

Screening number

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BPH FORM B04.2

April, 1995

Page 1 of 3

FORM NUMBER = (FORM)

FORM VERSION = (VERS)

NIH - BPH TRIAL

RANDOMIZATION INFORMATION

This form is to be completed after the Eligibility and Exclusion Inventory (Form B01) and Screening Visits 1 & 2 (Forms B02 and B03) are completed and the patient is ready to be randomized.

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 Randomization Visit (RVSTDT)

month	day	year

2. Date of Screening Visit 1 (RVISV1D)

month	day	year

Part II / ELIGIBILITY CONFIRMATION

C. Eligibility Assessment

- | | YES | NO | | |
|---|---|----|---|-------|
| 1. Is the patient eligible (See eligibility/exclusion inventory)? (REAEIG) | <table border="1"><tr><td>1</td></tr></table> | 1 | <table border="1"><tr><td>2HOLD</td></tr></table> | 2HOLD |
| 1 | | | | |
| 2HOLD | | | | |
| 2. Has the patient signed the informed consent form? (REASIGN) | <table border="1"><tr><td>1</td></tr></table> | 1 | <table border="1"><tr><td>2HOLD</td></tr></table> | 2HOLD |
| 1 | | | | |
| 2HOLD | | | | |
| 3. Have the following forms been completed: | | | | |
| a. Eligibility / Exclusion Inventory (REAEI) | <table border="1"><tr><td>1</td></tr></table> | 1 | <table border="1"><tr><td>2HOLD</td></tr></table> | 2HOLD |
| 1 | | | | |
| 2HOLD | | | | |
| b. Screening Visit 1 Inventory (REASV1I) | <table border="1"><tr><td>1</td></tr></table> | 1 | <table border="1"><tr><td>2HOLD</td></tr></table> | 2HOLD |
| 1 | | | | |
| 2HOLD | | | | |
| c. Screening Visit 2 Inventory (REASV2I) | <table border="1"><tr><td>1</td></tr></table> | 1 | <table border="1"><tr><td>2HOLD</td></tr></table> | 2HOLD |
| 1 | | | | |
| 2HOLD | | | | |
| 4. Has the patient successfully completed the placebo run-in phase (See Form B05)? (REAPLAC) | <table border="1"><tr><td>1</td></tr></table> | 1 | <table border="1"><tr><td>2STOP</td></tr></table> | 2STOP |
| 1 | | | | |
| 2STOP | | | | |
| 5. Is the elapsed time from the date of the first pre-randomization visit to the randomization visit less than or equal to 6 weeks (42 days)? (See Questions B.1 and B.2) (REATIME) | <table border="1"><tr><td>1</td></tr></table> | 1 | <table border="1"><tr><td>2STOP</td></tr></table> | 2STOP |
| 1 | | | | |
| 2STOP | | | | |

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D. Baseline Procedure

1. Were the results received from the Diagnostic Center for PSA? (**RBPREC**)

YES

NO

1

2HOLD

If YES:

- a. PSA value (**RBPSA**)

		.		ng/ml
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If the PSA value > 10 ng/ml, the patient is excluded from the study.

Part III / VITAL SIGNS

E. Blood Pressure Readings

1. Supine Blood Pressure (After lying 5 minutes)

- a. Blood Pressure (**RBPLS**)/(**RBPLD**)

			/				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 (**RBPLHR**)

			bpm
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2. Standing Blood Pressure (Immediately)

- a. Blood Pressure Reading 1 (**RBPSS1**)/(**RBPSD1**)

			/				mmHg
--	--	--	---	--	--	--	------

- b. Heart Rate 1 (**RBPSHR1**)

			bpm
--	--	--	-----

Wait 2 minutes

- c. Blood Pressure Reading 2 (**RBPSS2**)/(**RBPSD2**)

			/				mmHg
--	--	--	---	--	--	--	------

- d. Heart Rate 2 (**RBPSHR2**)

			bpm
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F. Orthostatic Hypotension

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

YES

NO

1

2

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 F.1 is answered YES, the patient is excluded from the study.

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Part IV / RANDOMIZATION

G. Perform computerized randomization

The computer will now prompt you to randomize the patient. If all the forms are entered and the patient is ready to be randomized, mark an 'X' where prompted. The computer will then give the patient's study number.

1. BPH study number (PATID)

clinic		patient		

2. Number of doxazosin tablets dispensed today (RRDDIST)

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3. Number of finasteride tablets dispensed today (RRFDIST)

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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
