



Participant ID: _____ pkdid
visit:

Clinical Center: _____ pccn

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

Registration Form

This form is to be completed at visit 10, immediately following signing of informed consent.

1. Date of visit: *dvdate* [][] / [][] / [][][][]

2. Informed Consent
If participant does not sign informed consent, check no, go to section 14 and check **Ineligible** for Participant Status: **do not** complete any other questions or sections.
If consent is signed, check yes and go to question 3.
Did the participant sign written consent? *sigcon* 0 No 1 Yes
Date the consent form was signed: *condate* [][] / [][] / [][][][]

In the next section, complete only the consent form questions which pertain to your site.

3. **CRISP III Consent Form – KANSAS**
1. I permit the de-identified information (identified by CRISP ID number only) collected for the CRISP study to be provided to the HALT or Otsuka investigators. *kanscrisp*
1 Yes 0 No Date: [][] / [][] / [][][][]
kanscrispdt
2. I permit de-identified information (identified by HALT ID or Otsuka ID number only) collected for the HALT or Otsuka study to be provided to the CRISP investigators. *kanshalt*
1 Yes 0 No Date: [][] / [][] / [][][][]
kanshalt dt
3. Storage of specimens
Biosamples (blood and urine) *kansbl durine*
 I agree to allow my blood and urine samples stored in the NIDDK Biosample Repository to be preserved for future research on Polycystic Kidney Disease.
 I do not agree to allow my blood and urine samples stored in the NIDDK Biosample Repository to be preserved for future research on Polycystic Kidney Disease.
4. Genetics Samples (DNA) [if collected] *kansdna*
 I agree to allow my DNA sample to be stored in the NIDDK Biosample Repository to be preserved for future research on Polycystic Kidney Disease.
 I do not agree to allow my DNA sample to be stored in the NIDDK Biosample Repository to be preserved for future research on Polycystic Kidney Disease.



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CRISP III Consent Form - EMORY

Procedures

1. I permit the de-identified information (identified by CRISP ID number only) collected for the CRISP study to be provided to the HALT or any other interventional trial investigators. *emrycrisp*

1 Yes 0 No

Date: / /

Emrycrispt

2. I permit de-identified information (identified by HALT ID number or any other interventional study number) collected for the study to be provided to the CRISP investigators. *emryhalt*

1 Yes 0 No

Date: / /

Emryhaltdt

3. NIDDK Central Repositories *emryniddk*

- Yes, I agree to have my blood and urine samples stored in the NIDDK Biosample Repository.
- No, I do not agree to have my blood and urine samples stored in the NIDDK Biosample Repository.

CRISP III Consent Form – UAB

Recruitment of Family Members

1. Please check the options with which you agree. *uabfammem*

- I will give the information to my family members
- I will not give the information to my family members

2. Storage of blood and urine samples *uabcrisp*

- I agree to allow my de-identified (identified by CRISP ID number only) blood and urine samples, stored in the NIDDK Biosample Repository, to be preserved for future research on Polycystic Kidney Disease.
- I do not agree to allow my de-identified (identified by CRISP ID number only) blood and urine samples, stored in the NIDDK Biosample Repository, to be preserved for future research on Polycystic Kidney Disease.

3. Clinical and genetic information collected during the CRISP studies *uabinfo*

- I give my permission to have my de-identified (identified by CRISP ID number only) data from the CRISP studies used in future research by the CRISP investigators.
- I do not give my permission to have my de-identified (identified by CRISP ID number only) data from the CRISP studies used in future research by the CRISP investigators.



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CRISP III Consent Form – MAYO

1. I permit the de-identified information (identified by CRISP ID number only) collected for the CRISP study to be provided to the HALT investigators. *mayocrisp*

1 Yes 0 No

Date: / /

Mayocrispdt

2. I permit de-identified information (identified by HALT ID number only) collected for the HALT study to be provided to the CRISP investigators. *mayohalt*

1 Yes 0 No

Date: / /

Mayohaltdt

3. I permit my sample to be stored and used in future research of autosomal dominant polycystic kidney disease at Mayo. *mayoautosom*

1 Yes 0 No

Date: / /

Mayoautosomdt

4. I permit my sample to be stored and used in future research at Mayo to learn about, prevent, or treat any other health problems. *mayolearn*

1 Yes 0 No

Date: / /

Mayolearndt

5. I permit Mayo to give my sample to researchers at other institutions: *mayoothinstit*

1 Yes 0 No

Date: / /

Mayoothinstitdt

6. I permit Mayo to give my sample to researchers at other institutions (not a commercial sponsor): *mayocommerc*

1 Yes 0 No

Date: / /

Mayocommercdt

7. Did the participant consent to have a DNA sample sent to the NIDDK Repository? 0 No 1 Yes
consntdna

If yes, date consented?

dnadate

/ /

8. Did the participant consent to have their blood and urine samples sent to the NIDDK Repository? 0 No 1 Yes
consntbld

If yes, date consented?

blldate

/ /



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Does this participant require Limited Participation?		0 <input type="checkbox"/> No - Continue		1 <input type="checkbox"/> Yes - Go to 10	
<i>limitedpart</i>					
4.	Is the participant currently enrolled in another study in addition to CRISP?	0 <input type="checkbox"/> No		1 <input type="checkbox"/> Yes	
<i>parten</i>					
If yes, which study?					
Yes	No	Study	Date of enrollment	and/or	Duration
<input type="checkbox"/>	<input type="checkbox"/>	Halt (Please complete Halt ID Form)	___/___/___	_____mths	_____yrs
		<i>enrolhalt</i>	<i>enrolhalt</i>	<i>haltdurmt</i>	<i>haltduyr</i>
<input type="checkbox"/>	<input type="checkbox"/>	Tempo	___/___/___	_____mths	_____yrs
		<i>enroltemp</i>	<i>enroltemp</i>	<i>tempdurmt</i>	<i>tempduyr</i>
<input type="checkbox"/>	<input type="checkbox"/>	Other, Specify: _____	___/___/___	_____mths	_____yrs
		<i>enroloth</i> <i>enrolspcy</i>	<i>enrolthdt</i>	<i>othdurmt</i>	<i>othduyr</i>
5.	Gender <i>gender</i>	1 <input type="checkbox"/> Male		2 <input type="checkbox"/> Female	
6.	Birth Weight <i>brwgt</i> _____ pounds	<i>broz</i> _____ ounces	<input type="checkbox"/> check if birth weight is unknown		<i>brunk</i>
7.	Was birth weight verified by the participant's birth certificate? <i>Brcert</i>	0 <input type="checkbox"/> No		1 <input type="checkbox"/> Yes	
		9998 <input type="checkbox"/> Unknown			
8.	Treating physician affiliation: <i>phys</i>	1 <input type="checkbox"/> CRISP physician		2 <input type="checkbox"/> Other nephrologist	
		3 <input type="checkbox"/> Other physician		9998 <input type="checkbox"/> Unknown	
8a.	Have you ever been told by a doctor or other health professional that you have diabetes or high blood sugar (If female, other than during pregnancy)?	0 <input type="checkbox"/> No		1 <input type="checkbox"/> Yes	
		2 <input type="checkbox"/> Don't Know		9998 <input type="checkbox"/> Missing	
<i>diablowsugar</i>					
If no or don't know, and male participant, go to 9.					
If no or don't know, and female participant, go to 8b.					
If yes, date:		Month	Day	Year	
		<input type="text"/>	<input type="text"/>	<input type="text"/>	
		/			
		/			
<i>diablowsugarmt</i> <i>diablowsugarda</i> <i>diablowsugaryr</i>					
<i>If male participant, go to 8c.</i>					
8b.	Have you ever been told by a doctor or other health professional that you have/had diabetes during pregnancy?	0 <input type="checkbox"/> No		1 <input type="checkbox"/> Yes	
		2 <input type="checkbox"/> Don't Know		9998 <input type="checkbox"/> Missing	
<i>diabpregn</i>					
If 8a=no or don't know and 8b=no or don't know, go to #9.					
If yes, date:		Month	Day	Year	
		<input type="text"/>	<input type="text"/>	<input type="text"/>	
		/			
		/			
<i>diabpregnmt</i> <i>diabpregnda</i> <i>diabpregnyr</i>					



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<p>8c. Did you ever take medications for diabetes? <i>diabmed</i></p> <p>If yes, medications: _____ <i>diabmed1</i> _____ <i>diabmed2</i> _____ <i>diabmed3</i> _____ <i>diabmed4</i> _____ <i>diabmed5</i></p>	<p>0 <input type="checkbox"/> No</p>	<p>1 <input type="checkbox"/> Yes</p>	<p>2 <input type="checkbox"/> Don't Know</p>	<p>777 <input type="checkbox"/> Not Applicable</p>	<p>9998 <input type="checkbox"/> Missing</p>
<p>8d. Are you now taking diabetic pills (also called hypoglycemic agents) to lower your blood sugar? <i>diabpills</i></p>	<p>0 <input type="checkbox"/> No</p>	<p>1 <input type="checkbox"/> Yes</p>	<p>2 <input type="checkbox"/> Don't Know</p>	<p>777 <input type="checkbox"/> Not Applicable</p>	<p>9998 <input type="checkbox"/> Missing</p>
<p>8e. Are you now taking insulin? <i>insulin</i></p>	<p>0 <input type="checkbox"/> No</p>	<p>1 <input type="checkbox"/> Yes</p>	<p>2 <input type="checkbox"/> Don't Know</p>	<p>777 <input type="checkbox"/> Not Applicable</p>	<p>9998 <input type="checkbox"/> Missing</p>
<p>9. Education (in total number of years) <i>educ</i> _____ years</p>					
<p>9a. Are you adopted? <i>adopt</i> 0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes</p>					
<p>10. Exclusion Criteria</p> <p><i>If yes is checked for any of the criteria listed in section 10, go to section 14 and check Ineligible for Participant Status; do not complete sections 11, 12, and 13.</i></p> <p><i>If all criteria listed in section 10 are no: If participant requires Limited Participation, i.e. is only contributing blood samples, only contributing MRIs, etc., go to section 12.</i></p> <p><i>If participant does not require Limited Participation, go to section 11.</i></p>					
<p>Does the participant have a current psychiatric or addiction non-compliance disorder that in the discretion of the principal investigator indicates that they will not successfully complete the study? <i>curpsyc</i></p>					
<p>0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes</p>					
<p>Does the participant have a current medical problem that in the discretion of the principal investigator would make unsafe their participation in the study? <i>cur</i></p>					
<p>0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes</p>					
<p>Does the participant have another condition that in the discretion of the principal investigator makes the participant ineligible? <i>ocrit</i></p>					
<p>0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes</p>					
<p>If yes, please specify: _____ <i>otcritsp</i></p>					



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11. Failed to Enroll Criteria

If the participant is unwilling to enroll in the study, indicate reason(s).

If yes is checked for **any** of the criteria listed in section 11, go to section 14 and check **Failed to Enroll** for Participant Status; **do not** complete section 12 or 13.

If all are no, go to section 12.

Is the participant unwilling to miss school/work? *schwork* 0 No 1 Yes

Is the participant unwilling to travel to clinics for visits? *travcl* 0 No 1 Yes

Is the participant unwilling to make a follow-up commitment? *fucom* 0 No 1 Yes

Is there any other circumstance that in the discretion of the principal investigator constitutes a valid reason for failing to enroll? *otennr* 0 No 1 Yes

If yes, please specify _____ *othensp*

12. Eligible but Modified Criteria – Part I

Review **all** possible conditions listed in section 12 with the participant. Check any that apply. If **any** of the MR contraindications are checked, go to section 14 and check **Eligible but Modified** for Participant Status. **Do not** complete section 13.

If none are checked, go to section 13.

Weight > 158.6 kg (350 lbs) *weight*

Pregnant *preg*

Cardiac Pacemaker *cardpac*

Implanted cardioverter defibrillator (ICD) *cardef*

Neurostimulation system *neuron*

Claustrophobia *claust*

Spinal cord stimulator *spinal*



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13. Eligible but Modified Criteria – Part II

Review **all** possible conditions listed in section 13 (continued on the next 2 pages) with the participant. Check any that apply. If **any** are checked, please discuss with the radiologist to determine the Participant Status.

If none are checked, go to section 14 and check **Eligible and Enrolled**.

- Bone growth/bone fusion stimulator *bonfus*
- Cochlear, otologic, or other ear implant *earimp*
- Insulin or other infusion pump *insul*
- Implanted drug infusion device *druginf*
- Eyelid spring or wire *eyel*
- Tissue expander (e.g. breast) *tissex*
- Hx of working with metal *hxwkmet*
- Hx of metal in eyes *hxmeteye*
- Aneurysm Clip(s) *aneu*
- Hearing aid *hearaid*
- Embolization coils *emcoil*
- Internal electrodes or wires *wires*
- Any type of prosthesis (eye, penile, etc.) *prost*
- Heart valve prosthesis *heart*
- Metallic stent, filter, or coil *metst*
- Artificial or or prosthetic limb *proslim*
- Shunt (spinal or intraventricular) *shunt*
- Vascular access port and/or catheter *vascath*
- Radiation seeds or implants *radseim*
- Swan-Ganz or thermodilution catheter *swan*
- Medication patch (Nicotine, Nitroglycerine) *patch*



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Any metallic fragment or foreign body *metfrag*

Wire mesh implant *wimeim*

Surgical staples, clips or metallic sutures *surstcl*

Joint replacement (hip, knee, etc.) *jorep*

Bone/joint pin, screw, nail, wire, plate, etc. *bojpin*

IUD, diaphragm or pessary *iud*

Dentures or partial plates *denppl*

Tattoo or permanent makeup *tattoo*

Body piercing jewelry *bopierc*

Other implant *otimp*
Please specify: _____ *impsp*

Breathing problem *breatpr*

Other *other*
Please specify: _____ *othersp*

14. Participant Status: *finenro* (Check only one)

1 Ineligible - **Stop**

2 Failed to Enroll - **Stop**

3 Eligible but Modified – **Continue, no MRI**

4 Eligible and Enrolled **Continue**

CRISP Member completing this form _____
cdidnum

Date Form Completed ___/___/___
cddate

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

Primary Entered by: _____ Date: ___/___/___
deidnum *dedate*

Secondary Entered by: _____ Date ___/___/___