

Patient number

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 Date form completed

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month day year

NIH - BPH CLINICAL TRIAL

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

1 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

1 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)
- ☐ ⁷ Crossover to invasive therapy (Complete Section I)

C. Death Specification

1 Date of death (WDDATE)

month	day	year

2. Probable cause of death (WDCAUS)

Patient number _____

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month	day	year
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D. AUA Symptom Score Specification

AUA Symptom Score:

a. Baseline (WSSBAS)

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b. Initial Event (WSSIEV)

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c. Confirming Event (WSSCEV)

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2. Date of initial event (WSSEVDT)

month	day	year
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3. Was the patient taking coded medication(s)? (WSSCODE)

YES	NO
1	2

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

4. Were the coded medication(s) discontinued? (WSSDISC)

1	2
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IF YES, THEN CONTINUE. IF NO, SKIP TO Question 5

a. Coded medication(s) discontinued:

☐ Doxazosin (WSSMDD)

☐ Finasteride (WSSMDF)

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

month	day	year
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5. Is the patient continuing follow-up visits? (WSSCFUV)

YES	NO
1	2

IF NO

a. Date of last visit (WSSLVST)

month	day	year
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E. Creatinine Rise Specification

Creatinine results:

a. Baseline (WCRBAS)

		.		mg/dl
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b. Initial Event (WCRIEV)

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

c. Confirming Event (WCRCEV)

		.		mg/dl
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2. Date of initial event (WCREVDT)

month	day	year
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Patient number Date form completed
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:

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 (WUEEVD)
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

4. Is the patient continuing follow-up visits? (WUECFUV) YES NO
☐ 1 ☐ 2

IF NO:

a. Date of last visit (WUELVST)
month day year

Patient number

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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)

month	day	year

4. Was there a crossover to known medical therapy? (WTNXTX)

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

If YES, CONTINUE.

- a. Specify the medical therapy
(check all that apply)

☐ Alpha-1 blocker (WTNXA1)

☐ 5-alpha inhibitor (WTNX5A)

☐ Other medication (WTNXO)

specify: (WTNXOX)

H Inactive Follow-up Specification

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

2. Date of last visit (WIFMDDT)

month	day	year

Patient number

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Crossover to Invasive Therapy Specification

Specify the invasive therapy: (WCTIT)

(check one)

☐ ¹ TURP

☐ ² TUIP

☐ ³ Radical prostatectomy

☐ ⁴ Open prostatectomy

☐ ⁵ TUNA

(WCTEVD^T)^{*}

☐ ⁶ Microwave Therapy

☐ ⁷ Laser Therapy

☐ ⁸ Stent

☐ ⁹ Other

specify: (WCTITX)

YES

NO

☐ ¹☐ ²

2. Was the patient taking coded medication(s)? (WCTCODE)

IF YES, THEN CONTINUE IF NO, SKIP TO Question 3.

a. Coded medication(s) discontinued

☐ ¹ Doxazosin (WCTMDD)

☐ ¹ Finasteride (WCTMDF)

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

month	day	year

YES

NO

☐ ¹☐ ²

3. Is the patient continuing follow-up visits? (WCTCFUV)

IF NO:

a. Date of last visit (WCTLVST)

month	day	year

J. Conclusion of Report

Additional comments

Initials of person completing form

(FORMIN)

first			last

Date form completed

month	day	year

Signature
