

Patient number

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Date form completed

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

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 Classification1. 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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D. AUA Symptom Score Specification

1. 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

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

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

YES	NO
1	2

IF NO:

a. Date of last visit (WSSLVST)

month	day	year

E. Creatinine Rise Specification

1 Creatinine results:

a. Baseline (WCRBAS)

		.		mg/dl
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b. Initial Event (WCRIEV)

		.		mg/dl
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c. Confirming Event (WCRCEV)

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

month	day	year

Patient number

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Date form completed

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

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

IF NO:

a. Date of last visit (WCRLVST)

month	day	year

F. Urinary Event Specification

1 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 (WUEEVDT)

month	day	year

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

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

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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I. Crossover to Invasive Therapy Specification

1. Specify the invasive therapy: (WCTIT)
(check one)

☐ TURP

☐ TUIP

☐ Radical prostatectomy

☐ Open prostatectomy

☐ TUNA

☐ Microwave Therapy

☐ Laser Therapy

☐ Stent

☐ Other

specify: (WCTITX)

2. Date of crossover to invasive therapy (WCTEVDT)

month	day	year

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

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

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

- a. Coded medication(s) discontinued

☐ Doxazosin (WCTMDD)

☐ Finasteride (WCTMDF)

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

month	day	year

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

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

IF NO:

- a. Date of last visit (WCTLVST)

month	day	year

J. Conclusion of Report

1. Additional comments:

Initials of person completing form
(FORMIN)

first			last

Date form completed

month	day	year

Signature _____