FORM NUMBER = (FORM)
FORM VERSION = (VERS)

Patient number ☐☐☐☐☐ Date form completed ☐☐ / ☐☐ / ☐☐
month day year

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

1 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)

☐ 6 Treatment non-compliance (Complete Section G)

☐ 6 Inactive follow-up (Complete Section H)

☐ 7 Crossover to known therapy (Complete Section I)

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

C. Death Specification

Date of death (WDDATE) [ ][ ][ ] month day year

2. Probable cause of death (WDCAUS)

D. AUA Symptom Score Specification

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

[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

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

Date of last visit (WSSLVST) [ ][ ][ ] month day year

Patient number ☐☐☐☐ Date form completed ☐☐ ☐☐ ☐☐
month day year

E. Creatinine Rise Specification

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

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

[1] Acute urinary retention event

[2] Recurrent urinary tract infection

[3] Incontinence event

2. Date of event (WUEEVDT) ☐☐ ☐☐ ☐☐
month day year

Patient number [ ][ ][ ][ ][ ] Date form completed [ ][ ][ ] 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

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

Crossover to Known Therapy Specification

Specify the primary reason for crossover to known therapy (WCTRSN)
(check one)

☐ 1 Medical therapy

☐ 2 Invasive therapy

If medical therapy, CONTINUE. If invasive therapy, SKIP to Question 3

2. Specify the medical therapy
(check all that apply)

☐ 1 Alpha-1 blocker (WCTMA1)

☐ 1 5-alpha inhibitor (WCTM5A)

☐ 1 Other medication (WCTMO)

specify: _____ (WCTMOX)

SKIP to Question 4

3. Specify the invasive therapy (WCTIT)
(check one)

☐ 1 TURP

☐ 2 TUIP

☐ 3 Radical prostatectomy

☐ 4 Open prostatectomy

4 Was the patient taking coded medication(s)? (WCTCODE) YES ☐ 1 NO ☐ 2

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

a. Coded medication(s) discontinued

☐ 1 Doxazosin (WCTMDD)

☐ 1 Finasteride (WCTMDF)

b Date coded medication(s) discontinued (WCTMDDT) ☐☐/☐☐/☐☐ (month day year)

Patient number ☐☐☐ Date form completed ☐☐/☐☐/☐☐ (month / day / year)

5. 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

1 Additional comments:

_____

_____

_____

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

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

Signature _____