

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)

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clinic patient

2. Patient's initials (INITS)

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first last

3. Patient's date of birth (DOB)

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month day year

B. Visit Information

1. Date of visit (FVSTDT)

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month day year

2. Week of visit (FVIWK)

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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)

			/			
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 mmHg

b. Heart Rate (FBPLHR)

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 bpm

2. Standing Blood Pressure (Immediately)

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

			/			
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 mmHg

b. Heart Rate 1 (FBPSHR1)

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 bpm

Wait 2 minutes

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

			/			
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 mmHg

d. Heart Rate 2 (FBPSHR2)

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 bpm

Patient number

Date of visit / /
month day year

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 (**FCDDAYS**)

F. Doxazosin Compliance

If doxazosin was dispensed at the last visit, returned and/or dispensed today, CONTINUE.

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

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.

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) | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Is the patient currently taking coded finasteride? (FCFCODE) | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Is the patient currently taking any medication other than the coded medications? (FCMCON) | <input type="checkbox"/> | <input type="checkbox"/> |

If YES, list below:

a.	(FCMCONA) (FCMCONA)	<input type="text"/>	f.	(FCMCONF) (FCMCONF)	<input type="text"/>
b.	(FCMCONB) (FCMCONB)	<input type="text"/>	g.	(FCMCONG) (FCMCONG)	<input type="text"/>
c.	(FCMCONC) (FCMCONC)	<input type="text"/>	h.	(FCMCONH) (FCMCONH)	<input type="text"/>
d.	(FCMCOND) (FCMCOND)	<input type="text"/>	i.	(FCMCONI) (FCMCONI)	<input type="text"/>
e.	(FCMCONE) (FCMCONE)	<input type="text"/>	j.	(FCMCONJ) (FCMCONJ)	<input type="text"/>

4. Has the patient taken viagra (sildenafil citrate) since the last visit? (FCMVIAG)

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? (FAELVST) YES NO

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) Form entered in computer?

first last

Signature of P.I. _____ Date _____