Patient number

Date form completed
month

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)** ☐☐

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)** ☐☐

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 [ ][ ][ ][ ][ ] Date form completed [ ][ ][ ] month day year

D. AUA Symptom Score Specification

1 Specify the type of AUA Symptom Score event (check one) **(WSSTYP)**

[1] 4 point event

[2] 8 point event

2. AUA Symptom Score:

a. Baseline **(WSSBAS)** [ ][ ]

b. Initial Event **(WSSIEV)** [ ][ ]

c. Confirming Event **(WSSCEV)** [ ][ ]

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 [1] NO [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

1. Creatinine results

a. Baseline **(WCRBAS)** [ ][ ].[ ] mg/dl

b. Initial Event **(WCRIEV)** [ ][ ].[ ] mg/dl

c. Confirming Event **(WCRCEV)** [ ][ ].[ ] mg/dl

2. Date of initial event **(WCREVDT)** ☐☐/☐☐/☐☐ (month day year)

3. Was the patient taking coded medication(s)? **(WCRCODE)** YES ☐1 NO ☐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 ☐1 NO ☐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 **(WUEEVDT)** ☐☐/☐☐/☐☐ (month day year)

3. Was the patient taking coded medication(s)? **(WUECODE)** YES ☐1 NO ☐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 [1] NO [2]

IF NO

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

G. Treatment Non-compliance Specification

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

_____

_____

2. Coded medication(s) discontinued:

[1] Doxazosin **(WTNMDD)**

[1] Finasteride **(WTNMDF)**

3. Date coded medications discontinued **(WTNMDDT)** ☐☐ 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)** ☐☐ month ☐☐ day ☐☐ year

. Conclusion of Report

1 Additional comments:

_____

_____

_____

Initials of person completing form **(FORMIN)** ☐☐☐☐ first last

Date form completed **(FORMDT)** ☐☐ month ☐☐ day ☐☐ year

Signature _____