmkm*

1 ☐ **Definitely** 2 ☐ **Probably** 3 ☐ **Possibly** 4 ☐ **Unlikely** 5 ☐ **Not Related** 6 ☐ **Unknown**

22. Setting in which the event occurred: *evtset*

1 ☐ **Hospital** 2 ☐ **Outpatient** 3 ☐ **At Home** 4 ☐ **Nursing Home** 5 ☐ **Not Reported**

23. Therapy for event: *evtthr* 1 ☐ **Yes** *(specify drug and non-drug therapy in #25 below)* 0 ☐ **No**

24. Action taken with masked medication due to this event: *evtammt*

1 ☐ **Continued** 5 ☐ **Protocol Completed**
2 ☐ **Reduced** 6 ☐ **Discontinue & Reintroduce**
3 ☐ **Discontinued** 7 ☐ **Not Applicable**
4 ☐ **Increased**

25. Description: *descrip*

_____

_____

_____

_____

_____

_____

_____

Drug & Non-drug Therapies to treat event *therapy*	Formulation *formul*	Strength *strength*	Daily Dose *dose*	Route *route*	Onset Date *onsm onsd onsy*	Onset Time *onsh onsn*	End Date *endm endd endy*	End Time *endh endn*	Related to Event? *relate*
									1 ☐ Yes 0 ☐ No
									1 ☐ Yes 0 ☐ No
									1 ☐ Yes 0 ☐ No

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SERIOUS ADVERSE EVENT REPORT FORM *rptif* ___ Initial Report ___Follow-up Report # ___*followup* **Form # 13**

III. MEDICATIONS AND MEDICAL CONDITIONS

26. Administration of masked medication: *adminmm*

1 ☐ **Correct** 2 ☐ **Incorrect** *(see #26a)* 3 ☐ **Pretreatment** 4 ☐ **>30 days post-treatment**

a. If incorrect, check one or more of the following:

☐ **Overdose** *evnniv* ☐ **Abuse** *evmmab* ☐ **Other** *evmmoth (describe in #34)*

27. Date of most recent masked medication __ __/__ __ /__ __ __
rmmm rmmd rmmy

28. Have any blood pressure medications changed due to event(s)? *chngmm*

1 ☐ **Yes** 0 ☐ **No** 2 ☐ **Unknown**

29. Drug Card Number:*drugcdnum* _____ **Was treatment code broken:** *trtcdbrk* 1☐ **Yes** 0☐ **No**

30. Was a rechallenge of masked medication performed? *rechallmm*

0 ☐ **No**

1 ☐ **Yes, outcome unknown (event #** *evresua* ☐1 *evresub* ☐ 2 *evresuc* ☐3 *evresud* ☐ 4 **)**

2 ☐ **Yes, positive (event #** *evrespa* ☐1 *evrespb* ☐ 2 *evrespc* ☐3 *evrespd* ☐ 4 **)**

Comment *commountcp* _____

3 ☐ **Yes negative (event #** *evresna* ☐1 *evresnb* ☐ 2 *evresnc* ☐3 *evresnd* ☐ 4 **)**

Comment *commoutcn* _____

31. Have existing concomitant medications changed due to event(s)? *chngcm*

1 ☐ **Yes** 0 ☐ **No** 2 ☐ **Unknown**

32. Relevant concomitant medications, *including masked drug, excluding therapies used to treat the event(s) reported:*

Relevant Medications *medname*	Formulation *formul*	Strength *strength*	Daily Dose *dose*	Route *route*	Onset Date *onsm onsd onsy*	Onset Time *onsh onsn*	End Date *endm endd endy*	End Time *endh endn*	Indication *indicate*	Related to Event? *event*
										1 ☐ Yes 0 ☐ No
										1 ☐ Yes 0 ☐ No
										1 ☐ Yes 0 ☐ No

SERIOUS ADVERSE EVENT REPORT FORM *rptif* ___ Initial Report ___Follow-up Report # ___*followup* **Form # 13**

33. List *relevant* concomitant diagnoses and dates of onset:

Concomitant Diagnoses *diagnose*	**Dates of Onset**
1.	
2.	
3.	

34. Comments: *comments* _____

_____

_____

_____

_____

_____

_____

_____

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SERIOUS ADVERSE EVENT REPORT FORM *rptif* ___ Initial Report ___Follow-up Report # ___*followup* Form # 13

ACUTE KIDNEY INJURY

If AKI (36c) is identified, an associated event will be completed to detail the occurrence.

IV. **AKI ASSESSMENT**

35. Presence of lab values within the medical record: ☐ Medical records are requested, or will be requested; the PI determination on AKI is pending. *akipending*

A. Medical records are available *akimedrcd* 1 ☐ **Yes** 0 ☐ **No**

B. Medical records contain labs *akimedlabs* 1 ☐ **Yes** 0 ☐ **No**

C. Medical records contain labs detailing creatinine *akicreat* 1 ☐ **Yes** 0 ☐ **No**
(creatinine or language indicating renal status during admission)

36. PI AKI determination during admission – Indicate one of the four selections below (using AKIN criteria with baseline defined as prior to admission, if possible): *piakidetermin*

1 ☐ **No AKI**

2 ☐ **Low probability of AKI (data not available)**

3 ☐ **AKI Identified**

4 ☐ **Unsure/Insufficient data to identify AKI**

37. LAB DATA:

A. PCC CSC sample drawn __ __/__ __ /__ __ __ *pccval* **value =** _____(mg/dl)
pccm pccd pccy

B. Admission creatinine: *creatval* **value =** _____(mg/*d*l) ☐ *missing* *msgcr*

C. Only creatinine available in MR summary *creatmrval* **value =** _____(mg/dl) ☐ *missing* *msgmr*

D. Highest reported creatinine value during admission *hcreatval* **value =** _____(mg/dl) ☐ *missing* *msghcr*

38. PI determination of AKI causation

If AKI was indicated, please indicate the cause (if possible): _____ *akicause*

39. Comments related to AKI review (Q35-38): *akicomment* _____

_____

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SERIOUS ADVERSE EVENT REPORT FORM *rptif* ___ Initial Report ___Follow-up Report # ___*followup* **Form # 13**

Comments related to AKI review (cont.)_____

_____

_____

_____

_____

_____

****

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

Reviewed by Study Investigator:_____ **Date:** _____/_____/_____
(signature required) *pism* Month *pisd* Day *pisy* Year

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

Primary Entered by: _____ Date: __ __/__ __/__ __ __
deidnum *dem* Month *ded* Day *dey* Year

Secondary Entered by: _____ Date __ __/__ __/__ __ __ __