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:** ____/____/____
month *dvm* day *dvd* year *dvy*

visit: ___**Form was not completed** *misfrm*

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

ENROLLMENT FORM

Form # 10

This form will serve to document participants' eligibility for the study at the time of enrollment, which must occur before the start of drug washout or randomization. It is to be completed after all screening criteria have been successfully met, and must be signed by the PI at the time of enrollment. The form must be entered within three business days after the start of drug washout, or before randomization if no washout is required. All lab values must be drawn at the S visit, processed at the PCC lab, and entered on Form 9 before this form can be entered. All eligibility criteria must have separate source documentation.

INCLUSION CRITERIA

1. Age at the Screening Visit:

a) Is participant's age 15-17? (If yes, participant is eligible for Study A only) ☐ Yes ☐ No

b) Is participant's age 18-49? (If yes, participant is eligible for either Study A or B) ☐ Yes ☐ No

c) Is participant's age 50-64? (If yes, patient is eligible for Study B only) ☐ Yes ☐ No

2. Gender: ☐ Male ☐ Female

3. Race: ☐ Black ☐ Non-Black

4. Is there a family history of ADPKD? *hpkdyn* 1 ☐ Yes 0 ☐ No
(If yes, go to #5. If no, mark #5 "N/A" and go to #6.)

5. In participants with a family history of ADPKD: *famhna* 1 ☐ N/A

a. If age <30, is there radiologic documentation of at least two renal cysts? (unilateral or bilateral) *cysta* 1 ☐ Yes 2 ☐ No 3 ☐ N/A

b. If age 30-59, is there radiologic documentation of at least two cysts in each kidney? *cystb* 1 ☐ Yes 2 ☐ No 3 ☐ N/A

c. If age 60-64, is there radiologic documentation of at least four cysts in each kidney? *cystc* 1 ☐ Yes 2 ☐ No 3 ☐ N/A

6. If no family history of ADPKD, is there radiologic documentation of bilateral renal cysts (with a total of at least twenty cysts) in the absence of findings suggestive of other cystic renal disease? *nhcyst* 1 ☐ Yes 2 ☐ No 3 ☐ N/A

7. GFR at the Screening Visit (S): Using PCC value for creatinine drawn at S visit and the HALT-PKD GFR calculator.

a) Is the GFR >60 ml/min/1.73 m^2 ? (If yes, participant is a candidate for Study A only) ☐ Yes ☐ No

b) Is the GFR 30-60 ml/min/1.73 m^2 ? (If yes, participant is a candidate for Study B only) ☐ Yes ☐ No

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month *dvm* day *dvd* year *dvy*

visit: ___**Form was not completed** *misfrm*

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ENROLLMENT FORM

Form # 10

8. Are anithypertensives or diuretics currently used for blood pressure control? 1 ☐ Yes 0 ☐ No
(If yes, mark "N/A" for #9 and skip to number 10 below. If no, continue.) *bpcyn*

9. If #8 above is "no," is there documentation within the past year of hypertension or high-normal blood pressure *(systolic BP ≥130 and/or diastolic BP ≥80 mm Hg on three separate occasions)***?** (If *yes*, enter data below. If *no*, participant is not eligible for either study.) *hbpadt* 1 ☐ Yes 2 ☐ No 3 ☐ N/A

Systolic (mm Hg)	**Diastolic** (mm Hg)	**Date of Reading**
hbsys1	*hbdia1*	*hbm1* / *hbd1* / *hby1*
hbsys2	*hbdia2*	*hbm2* / *hbd2* / *hby2*
hbsys3	*hbdia3*	*hbm3* / *hbd3* / *hby3*

10. Has the participant signed the most recent version of the informed consent? *cntyn* 1 ☐ Yes 0 ☐ No

Date consent was signed by participant: *dcm/dcd/dcy* ☐☐/☐☐/☐☐☐☐

EXCLUSION CRITERIA

1. If the participant is female: *femna* 1 ☐ N/A

a) Is the participant currently pregnant or intending to become pregnant within four-five years *preg* 1 ☐ Yes 0 ☐ No

b) Is the participant currently lactating, or has childbirth occurred within the past 6 months (if past the first trimester), or within the past 2 months (if pregnancy was terminated during the first trimester)? *gbrth* 1 ☐ Yes 0 ☐ No

2. Has there been any documented renal vascular disease? *ervd* 1 ☐ Yes 0 ☐ No

3. Does the participant have findings suggestive of kidney disease other than ADPKD? *eokd* 1 ☐ Yes 0 ☐ No

4. Has the participant been diagnosed with diabetes:

a) requiring insulin or oral hypoglycemic agents *ediab* 1 ☐ Yes 0 ☐ No

b) fasting glucose level of ≥126 or random non-fasting glucose level of ≥200 ☐ Yes ☐ No

5. Is the serum potassium level out of range? (select one category below for K value) *iespt* 1 ☐ Yes 0 ☐ No

iesptx

1 ☐ **Serum potassium is ≤5.0 mEq/L** (implies "no" – participant is eligible)

2 ☐ **Serum potassium is >5.5 mEq/L** (implies "yes" – participant is NOT eligible, skip to # 6)

3 ☐ **Serum potassium is >5.0 and ≤5.5 mEq/L** (implies that participant *may be* eligible, go to # 5a below)

ENROLLMENT FORM

Form # 10

a) If potassium level is >5.0 and ≤5.5 mEq/L, indicate the current BP therapy: *iespty*

1 ☐ **Participant is currently on ACE or ARB** (implies "no" – participant is eligible)

2 ☐ **Participant is NOT currently on ACE or ARB** (implies "yes" – participant is NOT eligible)

6. Does the participant have a history of angioneurotic edema or other absolute contraindication to ACE-I or ARB? *eace* 1 ☐ Yes 0 ☐ No

(Intolerable ACE-I-induced cough is defined as having developed within six months of initiation of ACE-I in the absence of other causes and resolving upon discontinuation of ACE-I therapy)

7. Does the participant have an indication other than hypertension for beta-blocker or calcium channel blocker therapy (e. g. angina, past myocardial infarction, arrhythmia)? *eblk* 1 ☐ Yes 0 ☐ No

If yes, has this been approved and documented by the principal investigator? *eblkpi* 1 ☐ Yes 0 ☐ No

8. Does the participant have a systemic illness necessitating the use of NSAIDs, immunosuppressant, or immunomodulatory medications? *esys* 1 ☐ Yes 0 ☐ No

Does the participant have a systemic illness with renal involvement? *esysr* 1 ☐ Yes 0 ☐ No

10. Has the participant had a non-elective hospital admission for an acute illness in the past two months? *ehspt* 1 ☐ Yes 0 ☐ No

11. Does the participant have any serious comorbid condition for which life expectancy is <2 years? *edie* 1 ☐ Yes 0 ☐ No

12. Does the participant have a history of non-compliance, drug or alcohol dependence within the past year or other psychiatric disturbance that would preclude successful completion of the study? (Per PI) *edrug* 1 ☐ Yes 0 ☐ No

13. Does the participant have a known unclipped cerebral aneurysm ≥7 mm? *eane* 1 ☐ Yes 0 ☐ No

14. Has the participant been treated (within 30 days of the start of HALT-PKD study medication) on any interventional study that would, in the PI's opinion, interfere with HALT-PKD, or taken creatinine supplements within three months prior to the screening visit? *eothmed* 1 ☐ Yes 0 ☐ No

15. Does the participant have congenital absence of a kidney? *ekdny* 1 ☐ Yes 0 ☐ No

16. Does the participant have a known allergy to sorbitol or sodium polystyrene sulfonate? *eallg* 1 ☐ Yes 0 ☐ No

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ENROLLMENT FORM

Form # 10

****Additional Exclusion Criteria for Study A Only** ☐ **N/A**

17. Has the participant received a partial or total nephrectomy, or renal cyst reduction within the past year, performed percutaneously, laparoscopically, or by open surgical procedure? *ecrdt* 1 ☐ Yes 2 ☐ No 3 ☐ N/A

18. Does the participant have a cardiac pacemaker? *epace* 1 ☐ Yes 2 ☐ No 3 ☐ N/A

19. Does the participant have a contraindication to MR, such as metal clips (e.g. Clipped cerebral aneurysm)**, implants, prosthesis, etc.** (This exclusion may be center-specific) *emr* 1 ☐ Yes 2 ☐ No 3 ☐ N/A

20. Does the participant have untreatable claustrophobia or body weight >159 kg (350 lbs) *ebig* 1 ☐ Yes 2 ☐ No 3 ☐ N/A

21. Does the participant have a spot-urine albumin-to-creatinine ratio of ≥0.5? ☐ Yes ☐ No ☐ N/A

****Additional Exclusion Criterion for Study B Only**** ☐ **N/A**

22. Does the participant have a history of a total nephrectomy (A history of cyst reduction procedures or partial nephrectomy will not preclude participation in Study B) *etotn* 1 ☐ Yes 2 ☐ No 3 ☐ N/A

23. Does the participant have a spot-urine albumin-to-creatinine ratio of ≥1.0? ☐ Yes ☐ No ☐ N/A

FINAL ELIGIBILITY STATUS

1. For which study is the participant eligible? *studelig* 2 ☐ A 3 ☐ B 1 ☐ Neither

As determined by inclusion criteria #1 and 7 of this form and additional exclusion criteria above.
**Note: If the participant is not eligible for either study, complete a Screen Failure Form #14.

2. Is a drug washout period required? *edrugwo* 1 ☐ Yes 0 ☐ No

If yes, planned start date of the drug washout (B0): *sdwm/sdwd/sdwy* ____/____/____

3. Date of scheduled Baseline Visit (B1): *sbvm/ sbvd/sbvy* ____/____/____

Note: If the current visit is a combined screening/baseline (SB1), enter today's date.

****

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