

Patient number

Date of visit / /
month day year

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)

<input type="text"/>				
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clinic patient

2. Patient's initials (INITS)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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first last

3. Patient's date of birth (DOB)

<input type="text"/>	<input type="text"/>	<input type="text"/>
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month day year

B. Visit Information

1. Date of visit (FVSTDT)

<input type="text"/>	<input type="text"/>	<input type="text"/>
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month day year

2. Week of visit (FVIWK)

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Part II / VITAL SIGNS

C. Blood Pressure Readings

1. Supine Blood Pressure (After lying 5 minutes)

a. Blood Pressure Reading (FBPLS)/(FBPLD)

<input type="text"/>	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
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 mmHg

b. Heart Rate (FBPLHR)

<input type="text"/>	<input type="text"/>	<input type="text"/>
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 bpm

2. Standing Blood Pressure (Immediately)

a. Blood Pressure Reading 1 (FBPSS1)/(FBPSD1)

<input type="text"/>	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
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 mmHg

b. Heart Rate 1 (FBPSHR1)

<input type="text"/>	<input type="text"/>	<input type="text"/>
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 bpm

Wait 2 minutes

c. Blood Pressure Reading 2 (FBPSS2)/(FBPSD2)

<input type="text"/>	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
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 mmHg

d. Heart Rate 2 (FBPSHR2)

<input type="text"/>	<input type="text"/>	<input type="text"/>
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 bpm

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D. Orthostatic Hypotension

1. Did the patient have orthostatic hypotension? (**FORTHYP**) 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 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. Dose of doxazosin (**FCDDOSE**) 1 mg 2 mg 4 mg 8 mg
 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**)

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

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**)

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

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

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4. Number of finasteride tablets dispensed today (FCFDIST)

H. Concomitant Medications

- | | | |
|--|----------------------|----------------------|
| | YES | NO |
| 1. Is the patient currently taking coded doxazosin? (FCDCODE) | <input type="text"/> | <input type="text"/> |
| 2. Is the patient currently taking coded finasteride? (FCFCODE) | <input type="text"/> | <input type="text"/> |
| 3. Is the patient currently taking any medication other than the coded medications? (FCMCON) | <input type="text"/> | <input type="text"/> |

If YES, list below:

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

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, discontinued coded medications, other complications or pre-existing conditions that worsened? (FAELVST) | YES | NO |
| | <input type="text"/> | <input type="text"/> |

If YES, an Adverse Event Report (Form E04) MUST be completed.

Part IV / UROFLOW MEASUREMENTS AND PSA SPECIMEN

J. Uroflow Measurements

- | | | |
|----------------------------------|---|--------|
| 1. Voiding Time (FUMVT) | <input type="text"/> <input type="text"/> <input type="text"/> | sec |
| 2. Flow Time (FUMFT) | <input type="text"/> <input type="text"/> <input type="text"/> | sec |
| 3. Time to Maximum Flow (FUMTMF) | <input type="text"/> <input type="text"/> <input type="text"/> | sec |
| 4. Maximum Flow Rate (FUMMXFR) | <input type="text"/> <input type="text"/> . <input type="text"/> | ml/sec |
| 5. Mean Flow Rate (FUMMNFR) | <input type="text"/> <input type="text"/> . <input type="text"/> | ml/sec |
| 6. Voided Volume (FUMVV) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | ml |
| 7. Post Void Residual (FUMPVR) | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | 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.

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K. PSA Serum Specimen

1. Is this a 6-month follow-up visit? **(FPSA6MO)** YES NO
 1 2

If YES, serum should be drawn for PSA.

a. Date sent to the Diagnostic Center **(FPSASDT)**
month day year

Initials of person completing form **(FORMIN)**
first last

Form entered in computer?

Signature of P.I. _____

Date _____