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

NIH - BPH TRIAL

STANDARD FOLLOW-UP VISIT INVENTORY

This form should be completed at all quarterly standard follow-up visits. At these visits, also complete AUA Symptom Questionnaire (Form Q01).

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 **(FVSTDT)** [ ][ ] / [ ][ ] / [ ][ ] (month / day / year)
2. Week of visit **(FVIWK)** [ ][ ][ ]

Part II / VITAL SIGNS

C. Blood Pressure Readings

1. Supine Blood Pressure (After lying 5 minutes)
   a. Blood Pressure Reading **(FBPLS)/(FBPLD)** [ ][ ][ ] / [ ][ ][ ] mmHg
   b. Heart Rate **(FBPLHR)** [ ][ ][ ] bpm
2. Standing Blood Pressure (Immediately)
   a. Blood Pressure Reading 1 **(FBPSS1)/(FBPSD1)** [ ][ ][ ] / [ ][ ][ ] mmHg
   b. Heart Rate 1 **(FBPSHR1)** [ ][ ][ ] bpm

Wait 2 minutes

   c. Blood Pressure Reading 2 **(FBPSS2)/(FBPSD2)** [ ][ ][ ] / [ ][ ][ ] mmHg
   d. Heart Rate 2 **(FBPSHR2)** [ ][ ][ ] bpm

D. Orthostatic Hypotension

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

E. Number of days since last visit **(FCDAYS)** ☐☐☐

F. Doxazosin Compliance

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

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

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

3. Number of doxazosin tablets returned today **(FCDRET)** ☐☐☐

4. Compliance **(FCDCOMP)**

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

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

5. Number of doxazosin tablets dispensed today **(FCDDIST)** ☐☐☐

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 **(FCFDISL)** ☐☐☐

2. Number of finasteride tablets returned today **(FCFRET)** ☐☐☐

3. Compliance **(FCFCOMP)**

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

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

4. Number of finasteride tablets dispensed today **(FCFDIST)** ☐☐☐

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

H. Concomitant Medications

	YES	NO
1. Is the patient currently taking coded doxazosin? **(FCDCODE)**	1	2
2. Is the patient currently taking coded finasteride? **(FCFCODE)**	1	2
3. Is the patient currently taking any medication other than the coded medications? **(FCMCON)**	1	2

If YES, list below:

a.	**(FCMCONA) (FCMCODA)** ☐☐	f.	**(FCMCONF) (FCMCODF)** ☐☐
b.	**(FCMCONB) (FCMCODB)** ☐☐	g.	**(FCMCONG) (FCMCODG)** ☐☐
c.	**(FCMCONC) (FCMCODC)** ☐☐	h.	**(FCMCONH) (FCMCODH)** ☐☐
d.	**(FCMCOND) (FCMCODD)** ☐☐	i.	**(FCMCONI) (FCMCODI)** ☐☐
e.	**(FCMCONE) (FCMCODE)** ☐☐	j.	**(FCMCONJ) (FCMCODJ)** ☐☐

I. Adverse Events

	YES	NO
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? **(FAELVST)**	1	2

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

Part IV / UROFLOW MEASUREMENTS

J. Uroflow Measurements

1. Voiding Time **(FUMVT)** ☐☐☐ sec
2. Flow Time **(FUMFT)** ☐☐☐ sec
3. Time to Maximum Flow **(FUMTMF)** ☐☐☐ sec
4. Maximum Flow Rate **(FUMMXFR)** ☐☐.☐ ml/sec
5. Mean Flow Rate **(FUMMNFR)** ☐☐.☐ ml/sec
6. Voided Volume **(FUMVV)** ☐☐☐☐ ml
7. Post Void Residual **(FUMPVR)** ☐☐☐☐ ml

Mark the date and patient number (either screening or study number) on each printout. Make two copies of the uroflow printout. One copy is filed with the source documents; the other along with the original printout is placed in the envelope in the patient's binder.

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

Signature of P.I. _____ Date _____