Screening number **S** ☐☐☐☐

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)** ☐☐

2. Screening number **(SCREEN)** S ☐☐☐

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)** ☐☐

> See Manual of Operations for coding grade level last completed.

Part II / HISTORY AND PHYSICAL EXAMINATION

D. Medical History

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

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

	YES	NO
17. History of urinary retention **(SHXUR)**	1	2
18. Prior episode of gross hematuria **(SHXGH)**	1	2
19. History of microscopic hematuria **(SHXMH)**	1	2
20. Prior biopsy of prostate **(SHXBIOP)**	1	2

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

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

    YES ☐1   NO ☐2   unknown ☐3

    If YES:

    a. Check all that apply.

    | 1 Father **(SHXBF)** | 1 Maternal uncle **(SHXBMU)** |
    | 1 Brother **(SHXBB)** | 1 Paternal uncle **(SHXBPU)** |
    | 1 Maternal grandfather **(SHXBMG)** | 1 Unknown **(SHXBUNK)** |
    | 1 Paternal grandfather **(SHXBPG)** | |

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

    YES ☐1   NO ☐2   unknown ☐3

    If YES:

    a. Check all that apply.

    | 1 Father **(SHXPF)** | 1 Maternal uncle **(SHXPMU)** |
    | 1 Brother **(SHXPB)** | 1 Paternal uncle **(SHXPPU)** |
    | 1 Maternal grandfather **(SHXPMG)** | 1 Unknown **(SHXPUNK)** |
    | 1 Paternal grandfather **(SHXPPG)** | |

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

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

YES ☐1   NO ☐2

If YES:

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

☐1 surgery

☐2 medication

☐3 watchful-waiting

F. <u>Blood Pressure Readings</u>

1. Supine Blood Pressure (After lying 5 minutes)

a. Blood Pressure **(SBPLS)/(SBPLD)**   ☐☐☐ / ☐☐☐ mmHg

If the supine blood pressure is < 90 mmHg systolic OR < 70 mmHg diastolic, the patient is excluded from the study.

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b. Heart Rate **(SBPLHR)**   ☐☐☐ bpm

2. Standing Blood Pressure (Immediately)

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

b. Heart Rate 1 **(SBPSHR1)**   ☐☐☐ bpm

Wait 2 minutes

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

d. Heart Rate 2 **(SBPSHR2)**   ☐☐☐ bpm

G. <u>Orthostatic Hypotension</u>

YES ☐1   NO ☐2

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

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. <u>Physical Examination</u>

1. Height **(SPEHT)**   ☐☐ inches

2. Weight **(SPEWT)**   ☐☐☐ lbs.

3. Examinations

	normal	abnormal	If abnormal, please note
a. Head, ears, nose, throat **(SPXHENT)**	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

	YES	NO
b. Nodules or indurations **(SPRNOD)**	1 ☐	2 ☐
c. Asymmetry **(SPRASYM)**	1 ☐	2 ☐
d. Suspicious for cancer **(SPRCAN)**	1 ☐	2 ☐
e. Tenderness **(SPRTEN)**	1 ☐	2 ☐

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 ml/sec or > 15.0 ml/sec, the patient is ineligible for the study.

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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.

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) (SCMCODF)**
b.	**(SCMCONB) (SCMCODB)**	g.	**(SCMCONG) (SCMCODG)**
c.	**(SCMCONC) (SCMCODC)**	h.	**(SCMCONH) (SCMCODH)**
d.	**(SCMCOND) (SCMCODD)**	i.	**(SCMCONI) (SCMCODI)**
e.	**(SCMCONE) (SCMCODE)**	j.	**(SCMCONJ) (SCMCODJ)**

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

2. Erythrocyte count (RBC) **(SBCRBC)** ▢.▢ 10^6/ul

3. Hemoglobin **(SBCHGB)** ▢▢.▢ g/dL

4. Hematocrit **(SBCHCT)** ▢▢.▢ %

5. Platelet count **(SBCPC)** ▢▢▢▢ 10^3/ul

M.   <u>Serum Chemistries</u>

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.

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)**   ☐.☐ g/dL

16. Cholesterol **(SSCCHO)**   ☐☐ mg/dL

N. Urinalysis

    1. Dipstick

        a. pH **(SURDPH)**   ☐ . ☐

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

    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
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)** ☐ ☐ ☐ ☐
           first   last

Form entered in computer? ☐

Signature of P.I. _____   Date _____