

Screening number

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NIH - BPH TRIAL

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), the Sexual Function Questionnaire (Form Q02), the Patient Tracking Information (Form T01) and begin completing the Eligibility and Exclusion Inventory (Form B01).

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

3. Grade level last completed (SGIGRAD)

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See Manual of Operations for coding grade level last completed.

Part II / HISTORY AND PHYSICAL EXAMINATIOND. 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 (SHXDMM)	<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"/>
19. History of microscopic hematuria (SHXMH)	<input type="checkbox"/>	<input type="checkbox"/>
20. Prior biopsy of prostate (SHXBIOP)	<input type="checkbox"/>	<input type="checkbox"/>

If the patient has had a biopsy within 1 month prior to this first visit, the patient is excluded from the study.

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21. Family history of BPH (**SHXBPH**)

YES ☐ 1 NO ☐ 2 unknown ☐ 3

If YES:

a. Check all that apply.

<input type="checkbox"/> 1	Father (SHXBF)
<input type="checkbox"/> 1	Brother (SHXBB)
<input type="checkbox"/> 1	Maternal grandfather (SHXBMG)
<input type="checkbox"/> 1	Paternal grandfather (SHXBPG)

<input type="checkbox"/> 1	Maternal uncle (SHXBMU)
<input type="checkbox"/> 1	Paternal uncle (SHXBPU)
<input type="checkbox"/> 1	Unknown (SHXBUNK)

22. Family history of prostate cancer (**SHXPC**)

YES ☐ 1 NO ☐ 2 unknown ☐ 3

If YES:

a. Check all that apply.

<input type="checkbox"/> 1	Father (SHXPF)
<input type="checkbox"/> 1	Brother (SHXPB)
<input type="checkbox"/> 1	Maternal grandfather (SHXPMG)
<input type="checkbox"/> 1	Paternal grandfather (SHXPPG)

<input type="checkbox"/> 1	Maternal uncle (SHXPMU)
<input type="checkbox"/> 1	Paternal uncle (SHXPPU)
<input type="checkbox"/> 1	Unknown (SHXPUNK)

23. Vasectomy (**SHXVAS**)

YES ☐ 1 NO ☐ 2

If YES:

a. Year of vasectomy (**SHXVYR**)

year

24. Impotence (**SHXIMP**)

YES ☐ 1 NO ☐ 2 intermittent ☐ 3

25. Other genitourinary disease (**SHXOGU**)

YES ☐ 1 NO ☐ 2

If YES:

a. specify (**SHXOGUX**)

E. BPH Symptoms

1. Duration of symptoms (**SBSDUR**) . years

2. Stability of symptoms during past year (**SBSSTAB**)

☐ 1 improved
☐ 2 stable
☐ 3 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. 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 mmHg systolic OR < 70 mmHg diastolic, the patient is excluded from the study.

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

<input type="text"/>	<input type="text"/>	<input type="text"/>	bpm
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2. Standing Blood Pressure (Immediately)

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

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

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

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

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

H. Physical Examination

1. Height **(SPEHT)**

<input type="text"/>	<input type="text"/>	inches
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2. Weight **(SPEWT)**

<input type="text"/>	<input type="text"/>	<input type="text"/>	lbs.
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3. Examinations

	normal	abnormal	If abnormal, please note
a. Head, ears, nose, throat (SPXHENT)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
b. Eyes (SPXEYES)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
c. Neck (include bruits) (SPXNECK)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
d. Heart (SPXHRT)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
e. Lungs and respiration (SPXLUNG)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
f. Abdomen (include bruits) (SPXABD)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
g. Liver (SPXLIV)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
h. Skin (SPXSKIN)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
i. Neurological (SPXNEU)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____
j. Urogenital (SPXURO)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	_____

4. Rectal Examination

a. Prostate size (SPRSIZE)	<input type="text"/> <input type="text"/> <input type="text"/> g
b. Nodules or indurations (SPRNOD)	YES <input type="checkbox"/> 1 NO <input type="checkbox"/> 2
c. Asymmetry (SPRASYM)	<input type="checkbox"/> 1 <input type="checkbox"/> 2
d. Suspicious for cancer (SPRCAN)	<input type="checkbox"/> 1 <input type="checkbox"/> 2
e. Tenderness (SPRTEN)	<input type="checkbox"/> 1 <input type="checkbox"/> 2

I. Uroflow Measurements

1. Voiding Time (SUMVT)	<input type="text"/> <input type="text"/> <input type="text"/> sec
2. Flow Time (SUMFT)	<input type="text"/> <input type="text"/> <input type="text"/> sec
3. Time to Maximum Flow (SUMTMF)	<input type="text"/> <input type="text"/> <input type="text"/> sec
4. Maximum Flow Rate (SUMMXFR)	<input type="text"/> <input type="text"/> . <input type="text"/> ml/sec

If I.4 is < 4.0 ml/sec or > 15.0 ml/sec, the patient is ineligible for the study.

5. Mean Flow Rate (SUMMNFR)	<input type="text"/> <input type="text"/> . <input type="text"/> ml/sec
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6. Voided Volume (SUMVV)

				ml
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If I.6 is < 125 ml, the patient is ineligible for the study.

7. Post Void Residual (SUMPVR)

				ml
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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.

Part III / CONCOMITANT MEDICATIONS AND LABORATORY RESULTS

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

See Manual of Operations for exclusionary medications.

K. PSA Serum Specimen

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

YES ¹ ☐ NO ² ☐ HOLD

If YES:

a. Date sent to the Diagnostic Center (SPSADT)

month	day	year

L. Complete Blood Count

1. Leucocyte count (WBC) (SBCWBC)

		.		10 ³ /ul
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2. Erythrocyte count (RBC) (SBCRBC)

		.		10 ⁶ /ul
--	--	---	--	---------------------

3. Hemoglobin (SBCHGB)

		.		g/dL
--	--	---	--	------

4. Hematocrit (SBCHCT)

		.		%
--	--	---	--	---

5. Platelet count (SBCPC)

				10 ³ /ul
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M. Serum Chemistries

1. Sodium (**SSCSOD**)

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 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

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

8. Uric Acid (**SSCUA**)

		.	
--	--	---	--

 mg/dL
9. Calcium (**SSCCAL**)

		.	
--	--	---	--

 mg/dL
10. Phosphorus (**SSCPHO**)

		.	
--	--	---	--

 mg/dl
11. ALT (SGPT) (**SSCALT**)

--	--	--

 U/L

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

12. Alkaline Phosphatase (**SSCAP**)

--	--	--

 U/L
13. Total Bilirubin (**SSCTBIL**)

	.	
--	---	--

 mg/dL
14. Total Protein (**SSCTPRO**)

	.	
--	---	--

 g/dL
15. Albumin (**SSCALB**)

	.	
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 g/dL
16. Cholesterol (**SSCCHO**)

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 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)	<table border="1"><tr><td>1</td></tr></table>	1	<table border="1"><tr><td>2</td></tr></table>	2	<table border="1"><tr><td>3</td></tr></table>	3	<table border="1"><tr><td>4</td></tr></table>	4	<table border="1"><tr><td>5</td></tr></table>	5	<table border="1"><tr><td>6</td></tr></table>	6
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c. Blood (SURDBLD)	<table border="1"><tr><td>1</td></tr></table>	1	<table border="1"><tr><td>2</td></tr></table>	2	<table border="1"><tr><td>3</td></tr></table>	3	<table border="1"><tr><td>4</td></tr></table>	4	<table border="1"><tr><td>5</td></tr></table>	5	<table border="1"><tr><td>6</td></tr></table>	6
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d. Ketones (SURDKET)	<table border="1"><tr><td>1</td></tr></table>	1	<table border="1"><tr><td>2</td></tr></table>	2	<table border="1"><tr><td>3</td></tr></table>	3	<table border="1"><tr><td>4</td></tr></table>	4	<table border="1"><tr><td>5</td></tr></table>	5	<table border="1"><tr><td>6</td></tr></table>	6
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e. Protein (SURDPRO)	<table border="1"><tr><td>1</td></tr></table>	1	<table border="1"><tr><td>2</td></tr></table>	2	<table border="1"><tr><td>3</td></tr></table>	3	<table border="1"><tr><td>4</td></tr></table>	4	<table border="1"><tr><td>5</td></tr></table>	5	<table border="1"><tr><td>6</td></tr></table>	6
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f. Leucocyte Esterase (SURDLE)	<table border="1"><tr><td>1</td></tr></table>	1	<table border="1"><tr><td>2</td></tr></table>	2	<table border="1"><tr><td>3</td></tr></table>	3	<table border="1"><tr><td>4</td></tr></table>	4	<table border="1"><tr><td>5</td></tr></table>	5	<table border="1"><tr><td>6</td></tr></table>	6
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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)	<table border="1"><tr><td>1</td></tr></table>	1	<table border="1"><tr><td>2</td></tr></table>	2	<table border="1"><tr><td>3</td></tr></table>	3	<table border="1"><tr><td>4</td></tr></table>	4	<table border="1"><tr><td>5</td></tr></table>	5
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b. RBC (SURMRBC)	<table border="1"><tr><td>1</td></tr></table>	1	<table border="1"><tr><td>2</td></tr></table>	2	<table border="1"><tr><td>3</td></tr></table>	3	<table border="1"><tr><td>4</td></tr></table>	4	<table border="1"><tr><td>5</td></tr></table>	5
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c. Epithelial Cells (SURMEC)	<table border="1"><tr><td>1</td></tr></table>	1	<table border="1"><tr><td>2</td></tr></table>	2	<table border="1"><tr><td>3</td></tr></table>	3	<table border="1"><tr><td>4</td></tr></table>	4	<table border="1"><tr><td>5</td></tr></table>	5
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d. Mucous (SURMMUC)	<table border="1"><tr><td>1</td></tr></table>	1	<table border="1"><tr><td>2</td></tr></table>	2	<table border="1"><tr><td>3</td></tr></table>	3	<table border="1"><tr><td>4</td></tr></table>	4	<table border="1"><tr><td>5</td></tr></table>	5
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e. Bacteria (SURMBAC)	<table border="1"><tr><td>1</td></tr></table>	1	<table border="1"><tr><td>2</td></tr></table>	2	<table border="1"><tr><td>3</td></tr></table>	3	<table border="1"><tr><td>4</td></tr></table>	4	<table border="1"><tr><td>5</td></tr></table>	5
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f. Casts - Hyaline (SURMCHY)	<table border="1"><tr><td>1</td></tr></table>	1	<table border="1"><tr><td>2</td></tr></table>	2	<table border="1"><tr><td>3</td></tr></table>	3	<table border="1"><tr><td>4</td></tr></table>	4	<table border="1"><tr><td>5</td></tr></table>	5
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g. Casts - Other (SURMCO)	<table border="1"><tr><td>1</td></tr></table>	1	<table border="1"><tr><td>2</td></tr></table>	2	<table border="1"><tr><td>3</td></tr></table>	3	<table border="1"><tr><td>4</td></tr></table>	4	<table border="1"><tr><td>5</td></tr></table>	5
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Initials of person completing form (FORMIN)

first		last	

Form entered in computer?

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Signature of P.I.

Date