FORM NUMBER = (FORM)
FORM VERSION = (VERS)

NIH - BPH TRIAL

POST END-OF-STUDY VISIT INVENTORY

This form should be completed at any visit that takes place after the end-of-study visit. Separation visits will be scheduled for all patients who are accessible whether or not they have continued on coded medications after the end-of-study visit.

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 **(EVSTDT)** [ ][ ] / [ ][ ] / [ ][ ] month day year
2. Week of visit **(EVIWK)** [ ][ ][ ]
3. Type of visit (Check all that apply.)
   - [1] Follow-up Visit **(EVITYP)**
   - [1] Separation Visit **(EVITYPS)**

If this is a Follow-up Visit with or without Separation Visit, CONTINUE.
If this is a Separation Visit ONLY, SKIP to section E.

Part II / VITAL SIGNS

C. Blood Pressure Readings

1. Supine Blood Pressure (After lying 5 minutes)
   a. Blood Pressure Reading **(EBPLS)/(EBPLD)** [ ][ ][ ] / [ ][ ][ ] mmHg
   b. Heart Rate **(EBPLHR)** [ ][ ][ ] bpm
2. Standing Blood Pressure (Immediately)
   a. Blood Pressure Reading 1 **(EBPSS1)/(EBPSD1)** [ ][ ][ ] / [ ][ ][ ] mmHg
   b. Heart Rate 1 **(EBPSHR1)** [ ][ ][ ] bpm

Wait 2 minutes

   c. Blood Pressure Reading 2 **(EBPSS2)/(EBPSD2)** [ ][ ][ ] / [ ][ ][ ] mmHg
   d. Heart Rate 2 **(EBPSHR2)** [ ][ ][ ] bpm

Patient number [ ][ ][ ][ ][ ] Date of visit [ ][ ] month [ ][ ] day [ ][ ] year

D. Orthostatic Hypotension

1. Did the patient have orthostatic hypotension? **(EORTHYP)** YES [1] NO [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 AND ADVERSE EVENTS

E. General Medication Dispensing Information

1. Were coded medications dispensed post End-of-Study? **(EGMCODM)** YES [1] NO [2]

   If YES, CONTINUE.
   If NO, SKIP to section J.

2. Is the patient currently taking coded doxazosin? **(EGMCODD)** [1] [2]

3. Is the patient currently taking coded finasteride? **(EGMCODF)** [1] [2]

4. Number of days since last visit **(EGMDAYS)** [ ][ ][ ]

F. Doxazosin Compliance

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

1. Dose of doxazosin **(ECDDOSE)** 1 mg [1] 2 mg [2] 4 mg [3] 8 mg [4]

2. Number of doxazosin tablets dispensed at the last visit **(ECDDISL)** [ ][ ][ ]

3. Number of doxazosin tablets returned today **(ECDRET)** [ ][ ][ ]

4. Compliance **(ECDCOMP)**

$$\frac{\text{tabs dispensed (\#2) - tabs returned (\#3)}}{\text{days since last visit (question E)}} \times 100$$ [ ][ ][ ][ ][ ] %

5. Number of doxazosin tablets dispensed today **(ECDDIST)** [ ][ ][ ]

G. Finasteride Compliance

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

1. Number of finasteride tablets dispensed at the last visit **(ECFDISL)** [ ][ ][ ]

2. Number of finasteride tablets returned today **(ECFRET)** [ ][ ][ ]

3. Compliance **(ECFCOMP)**

$$\frac{\text{tabs dispensed (\#1) - tabs returned (\#2)}}{\text{days since last visit (question E)}} \times 100$$ [ ][ ][ ][ ][ ] %

4. Number of finasteride tablets dispensed today **(ECFDIST)** [ ][ ][ ]

Patient number ☐☐☐☐☐ Date of visit ☐☐ ☐☐ ☐☐ (month day year)

H. Concomitant Medications

1. Is the patient currently taking any medication other than the coded medications? **(ECMCON)** YES ☐1 NO ☐2

If YES, list below:

a.	**(ECMCONA)**	**(ECMCODA)**	f.	**(ECMCONF)**	**(ECMCODF)**
b.	**(ECMCONB)**	**(ECMCODB)**	g.	**(ECMCONG)**	**(ECMCODG)**
c.	**(ECMCONC)**	**(ECMCODC)**	h.	**(ECMCONH)**	**(ECMCODH)**
d.	**(ECMCOND)**	**(ECMCODD)**	i.	**(ECMCONI)**	**(ECMCODI)**
e.	**(ECMCONE)**	**(ECMCODE)**	j.	**(ECMCONJ)**	**(ECMCODJ)**

2. Has the patient taken viagra (sildenafil citrate) since the last visit? **(ECMVIAG)** ☐1 ☐2

I. Adverse Events

1. Since the last scheduled follow-up visit, has the patient had any adverse experiences, drug reactions, side effects, abnormal laboratory values, hospitalizations, other complications or pre-existing conditions that worsened? **(EAELVST)** YES ☐1 NO ☐2

If YES, an Adverse Event Report (Form E05) MUST be completed.

If this is a separation visit, CONTINUE.

J. Treatment Group Disclosure

For all patients the treatment group assignment should be obtained from the MTOPS staff website or study computer.

1. Was the patient informed of his treatment group assignment? **(ETGD)** YES ☐1 NO ☐2

If YES, CONTINUE.

a. Treatment group assignment disclosed to patient **(ETGDAPT)**

☐1 Double placebo
☐2 Doxazosin & placebo
☐3 Finasteride & placebo
☐4 Doxazosin & finasteride

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

Signature of P.I. _____ Date _____