

Patient number

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Date form completed

month	day	year	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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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

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

1

 NO

2

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

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

1

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

1

 NO

2

IF NO

a. Date of last visit (WSSLVST)

month	day	year

E. Creatinine Rise Specification

Creatinine results:

- a. Baseline (WCRBAS)

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 mg/dl
- b. Initial Event (WCRIEV)

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 mg/dl
- c. Confirming Event (WCRCEV)

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 .

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 mg/dl

2. Date of initial event (WCREVDT)

month	day	year

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: Doxazosin (WCRMDD)
 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 (WUEEVDT)
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: Doxazosin (WUEMDD)
 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

Date form completed
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)**

month day year

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

YES NO

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

Date form completed
month day year

Crossover to Invasive Therapy Specification

Specify the invasive therapy: **(WCTIT)**
(check one)

- ¹ TURP
- ² TUIP
- ³ Radical prostatectomy
- ⁴ Open prostatectomy
- ⁵ TUNA

(WCTEVDI)*

- ⁶ Microwave Therapy
- ⁷ Laser Therapy
- ⁸ Stent
- ⁹ Other

specify: **(WCTITX)** _____

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

YES ¹ NO ²

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

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

YES ¹ NO ²

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 _____