



MODIFIED PARTICIPATION CHECKLIST FOR FORM 96

Form # 96B

Study personnel may complete this checklist and participant may sign it as source documentation, if permitted by the institution's IRB. Checklist is optional and may not be necessary in cases of pregnancy (reported via Form 11, refer to protocol section 12.6.1). Modified Participation Form 28 must be entered within two weeks.

Participant ID: _____

1. Date of Modified Participation: ____/____/____

2. Reason(s) for Modified Participation: (Check all that apply)

- a) Participant has withdrawn consent, not otherwise specified Yes No
- b) Participant is unable or unwilling to travel to a HALT PKD Clinic Center Yes No
- c) Participant has withdrawn at the request of the treating physician (PCP/nephrologists) Yes No
- d) Participant is unable or unwilling to take study medications Yes No
- e) Participant finds the length of follow-up to be burdensome Yes No
- f) Participant finds frequency of full follow-up visit burdensome Yes No
- g) Participant's work status has changed, making full participation burdensome Yes No
- h) Participant has an illness or has been hospitalized Yes No
- i) Participant's family member has an illness or has been hospitalized Yes No
- j) Investigator has modified participation for other reasons: (describe below) Yes No
- k) Other (specify): _____ Yes No

3. Will the participant continue taking study medication? Yes No (If no, skip to #4)

Participants who continue taking study medications MUST agree to complete ALL of the following:

a. All study visits (includes PCC visits every six and twelve months, telephone visits every three months).

Note: PCC visits include blood pressure measurement and all required lab work (see options below).

b. All required lab work (includes all routine safety labs required per protocol or PI, see options below).

c. Home blood pressure monitoring per protocol.

Indicate which of the following study procedures this participant chooses to complete:

- a. MRI/MRA at 24 months Yes No N/A (Study B or already passed)
- b. MRI/MRA at 48 months Yes No N/A (Study B or already passed)
- c. All Urine Collections Yes No
- d. All Specimen Banking Yes* No* *Note: Only mark d yes if c above is also yes.
- e. Pain/QOL Questionnaires Yes No



MODIFIED PARTICIPATION CHECKLIST FOR FORM 96

Form # 96B

4. For participants *discontinuing* study medication

The following options are available to *participants who discontinue study medication*:

- a. 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.
 - b. 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.
 - c. Participant only allows PCC to obtain records from PCP/nephrologist for local serum creatinine and BP.
 - d. Refusal of all follow-up, but may do MRI/MRA (continue to follow participant for survival if possible)
- *Local lab work = all routine tests at a local lab, serum creatinine tested centrally (no urine collected).

NOT Required: Home BP monitoring, 3-month phone calls, Pain/QOL Questionnaires, and Safety Labs.

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

A. Frequency of Follow-up Activities (Select ONE of the four options in section A below):

- 1) **Follow-up at the PCC** (choose frequency below): N/A
 Every 6 months OR Every 12 months
 - a. If 12-month visits only, does the participant agree to complete 6-month local lab work?
(routine tests locally, serum creatinine to be analyzed centrally) Yes No N/A
 - b. Does the participant agree to all urine collections (including 24hr) and all specimen banking?
 Yes No N/A
- 2) **Follow-up with the PCP and/or Nephrologist** (choose frequency below): N/A
 Office BP and Blood Work (sCr sent to central lab as arranged by PCC; other labs done locally)
 Every 6 months OR Every 12 months
 - a. Does the participant agree to a single PCC visit at the end of the study? Yes No
- 3) **Records Only:** OR N/A
 Refuses A1 and A2 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)
- 4) **Refuses all follow-up:** OR N/A
 Do not contact participant or PCP/nephrologists. Continue to follow for survival if possible.

B. Frequency of MRI/MRA, regardless of selection(s) made in section A above.

- a. At 24 months Yes No N/A (Study B or already passed)
- b. At 48 months Yes No N/A (Study B or already passed)

Comments: _____

Participant's Signature: _____ Date: ____/____/____

Coordinator's Signature: _____ Date: ____/____/____

Investigator's Signature: _____ Date: ____/____/____