

Screening number

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BPH FORM B01.1

October, 1993

Page 1 of 3

FORM NUMBER = (FORM)

FORM VERSION = (VERS)

## NIH - BPH CLINICAL TRIAL: PILOT STUDY

### ELIGIBILITY AND EXCLUSION INVENTORY

This form is to be completed during the baseline period (i.e. the patient must attend at least the first screening visit.

#### 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 (first two initials of first name and first two initials of last name) (INITS)

first		last	

4. Patient's date of birth (DOB)

month	day	year

##### B. Visit Information

1. Date of Screening Visit 1 (EVSTDT)

month	day	year

#### Part II / ELIGIBILITY AND EXCLUSION SCREENING

##### C. Inclusion Criteria

1. The patient has voluntarily signed the informed consent agreement prior to the performance of any study procedures. (EICIC)

YES

NO

1
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2
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2. The patient is a male at least 50 years of age. (EICAGE)

1
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2
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3. The patient's peak urinary flow rate is at least 4 ml/sec, but not greater than 15 ml/sec, and the voided volume is at least 125 ml. (EICUFR)

1
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2
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4. The AUA symptom severity score is greater than or equal to 8. (EICAUA)

1
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2
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If all items in section C are answered yes, CONTINUE. If not, the patient is ineligible, SKIP to Part III.

Screening number

S				
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**D. Exclusion Criteria**

	YES	NO
1. The patient has had any prior intervention for BPH (either medical or surgical). <b>(EECSURG)</b>	<input type="checkbox"/>	<input type="checkbox"/>
2. The patient has received any prior experimental intervention for prostate disease (either medical or surgical) or is presently enrolled in any study protocol. <b>(EECEXP)</b>	<input type="checkbox"/>	<input type="checkbox"/>
3. The patient has had a previous hypersensitivity, idiosyncrasy, or clinically suspended drug reaction to alpha-blockers, quinazoline compounds, or finasteride. <b>(EECDRG)</b>	<input type="checkbox"/>	<input type="checkbox"/>
4. The patient has taken an alpha-1 blocker within 1 year of randomization. <b>(EECALPH)</b>	<input type="checkbox"/>	<input type="checkbox"/>
5. The patient has taken phenylephrine, pseudoephedrine, imipramine, an anticholinergic or cholinergic medication within 4 weeks of the first screening visit. <b>(EECCHOL)</b>	<input type="checkbox"/>	<input type="checkbox"/>
6. The patient has taken an estrogen, androgen, or a drug producing androgen suppression, or anabolic steroids. <b>(EECHORM)</b>	<input type="checkbox"/>	<input type="checkbox"/>
7. The patient has an inability to urinate. <b>(EECINAB)</b>	<input type="checkbox"/>	<input type="checkbox"/>
8. The patient has a supine blood pressure of less than 90/70 mmHg. <b>(EECBP)</b>	<input type="checkbox"/>	<input type="checkbox"/>
9. The patient has clinically significant renal or hepatic impairment (i.e. creatinine greater than 2.0 mg/dl or AST greater than 1.5 times the upper limit of normal). <b>(EECREN)</b>	<input type="checkbox"/>	<input type="checkbox"/>
10. The patient has a serum prostate specific antigen (PSA) level greater than 10 ng/ml. <b>(EECPSA)</b>	<input type="checkbox"/>	<input type="checkbox"/>
11. The patient requires the daily use of a pad or device for incontinence. <b>(EECINC)</b>	<input type="checkbox"/>	<input type="checkbox"/>
12. The patient has had an episode of unstable angina pectoris, a myocardial infarction, transient ischemic attack, or a cerebrovascular accident within the past six months. <b>(EECHRT)</b>	<input type="checkbox"/>	<input type="checkbox"/>
13. The patient has orthostatic hypotension, or a history of significant fainting spells or blackouts. Orthostatic hypotension is defined as a decrease in the systolic blood pressure of greater than 20 mmHg or a decrease in the diastolic blood pressure of greater than 10 mmHg between the supine and standing positions, or the development of significant postural hypotension. <b>(EECORHY)</b>	<input type="checkbox"/>	<input type="checkbox"/>
14. The patient has a history or current evidence of prostate cancer, bladder cancer, pelvic radiation, urethral stricture, prostate surgery or surgery for bladder neck obstruction. <b>(EECCAR)</b>	<input type="checkbox"/>	<input type="checkbox"/>
15. The patient has an active urinary tract disease or has undergone cystoscopy or biopsy of the prostate within two weeks prior to the first screening visit or has an imminent need for surgery. <b>(EECUTD)</b>	<input type="checkbox"/>	<input type="checkbox"/>

Screening number

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- |   | YES                        | NO                         |
|---|----------------------------|----------------------------|
| 16. The patient has known primary neurologic conditions such as multiple sclerosis or Parkinson's disease or other neurological diseases known to affect bladder function. (EECNEUR)  | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 17. The patient has had documented bacterial prostatitis within the past year. (EECPROS)  | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 18. The patient has had two documented urinary tract infections of any type in the past year. (EEC2UTI)   | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 19. The patient has a severe bleeding disorder which makes a biopsy impossible. (EECBLD)  | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 20. The patient has had cancer which is not considered cured (except basal cell or squamous cell carcinoma of the skin). A patient is considered cured if there has been no evidence of cancer within five years of randomization. (EECCAN) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 21. The patient has any serious medical condition likely to impede successful completion of the long-term study. (EECSMC)   | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 22. The patient has a diagnosis of a thought disorder (i.e. schizophrenia, bipolar disorder). (EECTD)   | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 23. The patient has a history of alcoholism or any other substance abuse which, in the opinion of the investigator, would affect compliance with the protocol. (EECALC)   | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

Part III / CONCLUSION

E. Conclusion

- |  | YES                        | NO                         |
|--|----------------------------|----------------------------|
| 1. All questions in Section C answered YES? (ECSECC)               | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 2. If Section D completed, are all questions answered NO? (ECSECD) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 3. Will the patient be randomized? (ECRAND)                        | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

If NO:

a. Specify below.

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Initials of person completing form (FORMIN)

first		last	

Date form completed

(FORMDT)

month	day	year

Signature

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