NIH - BPH TRIAL

STANDARD FOLLOW-UP VISIT INVENTORY

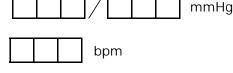
This form should be completed at all quarterly standard follow-up visits. At these visits, also complete AUA Symptom Questionnaire (Form Q01).

Part I / IDENTIFICATION

- A. Patient Identification
 - 1. Patient number (PATID)
 - 2. Patient's initials (INITS)
 - 3. Patient's date of birth (DOB)
- B. Visit Information
- 1. Date of visit (FVSTDT)
- 2. Week of visit (FVIWK)

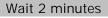
Part II / VITAL SIGNS

- C. Blood Pressure Readings
- 1. Supine Blood Pressure (After lying 5 minutes)
 - a. Blood Pressure Reading (FBPLS)/(FBPLD)
 - b. Heart Rate (FBPLHR)
- 2. Standing Blood Pressure (Immediately)
 - a. Blood Pressure Reading 1 (FBPSS1)/(FBPSD1)
 - b. Heart Rate 1 (FBPSHR1)



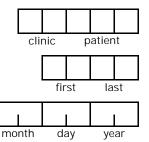
bpm

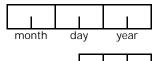
mmHg



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

d. Heart Rate 2 (FBPSHR2)





Patient number Date of visit BPH FORM FOR November, 190 Movember, 190 month day year	99										
D. Orthostatic Hypotension YES NO											
1. Did the patient have orthostatic hypotension? (FORTHYP)											
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.											
1 mg 2 mg 4 mg 8 mg 1. Dose of doxazosin (FCDDOSE) $1 mg 2 mg 4 mg 8 mg$											
2. Number of doxazosin tablets dispensed at the last visit (FCDDISL)											
3. Number of doxazosin tablets returned today (FCDRET)											
4. Compliance (FCDCOMP) <u>tabs dispensed (#2) - tabs returned (#3)</u> days since last visit (question E) X 100											
NOTE: Counsel patient if less than 80% compliant with doxazosin.											
5. Number of doxazosin tablets dispensed today (FCDDIST)											
G. <u>Finasteride_Compliance</u>											
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) tabs dispensed (#1) - tabs returned (#2) days since last visit (question E) X 100											
NOTE: Counsel patient if less than 80% compliant with finasteride.											
4. Number of finasteride tablets dispensed today (FCFDIST)											

Pat	ient	number			Da	ate of visit	nth day	year	-	BPH FORM F01.4 November, 1999 Page 3 of 3	
H. <u>Concomitant Medications</u> YES NO											
1.	1. Is the patient currently taking coded doxazosin? (FCDCODE)										
2. Is the patient currently taking coded finasteride? (FCFCODE)											
 3. Is the patient currently taking any medication other than the coded medications? (FCMCON) If YES, list below: 											
	a.	(FCMCONA)	(FCMCODA)		f.	(FCMCONF)	(FCMC	ODF)			
	b.	(FCMCONB)	(FCMCODB)		g.	(FCMCONG)	(FCMC	ODG)			
	C.	(FCMCONC)	(FCMCODC)		h.	(FCMCONH)	(FCMC	ODH)			
	d.	(FCMCOND)	(FCMCODD)		i.	(FCMCONI)	(FCMC	ODI)			
	e.	(FCMCONE)	(FCMCODE)		j.	(FCMCONJ)	(FCMC	ODJ)			
 4. Has the patient taken viagra (sildenafil citrate) since the last visit? (FCMVIAG) 1 2 1. <u>Adverse Events</u> 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 1 2 											
pre-existing conditions that worsened? (FAELVST)											
If YES, an Adverse Event Report (Form E05) MUST be completed.											
Part I	<u>V /</u>	UROFLOW MEA	SUREMENTS	1							
J. Uroflow Measurements											
1.	Voi	ding Time (FUI	VIVT)					sec			
2.	2. Flow Time (FUMFT) sec										
3.	Tim	ne to Maximum	Flow (FUMTI	MF)				sec			
4.	4. Maximum Flow Rate (FUMMXFR)										
5.	Mea	an Flow Rate (F	FUMMNFR)					ml/se	ec		
6.	Voi	ded Volume (F	UMVV)					ml			
7.	Pos	at Void Residual	(FUMPVR)					ml			
two	сор	ies of the uroflo	w printout. C)ne co	opy is f	hing or study nur iled with the sou envelope in the pa	irce docu	ments;			
Ini	tials (of person completinç	g form (FORMIN)	first	t la:		entered	in com	puter?		
Sig	gnat	ure of P.I.					Dat	e)	