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

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

NIH - BPH CLINICAL TRIAL: PILOT STUDY

STANDARD FOLLOW-UP VISIT INVENTORY

This form should be completed at all standard follow-up visits (Weeks 1, 2, 3, 4, Months 3, 6, 9, and 12). At this visit, 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 / COMPLIANCE AND ADVERSE EVENTS

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

D. Doxazosin Compliance

1. Is the patient taking coded medication? **(FCDCODE)** YES [1] NO [2]

   If NO, SKIP to Section E.

2. Dose of doxazosin **(FCDDOSE)** 1 mg [1] 2 mg [2] 4 mg [3] 8 mg [4]
3. Number of doxazosin tablets dispensed at the last visit **(FCDDISL)** ☐☐☐
4. Number of doxazosin tablets returned today **(FCDRET)** ☐☐☐
5. Compliance **(FCDCOMP)**

$$\frac{\text{tabs dispensed (\#3) - tabs returned (\#4)}}{\text{days since last visit (question C)}} \times 100$$ ☐☐☐ %

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

Patient number | | | | | |

Date of visit | | | | | | | | |
month day year

6. Number of doxazosin tablets dispensed today **(FCDDIST)** | | |

DOXAZOSIN LABELS

Remove labels from coded medication before dispensing.

Affix labels here.

E. Finasteride Compliance

	YES	NO
1. Is the patient taking the coded medication? **(FCFCODE)**	1	2

If NO, SKIP to Section F.

2. Number of finasteride tablets dispensed at the last visit **(FCFDISL)** | | |

3. Number of finasteride tablets returned today **(FCFRET)** | | |

4. Compliance **(FCFCOMP)**

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

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

5. Number of finasteride tablets dispensed today **(FCFDIST)** | | |

FINASTERIDE LABEL

Remove label from coded medication before dispensing.
Affix label here.

F. Concomitant Medications

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

If YES, list below:

a.	**(FCMCONA)**	f.	**(FCMCONF)**
b.	**(FCMCONB)**	g.	**(FCMCONG)**
c.	**(FCMCONC)**	h.	**(FCMCONH)**
d.	**(FCMCOND)**	i.	**(FCMCONI)**
e.	**(FCMCONE)**	j.	**(FCMCONJ)**

G. 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 Form (Form E04) MUST be completed.

Part III / VITAL SIGNS AND UROFLOW MEASUREMENTS

H. Blood Pressure Readings

1. Supine Blood Pressure (After lying 5 minutes)

a. Heart Rate **(FBPLHR)** | | | | bpm

b. Blood Pressure Reading **(FBPLS)/(FBPLD)** | | | | / | | | | mmHg

2. Standing Blood Pressure (Immediately)

a. Heart Rate 1 **(FBPSHR1)** | | | | bpm

b. Blood Pressure Reading 1 **(FBPSS1)/(FBPSD1)** | | | | / | | | | mmHg

Wait 2 minutes

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

c. Heart Rate 2 **(FBPSHR2)** ☐☐☐ bpm

d. Blood Pressure Reading 2 **(FBPSS2) / (FBPSD2)** ☐☐☐ / ☐☐☐ mmHg

I. Orthostatic Hypotension

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

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

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)

Date form completed **(FORMDT)** ☐☐ / ☐☐ / ☐☐ (month / day / year)

Signature _____