

Screening number

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BPH FORM B02.1

October, 1993

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FORM NUMBER = (FORM)

FORM VERSION = (VERS)

## NIH - BPH CLINICAL TRIAL: PILOT STUDY

### SCREENING VISIT 1 INVENTORY

This form is to be completed during Screening Visit 1. At this visit, also complete the AUA Symptom Questionnaire (Form Q01) and the Sexual Function Questionnaire (Form Q02).

#### Part I / IDENTIFICATION

##### A. Patient Identification

1. Clinic number (CLINIC)

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2. Screening number (SCREEN)

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3. Patient's initials (INITS)

first		last	

4. Patient's date of birth (DOB)

month	day	year

##### B. Visit Information

1. Date of visit (SVSTDT)

month	day	year

##### C. General Information

1. Race (SGIRACE)

- ☐ 1 White, not of Hispanic origin
- ☐ 2 Black, not of Hispanic origin
- ☐ 3 Asian or Pacific Islander
- ☐ 4 Hispanic
- ☐ 5 American Indian or Alaskan Native

2. Marital status (SGIMAR)

- ☐ 1 Single
- ☐ 2 Married
- ☐ 3 Separated
- ☐ 4 Divorced
- ☐ 5 Widowed

## Part II / HISTORY AND PHYSICAL EXAMINATION

 D. Medical History

	YES	NO
1. Congenital disease (SHXCONG)	<input type="checkbox"/>	<input type="checkbox"/>
2. Lung disease (SHXLUNG)	<input type="checkbox"/>	<input type="checkbox"/>
3. Heart disease (SHXHRT)	<input type="checkbox"/>	<input type="checkbox"/>
4. Hypertension (SHXHYP)	<input type="checkbox"/>	<input type="checkbox"/>
5. Renal disease (SHXREN)	<input type="checkbox"/>	<input type="checkbox"/>
6. Rheumatologic/collagen or vascular disease (SHXRCV)	<input type="checkbox"/>	<input type="checkbox"/>
7. Diabetes Mellitus (SHXDM)	<input type="checkbox"/>	<input type="checkbox"/>
8. Endocrinopathy (other than diabetes) (SHXENDO)	<input type="checkbox"/>	<input type="checkbox"/>
9. Liver disease (SHXLIV)	<input type="checkbox"/>	<input type="checkbox"/>
10. Gastro-intestinal tract disease (SHXGI)	<input type="checkbox"/>	<input type="checkbox"/>
11. Skin disease (SHXSKIN)	<input type="checkbox"/>	<input type="checkbox"/>
12. Organic CNS disease (SHXCNS)	<input type="checkbox"/>	<input type="checkbox"/>
13. Neoplastic disease (SHXNEO)	<input type="checkbox"/>	<input type="checkbox"/>
14. Anemia (SHXANEM)	<input type="checkbox"/>	<input type="checkbox"/>
15. Hematologic disease (other than anemia) (SHXHEM)	<input type="checkbox"/>	<input type="checkbox"/>
16. History of urinary tract infections (SHXUTI)	<input type="checkbox"/>	<input type="checkbox"/>

If the patient has had 2 UTI's within the past year, the patient is excluded from the study.

17. History of urinary retention (SHXUR)	<input type="checkbox"/>	<input type="checkbox"/>
18. Prior episode of gross hematuria (SHXGH)	<input type="checkbox"/>	<input type="checkbox"/>

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19. History of microscopic hematuria (SHXMH)

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

20. Prior biopsy of prostate (SHXBIOP)

<input type="checkbox"/>	<input type="checkbox"/>
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If the patient has had a biopsy within 2 weeks prior to this first visit, the patient is excluded from the study.

21. Family history of BPH (SHXBPH)

YES	NO	unknown
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If YES:

a. Check all that apply.

(SHXBF)	<input type="checkbox"/>	Father
(SHXBB)	<input type="checkbox"/>	Brother
(SHXBMG)	<input type="checkbox"/>	Maternal grandfather
(SHXBPG)	<input type="checkbox"/>	Paternal grandfather

<input type="checkbox"/>	Maternal uncle	(SHXBMU)
<input type="checkbox"/>	Paternal uncle	(SHXBPU)
<input type="checkbox"/>	Unknown	(SHXBUNK)

22. Family history of prostate (SHXPC)

YES	NO	unknown
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If YES:

a. Check all that apply.

(SHXPF)	<input type="checkbox"/>	Father
(SHXPB)	<input type="checkbox"/>	Brother
(SHXPMG)	<input type="checkbox"/>	Maternal grandfather
(SHXPPG)	<input type="checkbox"/>	Paternal grandfather

<input type="checkbox"/>	Maternal uncle	(SHXPMU)
<input type="checkbox"/>	Paternal uncle	(SHXPPU)
<input type="checkbox"/>	Unknown	(SHXPUNK)

23. Vasectomy (SHXVAS)

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

If YES:

a. Year of vasectomy (SHXVYR)

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

## E. BPH Symptoms

1. Duration of symptoms (SBSDUR)

<input type="text"/>	<input type="text"/>	.	<input type="text"/>	years
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2. Stability of symptoms during past year (SBSSTAB)

<input type="checkbox"/>	improved
<input type="checkbox"/>	stable
<input type="checkbox"/>	worsened

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3. Has the patient seen a urologist within the past 5 years about BPH symptoms **(SBSUROL)**

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

If YES:

- a. What was their recommendation? **(SBSUREC)**

<input type="checkbox"/>	surgery
<input type="checkbox"/>	medication
<input type="checkbox"/>	watchful-waiting

F. Blood Pressure Readings

1. Supine Blood Pressure (After lying 5 minutes)

- a. Heart Rate **(SBPLHR)**

<input type="text"/>	<input type="text"/>	<input type="text"/>	bpm
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- b. Blood Pressure **(SBPLS)/(SBPLD)**

<input type="text"/>	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	mmHg
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If the supine blood pressure is < 90/70 mmHg, the patient is excluded from the study.

2. Standing Blood Pressure (Immediately)

- a. Heart Rate 1 **(SBPSHR1)**

<input type="text"/>	<input type="text"/>	<input type="text"/>	bpm
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- b. Blood Pressure Reading 1 **(SBPSS1)/(SBPSD1)**

<input type="text"/>	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	mmHg
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Wait 2 minutes

- c. Heart Rate 2 **(SBPSHR2)**

<input type="text"/>	<input type="text"/>	<input type="text"/>	bpm
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- d. Blood Pressure Reading 2 **(SBPSS2)/(SBPSD2)**

<input type="text"/>	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	mmHg
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G. Orthostatic Hypotension

1. Did the patient have orthostatic hypotension? **(SORTHYP)**

YES	NO
<input type="checkbox"/>	<input type="checkbox"/>

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.

If G.1 is answered YES, the patient is excluded from the study.

H. Physical Examination

1. Height (SPEHT)

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 inches

2. Weight (SPEWT)

--	--	--

 lbs.

3. Examinations

a. Head, ears, nose, throat (SPXHENT)

normal	abnormal
1	2

b. Eyes (SPXEYES)

1	2
---	---

c. Neck (include bruits) (SPXNECK)

1	2
---	---

d. Heart (SPXHRT)

1	2
---	---

e. Lungs and respiration (SPXLUNG)

1	2
---	---

f. Abdomen (include bruits) (SPXABD)

1	2
---	---

g. Liver (SPXLIV)

1	2
---	---

h. Skin (SPXSKIN)

1	2
---	---

i. Neurological (SPXNEU)

1	2
---	---

j. Urogenital (SPXURO)

1	2
---	---

4. Rectal Examination

a. Prostate size (SPRSIZE)

--	--	--

 g

b. Nodules or indurations (SPRNOD)

YES	NO
1	2

c. Asymmetry (SPRASYM)

1	2
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d. Suspicious for cancer (SPRCAN)

1	2
---	---

e. Tenderness (SPRTEN)

1	2
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I. Uroflow Measurements

1. Voiding Time (SUMVT)

--	--	--

 sec

2. Flow Time (SUMFT)

--	--	--

 sec

3. Time to Maximum Flow (SUMTMF)

--	--	--

 sec

4. Maximum Flow Rate (SUMMXFR)

		.	
--	--	---	--

 ml/sec

If I.4 is &lt; 4.0 or &gt; 15.0 ml/sec, the patient is ineligible for the study.

5. Mean Flow Rate (SUMMNFR)

		.	
--	--	---	--

 ml/sec

6. Voided Volume (SUMVV)

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 ml

If I.6 is &lt; 125 ml, the patient is ineligible for the study.

7. Post Void Residual (SUMPVR)

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 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.

J. Concomitant Medications
 1. Is the patient taking any medication on a regular basis? (SCMCON)
 

YES
1

NO
2

If YES, list below:

a.	(SCMCONA)	f.	(SCMCONF)
b.	(SCMCONB)	g.	(SCMCONG)
c.	(SCMCONC)	h.	(SCMCONH)
d.	(SCMCOND)	i.	(SCMCONI)
e.	(SCMCONC)	j.	(SCMCONJ)

See Manual of Operations for exclusionary medications.

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Part III / LABORATORY RESULTS

K. PSA Serum Specimen

1. Was a serum specimen collected for PSA and hormones during Screening Visit 1? (SPSACOL)

YES

1
---

NO

2HOLD
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If YES:

- a. Date sent to the Diagnostic Center. (SPSADT)

month	day	year

L. Complete Blood Count

1. Hematocrit (SBCHCT)

		.		%
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2. Hemoglobin (SBCHGB)

		.		g/dl
--	--	---	--	------

3. Erythrocyte count (RBC) (SBCRBC)

	.		$10^6/\text{ul}$
--	---	--	------------------

4. Leucocyte count (WBC) (SBCWBC)

					/ul
--	--	--	--	--	-----

5. Platelet count (SBCPC)

				$10^3/\text{ul}$
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M. Serum Chemistries

1. Sodium (SSCSOD)

			mmol/L
--	--	--	--------

2. Potassium (SSCPOT)

	.		mmol/L
--	---	--	--------

3. Chloride (SSCCHL)

			mmol/L
--	--	--	--------

4. Bicarbonate (SSCBIC)

		mEq/L
--	--	-------

5. Glucose (SSCGLU)

				mg/dl
--	--	--	--	-------

6. Urea Nitrogen (SSCUN)

			mg/dl
--	--	--	-------

7. Creatinine (SSCCRE)

		.		mg/dl
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If M.7 > 2.0 mg/dl, the patient is excluded from the study.

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8. Uric Acid (SSCUA)

		.		mg/dl
--	--	---	--	-------

9. Calcium (SSCCAL)

		.		mg/dl
--	--	---	--	-------

10. Phosphorus (SSCPHO)

		.		mg/dl
--	--	---	--	-------

11. SGOT (AST) (SSCSGOT)

			U/L
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If M.11 > 1.5 times the upper limit of normal, the patient is excluded from the study.

12. Alkaline Phosphatase (SSCAP)

			U/L
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13. Total Bilirubin (SSCTBIL)

	.		mg/dl
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14. Total Protein (SSCTPRO)

	.		g/dl
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15. Albumin (SSCALB)

	.		g/dl
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16. Cholesterol (SSCCHO)

			mg/dl
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## N. Urinalysis

1. Dipstick

a. pH (SURDPH)

	.	
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	0	trace	1+	2+	3+	4+
b. Glucose (SURDGLU)	<div>1</div>	<div>2</div>	<div>3</div>	<div>4</div>	<div>5</div>	<div>6</div>
c. Blood (SURDBLD)	<div>1</div>	<div>2</div>	<div>3</div>	<div>4</div>	<div>5</div>	<div>6</div>
d. Ketones (SURDKET)	<div>1</div>	<div>2</div>	<div>3</div>	<div>4</div>	<div>5</div>	<div>6</div>
e. Protein (SURDPRO)	<div>1</div>	<div>2</div>	<div>3</div>	<div>4</div>	<div>5</div>	<div>6</div>
f. Leucocyte Esterase (SURDLE)	<div>1</div>	<div>2</div>	<div>3</div>	<div>4</div>	<div>5</div>	<div>6</div>



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2. If dipstick is positive (greater than 0) for blood or leucocyte esterase, please send specimen for microscopic urinalysis. Please use the following table to code the results.

1	None, Negative, WNL
2	1-5, Trace, Present, Slight, Rare, Occ
3	6-15, Moderate
4	16-30, Many, Frequent
5	> 30, Innumerable, TNTC

a. WBC (**SURMWBC**)

1	2	3	4	5
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b. RBC (**SURMRBC**)

1	2	3	4	5
---	---	---	---	---

c. Epithelial Cells (**SURMEC**)

1	2	3	4	5
---	---	---	---	---

d. Mucous (**SURMMUC**)

1	2	3	4	5
---	---	---	---	---

e. Bacteria (**SURMBAC**)

1	2	3	4	5
---	---	---	---	---

f. Casts - Hyaline (**SURMCHY**)

1	2	3	4	5
---	---	---	---	---

g. Casts - Other (**SURMCO**)

1	2	3	4	5
---	---	---	---	---

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

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

Date form completed

(**FORMDT**)

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

Signature \_\_\_\_\_