

Screening number

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)
- 2. Screening number (SCREEN)
- 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"/> 1	<input type="checkbox"/> 2
2. Lung disease (SHXLUNG)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
3. Heart disease (SHXHRT)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
4. Hypertension (SHXHYP)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
5. Renal disease (SHXREN)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
6. Rheumatologic/collagen or vascular disease (SHXRCV)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
7. Diabetes Mellitus (SHXDM)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
8. Endocrinopathy (other than diabetes) (SHXENDO)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
9. Liver disease (SHXLIV)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
10. Gastro-intestinal tract disease (SHXGI)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
11. Skin disease (SHXSKIN)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
12. Organic CNS disease (SHXCNS)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
13. Neoplastic disease (SHXNEO)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
14. Anemia (SHXANEM)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
15. Hematologic disease (other than anemia) (SHXHEM)	<input type="checkbox"/> 1	<input type="checkbox"/> 2
16. History of urinary tract infections (SHXUTI)	<input type="checkbox"/> 1	<input type="checkbox"/> 2

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"/> 1	<input type="checkbox"/> 2
18. Prior episode of gross hematuria (SHXGH)	<input type="checkbox"/> 1	<input type="checkbox"/> 2

19. History of microscopic hematuria **(SHXMH)** YES  NO   
 1  2
20. Prior biopsy of prostate **(SHXBIOP)** YES  NO   
 1  2

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   
 1  2  3

If YES:

a. Check all that apply.

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

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

22. Family history of prostate **(SHXPC)** YES  NO  unknown   
 1  2  3

If YES:

a. Check all that apply.

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

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

23. Vasectomy **(SHXVAS)** YES  NO   
 1  2

If YES:

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

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

If YES:

a. What was their recommendation? **(SBSUREC)**  surgery  
 medication  
 watchful-waiting

F. Blood Pressure Readings

1. Supine Blood Pressure (After lying 5 minutes)

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

b. Blood Pressure **(SBPLS)/(SBPLD)**    /    mmHg

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)**    bpm

b. Blood Pressure Reading 1 **(SBPSS1)/(SBPSD1)**    /    mmHg

Wait 2 minutes

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

d. Blood Pressure Reading 2 **(SBPSS2)/(SBPSD2)**    /    mmHg

G. Orthostatic Hypotension

1. Did the patient have orthostatic hypotension? **(SORTHYP)** YES NO

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.

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H. Physical Examination

1. Height (**SPEHT**)   inches

2. Weight (**SPEWT**)    lbs.

3. Examinations

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

4. Rectal Examination

- a. Prostate size (**SPRSIZE**)    g
- |   | YES                    | NO                     |
|---|------------------------|------------------------|
| b. Nodules or indurations ( <b>SPRNOD</b> ) | <input type="text"/> 1 | <input type="text"/> 2 |
| c. Asymmetry ( <b>SPRASYM</b> )             | <input type="text"/> 1 | <input type="text"/> 2 |
| d. Suspicious for cancer ( <b>SPRCAN</b> )  | <input type="text"/> 1 | <input type="text"/> 2 |
| e. Tenderness ( <b>SPRTEN</b> )             | <input type="text"/> 1 | <input type="text"/> 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 < 4.0 or > 15.0 ml/sec, the patient is ineligible for the study.

- 5. Mean Flow Rate **(SUMMNFR)**   .  ml/sec
- 6. Voided Volume **(SUMVV)**     ml

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

- 7. Post Void Residual **(SUMPVR)**     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)** <sup>1</sup> <sup>2</sup>

If YES, list below:

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

See Manual of Operations for exclusionary medications.

Part III / LABORATORY RESULTS

K. PSA Serum Specimen

1. Was a serum specimen collected for PSA and hormones during Screening Visit 1? (SPSACOL) YES  NO  <sup>2</sup>HOLD

If YES:

- a. Date sent to the Diagnostic Center. (SPSADT)    /    /     
 month day year

L. Complete Blood Count

1. Hematocrit (SBCHCT)   .  %  
 2. Hemoglobin (SBCHGB)   .  g/dl  
 3. Erythrocyte count (RBC) (SBCRBC)  .  10<sup>6</sup>/ul  
 4. Leucocyte count (WBC) (SBCWBC)      /ul  
 5. Platelet count (SBCPC)     10<sup>3</sup>/ul

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

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





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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) 12345
- b. RBC (SURMRBC) 12345
- c. Epithelial Cells (SURMEC) 12345
- d. Mucous (SURMMUC) 12345
- e. Bacteria (SURMBAC) 12345
- f. Casts - Hyaline (SURMCHY) 12345
- g. Casts - Other (SURMCO) 12345

Initials of person completing form (FORMIN)      
first last

Date form completed (FORMDT)     
month day year

Signature \_\_\_\_\_