

Screening number 

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FORM NUMBER = (FORM)  
FORM VERSION = (VERS)

## NIH - BPH TRIAL

### 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) for all patients.

#### 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		
<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px; text-align: center;">1</td></tr></table>	1	<table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px; text-align: center;">2</td></tr></table>	2
1			
2			

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

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1			
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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)

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1			
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4. The AUA symptom severity score is at least 8, and less than or equal to 30. (EICAUA)

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1			
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If any item in Section C is answered NO, the patient is ineligible to be randomized.

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D. Exclusion Criteria

	YES	NO
1. The patient has had any prior intervention for BPH (either medical or surgical). (EECSURG)	<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. (EECEXP)	<input type="checkbox"/>	<input type="checkbox"/>
3. The patient has had a previous hypersensitivity, idiosyncrasy, or clinically suspected drug reaction to alpha-blockers, quinazoline compounds, or finasteride. (EECDRG)	<input type="checkbox"/>	<input type="checkbox"/>
4. The patient has taken an alpha-1 blocker within 1 year of randomization. (EECALPH)	<input type="checkbox"/>	<input type="checkbox"/>
5. The patient has taken phenylephrine, pseudoephedrine, imipramine, an anti-cholinergic or cholinergic medication within 4 weeks of the first screening visit, with the exception of topical anti-cholinergic eye drops used for glaucoma for more than 3 months prior to the first screening visit. (EECCHOL)	<input type="checkbox"/>	<input type="checkbox"/>
6. The patient has taken an estrogen, androgen, or a drug producing androgen suppression, or anabolic steroids. If the patient has taken prescription cimetidine within 3 months prior to the first screening visit. (EECHORM)	<input type="checkbox"/>	<input type="checkbox"/>
7. The patient has an inability to urinate. (EECINAB)	<input type="checkbox"/>	<input type="checkbox"/>
8. The patient has a supine blood pressure of less than 90 mmHg systolic or 70 mmHg diastolic. (EECBP)	<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 ALT (SGPT) greater than 1.5 times the upper limit of normal). (EECREN)	<input type="checkbox"/>	<input type="checkbox"/>
10. The patient has a serum prostate specific antigen (PSA) level greater than 10 ng/ml. (EECPSA)	<input type="checkbox"/>	<input type="checkbox"/>
11. The patient requires the daily use of a pad or device for incontinence. (EECINC)	<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. (EECHRT)	<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. (EECORHY)	<input type="checkbox"/>	<input type="checkbox"/>
14. The patient has a history or current evidence of carcinoma of the prostate or bladder, pelvic radiation or surgery, urethral stricture, prior surgery for BPH or surgery for bladder neck obstruction. (EECCAR)	<input type="checkbox"/>	<input type="checkbox"/>

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- |   | YES                        | NO                         |
|---|----------------------------|----------------------------|
| 15. The patient has an active urinary tract disease or has undergone cystoscopy or biopsy of the prostate within one month prior to the first screening visit or has an imminent need for surgery. (EECUTD)                                 | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 16. The patient has a 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 |

If any item in Section D is answered YES, the patient is excluded from randomization.

### Part III / CONCLUSION

#### E. Conclusion

- |  | YES                        | NO                         |
|--|----------------------------|----------------------------|
| 1. Are all questions in Section C answered YES? (ECSECC) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 2. Are all questions in Section D answered NO? (ECSECD)  | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |

If either question E.1 or E.2 is answered NO, the patient cannot be randomized.

- |   |                            |                            |
|---|----------------------------|----------------------------|
| 3. Will the patient be randomized? (ECRAND) | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
|---|----------------------------|----------------------------|

If NO and the reason is not documented in Sections C or D:

a. Specify below (ECRANDX)

Initials of person completing form (FORMIN)

first		last	

Form entered in computer?

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