

Patient number

Date form completed

month

BPH FORM R02.1

November, 1994

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FORM NUMBER = (FORM)

FORM VERSION = (VERS)

NIH BPH CLINICAL TRIAL PILOT STUDY

CLINICAL REVIEW COMMITTEE REPORT

This form is completed by the Clinical Review Committee as documentation of the classification for a patient that had a pre-defined clinical event, discontinued one or both coded medications or discontinued follow-up visits. The Committee's classification is based on a review of the patient's complete data record in the master database at the Biostatistical Coordinating Center (BCC). The original of this form is kept at the BCC. A copy is sent to the corresponding clinical center to be filed in the patient's binder.

A. Patient Identification

Clinic number (CLINIC)

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2. Patient Identification number (PATID)

clinic		patient		

3. Patient's initials (INITS)

first		last	

4. Patient's date of birth (DOB)

month	day	year

5. CRC form number (CRCNO)

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B. CRC Classification

Specify the classification for this patient: (WCLASS)
(check one)

- ☐ ¹ Death (Complete Section C)
- ☐ ² AUA symptom score event (Complete Section D)
- ☐ ³ Creatinine rise event (Complete Section E)
- ☐ ⁴ Urinary event (Complete Section F)
- ☐ ⁵ Treatment non-compliance (Complete Section G)
- ☐ ⁶ Inactive follow-up (Complete Section H)

C. Death Specification

Date of death (WDDATE)

month	day	year

2. Probable cause of death (WDCAUS)

Patient number

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Date form completed

month	day	year

D. AUA Symptom Score Specification

1 Specify the type of AUA Symptom Score event (WSSTYP) ☐ 1 4 point event
(check one)

☐ 2 8 point event

2. AUA Symptom Score:

a. Baseline (WSSBAS)

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b. Initial Event (WSSIIEV)

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c. Confirming Event (WSSCEV)

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3 Date of initial event (WSSEVDT)

month	day	year

IF THIS IS AN 8 POINT EVENT, CONTINUE

4. Was the patient taking coded medication(s)? (WSSCODE)

YES	NO
<input type="checkbox"/> 1	<input type="checkbox"/> 2

IF YES, THEN CONTINUE IF NO, SKIP TO Question 5

a. Coded medication(s) discontinued

☐ 1 Doxazosin (WSSMDD)

☐ 1 Finasteride (WSSMDF)

b. Date coded medication(s) discontinued (WSSMDDT)

month	day	year

5 Is the patient continuing follow-up visits? (WSSCFUV)

YES	NO
<input type="checkbox"/> 1	<input type="checkbox"/> 2

IF NO:

a. Date of last visit (WSSLVST)

month	day	year

E. Creatinine Rise Specification

1. Creatinine results:

a. Baseline (WCRBAS)

		.		mg/dl
--	--	---	--	-------

b. Initial Event (WCRIEV)

		.		mg/dl
--	--	---	--	-------

c. Confirming Event (WCRCEV)

		.		mg/dl
--	--	---	--	-------

Patient number Date form completed
month day year

2. Date of initial event (WCREVDT)

month day year

3. Was the patient taking coded medication(s)? (WCRCODE)

YES NO
☐ ¹ ☐ ²

IF YES, THEN CONTINUE IF NO, SKIP TO Question 4

a. Coded medication(s) discontinued

☐ ¹ Doxazosin (WCRMDD)

☐ ¹ Finasteride (WCRMDF)

b. Date coded medication(s) discontinued (WCRMDDT)

month day year

4. Is the patient continuing follow-up visits? (WCRCFUV)

YES NO
☐ ¹ ☐ ²

IF NO:

a. Date of last visit (WCRLVST)

month day year

F. Urinary Event Specification

Specify the type of urinary event:
(check one) (WUETYP)

- ☐ ¹ Acute urinary retention event
☐ ² Recurrent urinary tract infection
☐ ³ Incontinence event

2. Date of event (WUEEVDI)

month day year

3. Was the patient taking coded medication(s)? (WUECODE)

YES NO
☐ ¹ ☐ ²

IF YES, THEN CONTINUE. IF NO, SKIP TO Question 4

a. Coded medication(s) discontinued:

☐ ¹ Doxazosin (WUEMDD)

☐ ¹ Finasteride (WUEMDF)

b. Date coded medication(s) discontinued (WUEMDDT)

month day year

Patient number	<input type="text"/>	Date form completed	<input type="text"/>	<input type="text"/>	<input type="text"/>
			month	day	year

4. Is the patient continuing follow-up visits? (WUECFUV) YES ☐ NO ☐

IF NO:

- a. Date of last visit (WUELVST)

<input type="text"/>	<input type="text"/>	<input type="text"/>
month	day	year

G. Treatment Non-compliance Specification

- 1 Specify the primary reason for discontinuing coded medications (WTNRSN)

2. Coded medication(s) discontinued:

☐ Doxazosin (WTNMDD)

☐ Finasteride (WTNMDF)

3. Date coded medications discontinued (WTNMDDT)

<input type="text"/>	<input type="text"/>	<input type="text"/>
month	day	year

H. Inactive Follow-up Specification

- 1 Specify the primary reason for discontinuing follow-up visits (WIFRSN)

2. Date of last visit (WIFMDDT)

<input type="text"/>	<input type="text"/>	<input type="text"/>
month	day	year

I. Conclusion of Report

- 1 Additional comments:

Initials of person completing form
(FORMIN)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
first			last

Date form completed

(FORMDT)

<input type="text"/>	<input type="text"/>	<input type="text"/>
month	day	year

Signature _____