



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 Action: ____/____/____
dacm dacd dacy

visit

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

____ Form not completed *misfrm*
____ Action Occurred During Washout (Before B2)
____ Action Occurred Between Visits (After B2)

STUDY MEDICATION FORM

Form # 63

This form is to be completed at each study visit or date of action, and entered within 3 business days. Date of Action is the date on which participant is given dosing instructions. If action occurs between visits, indicate above in lieu of visit code. At every visit, confirm existing step/dose, compliance, and all symptoms (reported on Symptoms Checklist Form 5) *before* assigning the next dose. Note: Home BP Form 12 must be entered before dispensing study medications at visit F5 and after.

WASHOUT DRUGS:

1 **Not on or needing washout drugs, or washout period is not required** (go to next section) *washdone*

1 **Participant will have washout *period*, but no washout *drugs*** *washnodrg*

Anticipated Start Date: ____/____/____ (go to next section) *washndm washndd washndyt*

1. **EXISTING DRUG/DOSE:** *washonmed*

1 **Currently taking** (go to #1A)

2 **Not taking** (go to #2)

A. Confirm the participant's existing drug/dose:

Participant Confirmed
wdrgcacnf

<i>Wdrgcaname</i> Drug:	<i>wdrgcamg</i> mg/tab:_____	<i>wdrgcantab</i> # tabs:_____	<input type="checkbox"/> QD <input type="checkbox"/> BID	<i>wdrgcam wdrgcad wdrgcay</i> started ____/____/____	1 <input type="checkbox"/>
<i>Wdrgcbname</i> Drug:	<i>wdrgcbmg</i> mg/tab:_____	<i>wdrgcbntab</i> # tabs:_____	<input type="checkbox"/> QD <input type="checkbox"/> BID	<i>wdrgcbm wdrgcgt wdrgcby</i> started ____/____/____	1 <input type="checkbox"/>

B. Have there been any significant drug-compliance problems since the last contact? *washmedprb*

1 Yes 0 No 2 N/A (If yes, describe in comment section below, #8)

2. **NEXT PERIOD:**

A. Is a Washout drug being *initiated*? *washmedinit* 1 Yes 0 No

B. Is a Washout dose being *modified*? *washmedmod* 1 Yes 0 No **Note: If 2A or 2B is marked yes, indicate reason(s) below.**

1 Yes 0 No **Hypertension per protocol (during washout):** *washmedra*

1 Yes 0 No **Hypotension per protocol (during washout):** *washmedrb*

1 Yes 0 No **Intolerable side effect(s)** _____ *washmedrc/washmedrse*

1 Yes 0 No **Other** _____ *washmedrd/washmedrso*

C. Drug/Dose: <i>wdrgnaname</i>	<i>wdrgnamg</i> mg/tab:_____	<i>wdrgnantab</i> # tabs:_____	<input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> D/C	<i>wdrgnam wdrgnad wdrgnay</i> begin ____/____/____
Drug/Dose: <i>wdrgnbnname</i>	<i>wdrgnbnmg</i> mg/tab:_____	<i>wdrgnbnntab</i> # tabs:_____	<input type="checkbox"/> QD <input type="checkbox"/> BID <input type="checkbox"/> D/C	<i>wdrgnbnm wdrgnbnbd wdrgnbnby</i> begin ____/____/____



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Form # 63

ACE/ARB THERAPY: *acearbdone*

0 On or needing ACE±ARB (go to #3) 1 Not on or needing ACE±ARB (go to next section)

3. EXISTING DRUG/DOSE: *acearbonmed* 1 On study meds (go to #3A) 2 Not on study meds (go to #4)

A. Confirm the participant's existing step/dose:

Participant Confirmed

<i>aadrncaname</i> Drug:	<i>aadrncamg</i> mg/tab:_____	<i>aadrncantab</i> # tabs:_____	<input type="checkbox"/> QD <input type="checkbox"/> BID	<i>aadrncam aadrncad aadrncay</i> started ____/____/____	<i>aadrncacnf</i> 1 <input type="checkbox"/>
	<i>aadrncamg2</i> mg/tab:_____	<i>aadrncantab2</i> # tabs:_____			
<i>aadrncbname</i> Drug:	<i>aadrncbmg</i> mg/tab:_____	<i>aadrncbntab</i> # tabs:_____	<input type="checkbox"/> QD <input type="checkbox"/> BID	<i>aadrncbm aadrncbd aadrncby</i> started ____/____/____	<i>aadrncbcnf</i> 1 <input type="checkbox"/>
	<i>aadrncbmg2</i> mg/tab:_____	<i>aadrncbntab2</i> # tabs:_____			

B. Have there been any significant drug-compliance problems since the last contact? *acearbmedprb* 1 Yes 0 No 2 N/A
 (If yes, describe in comment section below, #8)

4. NEXT PERIOD:

A. Is ACE±ARB being initiated? *acearbmedinit* 1 Yes (If yes, check "no" in B and indicate dose in C below) 0 No

B. Is ACE±ARB dose being modified? *acearbmedmod* 1 Yes (If yes, check reason and indicate dose in C below) 0 No

- 1 Yes 0 No **Hypertension per protocol:** *acearbmedra*
- 1 Yes 0 No **Hypotension per protocol** *acearbmedrb*
- 1 Yes 0 No **Hyperkalemia (potassium 5.6 mEq/l or greater):** _____ *acearbmedrc/acearbmedrsk*
- 1 Yes 0 No **Intolerable side effect(s)** _____ *acearbmedrd/acearbmedrse*
- 1 Yes 0 No **Other** _____ *acearbmedre/acearbmedrso*

C. Next Step/Dose:

<i>aadrnganame</i> Drug:	<i>aadrngamg</i> mg/tab:_____	<i>aadrngantab</i> # tabs:_____	<input type="checkbox"/> QD <input type="checkbox"/> BID OR <input type="checkbox"/> D/C	<i>aadrngam aadrngad aadrngay</i> begin ____/____/____	
	<i>aadrngamg2</i> mg/tab:_____	<i>aadrngantab2</i> # tabs:_____			
<i>aadrngbname</i> Drug:	<i>aadrngbmg</i> mg/tab:_____	<i>aadrngbntab</i> # tabs:_____	<input type="checkbox"/> QD <input type="checkbox"/> BID OR <input type="checkbox"/> D/C	<i>aadrngbm aadrngbd aadrngby</i> begin ____/____/____	
	<i>aadrngbmg2</i> mg/tab:_____	<i>aadrngbntab2</i> # tabs:_____			



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STUDY MEDICATION FORM

Form # 63

OPEN-LABEL DRUGS: openlabdone

0 On or needing open-label drugs (go to #5) 1 Not on or needing open-label drugs (go to next section)
5. EXISTING DRUG/DOSE: openlabonmed 1 Currently taking (go to #5A) 2 Not taking (go to #6)
A. Confirm the participant's existing step/dose: Participant Confirmed
Table with 6 columns: Drug name, mg/tab, # tabs, Frequency (QD/BID), Start date, Confirmed (Yes/No)
B. Have there been any significant drug-compliance problems since the last contact? openlabmedprb 1 Yes 0 No 2 N/A (If yes, describe in comment section below, #8)
6. NEXT PERIOD:
A. Is an Open-Label drug being initiated? openlabmedinit 1 Yes 0 No
B. Is an Open-Label drug being modified? openlabmedmod 1 Yes 0 No Note: If 6A or 6B is marked yes, indicate reason(s) below.
List of reasons for modification: Hypertension per protocol, Hypotension per protocol, Hyperkalemia (potassium 5.6 mEq/l or greater), Intolerable side effect(s), Other



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Open-Label Drugs Continued:

C. Next Step/Dose:

<i>oldrgnname</i> i. _____	<i>oldrgnamg</i> mg/tab: _____	<i>oldrgnantab</i> # tabs: _____	<input type="checkbox"/> QD <input type="checkbox"/> BID OR <input type="checkbox"/> D/C	<i>oldrgnam oldrgnad oldrgnay</i> begin ____/____/____
<i>oldrgnbname</i> ii. _____	<i>oldrgnbmg</i> mg/tab: _____	<i>oldrgnbntab</i> # tabs: _____	<input type="checkbox"/> QD <input type="checkbox"/> BID OR <input type="checkbox"/> D/C	<i>oldrgnbm oldrgnbd oldrgnby</i> begin ____/____/____
<i>oldrgncname</i> iii. _____	<i>oldrgncmg</i> mg/tab: _____	<i>oldrgncntab</i> # tabs: _____	<input type="checkbox"/> QD <input type="checkbox"/> BID OR <input type="checkbox"/> D/C	<i>oldrgncm oldrgncd oldrgncy</i> begin ____/____/____
<i>oldrgndname</i> iv. _____	<i>oldrgndmg</i> mg/tab: _____	<i>oldrgndntab</i> # tabs: _____	<input type="checkbox"/> QD <input type="checkbox"/> BID OR <input type="checkbox"/> D/C	<i>oldrgndm oldrgndd oldrgndy</i> begin ____/____/____
<i>oldrgnname</i> v. _____	<i>oldrgnemg</i> mg/tab: _____	<i>oldrgnentab</i> # tabs: _____	<input type="checkbox"/> QD <input type="checkbox"/> BID OR <input type="checkbox"/> D/C	<i>oldrgnem oldrgned oldrgney</i> begin ____/____/____

ALL STUDY DRUGS: (washout, ACE + ARB, and open-label drugs):

7. **How were drugs dispensed?** *dispense* 1 Picked up at PCC 2 Shipped 3 Called in to Local Pharmacy 4 Other 5 N/A

8. **Comments:** *comments* _____

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

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

Secondary Entered by: _____ Date ____/____/____