



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 Report _____ / _____ / _____
drm drd dry

visit:

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

MODIFIED PARTICIPATION FORM

Form # 28

This form is to be completed by designated personnel for any participant who changes a level of participation in the study by choice or necessity. Check all reasons that apply and describe events in the comment section. This form should not be entered when an endpoint is reached; complete Form 35. Note: Source documentation of the level of continued participation (per institutional guidelines) must be maintained in the participant's chart.

<p>1. Date of Modified Participation: _____ / _____ / _____ <small>month <i>dmpm</i> day <i>dmpd</i> year <i>dmpy</i></small></p>	<p>1 <input type="checkbox"/> Initial modification <small><i>modstat</i></small> 2 <input type="checkbox"/> Re-modification # _____ <small><i>modnum</i></small></p>
<p>2. Status Changed to:</p>	<p>1 <input type="checkbox"/> Full participation (<i>skip to comment</i>) <small><i>partis</i></small> 2 <input type="checkbox"/> <Full participation (<i>Continue</i>)</p>
<p>3. Reason(s) for Modified Participation: (ANSWER ALL ITEMS IN #3. CHECK "YES" or "NO" FOR ALL REASONS.)</p>	
<p>a) Participant has withdrawn consent, not otherwise specified <small><i>wdrcnt</i></small></p> <p>b) Participant is unable or unwilling to travel to a HALT PKD Clinic Center <small><i>wdrtrl</i></small></p> <p>c) Participant has withdrawn at the request of the treating physician (PCP/nephrologists) <small><i>wdrphc</i></small></p> <p>d) Participant is unable or unwilling to take study medications <small><i>wdrmed</i></small></p> <p>e) Participant finds the length of follow-up to be burdensome <small><i>wdrlgth</i></small></p> <p>f) Participant finds frequency of full follow-up visit burdensome <small><i>wdrfrq</i></small></p> <p>g) Participant's work status has changed, making full participation burdensome <small><i>wdrwrk</i></small></p> <p>h) Participant has an illness or has been hospitalized <small><i>wdrill</i></small></p> <p>i) Participant's family member has an illness or has been hospitalized <small><i>wdrfml</i></small></p> <p>j) Investigator has modified participation for other reasons: (describe in #5 below) <small><i>wdrpim</i></small></p> <p>k) Due to adverse event (specify) <small><i>wdrae/saeevent</i></small> _____</p>	<p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p> <p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p> <p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p> <p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p> <p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p> <p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p> <p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p> <p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p> <p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p> <p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p> <p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p> <p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p>
<p>Event Code: <small><i>ncateg</i></small> _____ Event Term: <small><i>nspecc</i></small> _____ Severity Grade: <small><i>ngrade</i></small> _____</p>	
<p>l) Pre-baseline Dropout (did not complete baseline visit and did not begin ACE+ARB) <small><i>wdrpbdo</i></small></p> <p>m) Other (specify): <small><i>wdrorsn / wdrtrsn</i></small> _____</p>	<p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p> <p>1 <input type="checkbox"/> Yes 0 <input type="checkbox"/> No</p>
<p>4. <u>LAST</u> study medication was stopped on _____ / _____ / _____ <small><i>dtcdm / dtcdmdd / dtcdmddy</i></small></p> <p><input type="checkbox"/> N/A <small><i>dtcdmdna</i></small></p>	



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MODIFIED PARTICIPATION FORM

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The following options are available to *participants modifying study participation*: Choose one

1. PCC visits every 6 or 12 months, (including routine lab work and office BP measurement).

Note, if participant agrees to annual PCC visits, 6-month local lab work* is optional.

2. Follow-up with PCP/Nephrologist every 6 or 12 months, including local lab work* and office BP.

Note: A final PCC visit at the end of the study is optional.

3. Participant only allows PCC to obtain records from PCP/☐ephrologists for local serum creatinine and BP.

4. Refusal of all follow-up.

*Local lab work = all routine tests at a local lab, serum creatinine tested centrally (no urine collected).

5. Indicate which of the following study procedures the participant *chooses* to complete:

Frequency of Follow-up Activities

a. Follow-up at the PCC: *fpcc* 0 ☐ Every 6 months OR 1 ☐ Every 12 months ☐ N/A *nafpcc*

1) **If 12-month visits only**, does the participant agree to complete 6-month *loclab* local lab work? (routine tests locally, serum creatinine to be analyzed centrally) 1 ☐ Yes 2 ☐ No 3 ☐ N/A

2) Does the participant agree to all urine collections (including 24hr) and all specimen banking? *colbank* 1 ☐ Yes 2 ☐ No 3 ☐ N/A

b. Follow-up with the PCP and/or Nephrologist: ☐ N/A *nafpcc*

1) Office BP and Blood Work (sCr sent to central lab as arranged by PCC; other labs done locally) *fpcc*

0 ☐ Every 6 months OR 1 ☐ Every 12 months

2) Does the participant agree to a single PCC visit at the end of the study? *fnlpc* 1 ☐ Yes 0 ☐ No

c. Records Only: *folrec* 1 ☐ Yes OR 0 ☐ N/A

Refuses 1 and 2 above, but agrees to be contacted and/or let PCC obtain records from PCP and/or nephrologists to report study endpoints (Local Serum Creatinine and BP Measurements)

d. Refuses all follow-up: *folref* 1 ☐ Yes OR 0 ☐ N/A

Do not contact participant or PCP/nephrologists.

6. Study A participant agree to MRI follow up:

a. At 24 months *mr2yrs* 1 ☐ Yes 0 ☐ No 3 ☐ N/A (Study B or already passed)

b. At 48 months *mr4yrs* 1 ☐ Yes 0 ☐ No 3 ☐ N/A (Study B or already passed)

c. At 60 months *mr5yrs* 1 ☐ Yes 0 ☐ No 3 ☐ N/A (Study B or already passed)

Comment *mpcmt* _____

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

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: ____/____/____