

Patient number

Date of visit
month day year

NIH - BPH TRIAL

INTERIM VISIT CHECKLIST

This form should be completed at any visits that are not scheduled follow-up visits.

Part I / IDENTIFICATION

A. Patient Identification

1. Patient number (PATID)
clinic patient
2. Patient's initials (INITS)
first last
3. Patient's date of birth (DOB)
month day year

B. Visit Information

1. Date of visit (IVSTDT)
month day year
2. Week of visit (IVIWK)

C. Reason for Interim Visit (Check all that apply)

Complete Parts II and III of this form for reasons 1-9 listed below. Also complete any sections or forms noted below.

- | | | |
|---|--------------------------|--|
| 1. AUA symptom score event (IRAUA4) | <input type="checkbox"/> | Complete AUA Symptom Score Event Report (Form E01) |
| 2. Creatinine rise event (IRCR) | <input type="checkbox"/> | Complete Creatinine Rise Event Report (Form E02) |
| 3. Acute urinary retention event (IRUR) | <input type="checkbox"/> | Complete Urinary Event Report (Form E03) |
| 4. Recurrent urinary tract infection event (IRUTI) | <input type="checkbox"/> | |
| 5. Incontinence event (IRINC) | <input type="checkbox"/> | |
| 6. Adverse event (IRAE) | <input type="checkbox"/> | Complete Adverse Event Report (Form E05) |
| 7. Blood pressure management (IRBPM) | <input type="checkbox"/> | Complete Parts II and III of this form ONLY |
| 8. Dispense medication (IRMED) | <input type="checkbox"/> | |
| 9. Intercurrent illness event (IRII) | <input type="checkbox"/> | Complete Part IV of this form |
| 10. TRUS and biopsy (IRBX) | <input type="checkbox"/> | Complete ONLY Part III of this form |
| 11. Blood draw (other than creatinine rise) (IRBLD) | <input type="checkbox"/> | Complete ONLY Part III of this form |

Patient number

Date of visit / /
month day year

Part II / VITAL SIGNS

D. Blood Pressure

1. Supine Blood Pressure (After lying 5 minutes)

a. Blood Pressure **(IBPLS)/(IBPLD)** / mmHg

b. Heart Rate **(IBLHR)** bpm

2. Standing Blood Pressure (Immediately)

a. Blood Pressure Reading 1 **(IBPSS1)/(IBPSD1)** / mmHg

b. Heart Rate 1 **(IBPSHR1)** bpm

Wait 2 minutes

c. Blood Pressure Reading 2 **(IBPSS2)/(IBPSD2)** / mmHg

d. Heart Rate 2 **(IBPSHR2)** bpm

E. Orthostatic Hypotension

1. Did the patient have orthostatic hypotension? **(IORTHYP)** YES NO
¹ ²

Orthostatic hypotension is defined as a decrease of more than 20mmHg in supine to standing systolic blood pressure or a decrease of more than 10mmHg in supine to standing diastolic blood pressure (in either standing blood pressure reading) or the development of significant postural hypotension.

Part III / MEDICATION DISPENSING AND COMPLIANCE

F. Number of days since last visit **(IDDDAYS)**

G. Doxazosin Compliance

If doxazosin was dispensed at the last visit, returned and/or dispensed today, CONTINUE. If not, SKIP to Section H.

1. Dose of doxazosin **(IDDDOSE)** 1 mg 2 mg 4 mg 8 mg
¹ ² ³ ⁴

2. Number of doxazosin tablets dispensed at the last visit **(IDDDISL)**

3. Number of doxazosin tablets returned today **(IDDDRET)**

Patient number

Date of visit
month day year

4. Compliance **(IDDCOMP)**
 $\frac{\text{tabs dispensed (\#2)} - \text{tabs returned (\#3)}}{\text{days since last visit (question F)}} \times 100$ %

NOTE: Counsel patient if less than 80% compliant with doxazosin.

5. Number of doxazosin tablets dispensed today **(IDDDIST)**

H. Finasteride Compliance

If finasteride was dispensed at the last visit, returned and/or dispensed today, CONTINUE. If not, SKIP to Section I.

1. Number of finasteride tablets dispensed at the last visit **(IDFDISL)**

2. Number of finasteride tablets returned today **(IDFRET)**

3. Compliance **(IDFCOMP)**
 $\frac{\text{tabs dispensed (\#1)} - \text{tabs returned (\#2)}}{\text{days since last visit (question F)}} \times 100$ %

NOTE: Counsel patient if less than 80% compliant with finasteride.

4. Number of finasteride tablets dispensed today **(IDFDIST)**

I. Concomitant Medications

	YES	NO
1. Is the patient currently taking coded doxazosin? (IDDCODE)	<input type="text"/> 1	<input type="text"/> 2
2. Is the patient currently taking coded finasteride? (IDFCODE)	<input type="text"/> 1	<input type="text"/> 2
3. Has the patient taken viagra (sildenafil citrate) since the last visit? (ICMVIAG)	<input type="text"/> 1	<input type="text"/> 2

Patient number

Date of visit
month day year

Part IV / INTERCURRENT ILLNESS EVENT

J. Intercurrent Illness Information

1. Specify intercurrent illness: **(IIISPEC)**

2. Is this a serious event? **(IIISE)** YES NO
 ¹ ²

3. Specify action taken: **(IIIACT)**

4. Intercurrent illness event declared? **(IIIDEC)** ¹ ²

Consultation with the Clinical Review Committee is required to declare an intercurrent illness stop point (i.e. discontinuation of coded medications).

If YES:

a. Date of confirmation by Clinical Review Committee **(IIICONF)**

month day year

Signature of P.I.

____ Date _____

Initials of person completing form **(FORMIN)**
first last Form entered in computer?