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

NIH - BPH TRIAL

SERIOUS ADVERSE EVENT REPORT

This form is to be completed for any event listed on the Adverse Event Report (Form E05) that is serious.

Notify the Biostatistical Coordinating Center IMMEDIATELY and fax this form and the corresponding Form E05 to (301) 881-3589.

A. Report Identification

1. Clinic number **(CLINIC)** ☐☐

2. Patient Identification number (Complete a **OR** b)

   a. If before randomization, Screening number **(SCREEN)** S☐☐☐☐

   b. If after randomization, Patient number **(PATID)** ☐☐☐☐☐ (clinic / patient)

3. Patient's initials **(INITS)** ☐☐☐☐ (first / last)

4. Patient's date of birth **(DOB)** ☐☐ / ☐☐ / ☐☐ (month / day / year)

5. Date of report **(ZRIRDT)** ☐☐ / ☐☐ / ☐☐ (month / day / year)

6. Date of onset of adverse experience **(ZRIODT)** ☐☐ / ☐☐ / ☐☐ (month / day / year)

7. Type of report **(ZRITYP)**
   - ☐ 1 Initial
   - ☐ 2 Follow-up

8. Event Number (See Form E05) **(ZRIEVT)** ☐☐

B. General Classification

1. Adverse experience description

   a. Short description **(ZGCAE)**

   ☐

   b. COSTART description (See COSTART Term Coding Glossary) **(ZGCOSTG)**

   ☐

2. Did the adverse experience result in: (Check all that apply)
   - ☐ 1 Death **(ZGCDEA)**
   - ☐ 1 Required or prolonged hospitalization **(ZGCHOSP)**
   - ☐ 1 Permanent or severe disability **(ZGCDISA)**

   If Death checked, CONTINUE.
   If Death not checked, SKIP to Question 3.

Patient number | | | | | | Date of report | month | day | year |

a. Date of death **(ZGCDDT)** | month | day | year |

b. Probable cause of death **(ZGCDCAU)**

3. Was the adverse experience: (Check all that apply)
- [1] Congenital anomaly **(ZGCCONA)**
- [1] Cancer **(ZGCCAN)**
- [1] Life-threatening **(ZGCLIFE)**
- [1] Due to an overdose **(ZGCOVD)**
- [1] Treatment to prevent a serious event **(ZGCTXT)**

AT LEAST ONE ITEM IN QUESTIONS B.2 OR B.3 MUST BE CHECKED. CONTACT THE BIOSTATISTICAL COORDINATING CENTER STAFF IMMEDIATELY AT (301) 881-9260 AND FAX THE FORM TO (301) 881-3589.

C. Event Information

1. Onset of adverse experience **(ZEIONST)**
- [1] gradual
- [2] sudden
- [3] unknown

	YES	NO
2. Was the coded medication interrupted or stopped? **(ZEICINT)**	[1]	[2]

If YES, CONTINUE.
If NO, SKIP to Question 3.

a. Was the adverse experience reversible when the coded medication(s) was withdrawn? **(ZEICREV)**	[1]	[2]
b. Was the coded medication(s) re-started? **(ZEICRST)**	[1]	[2]

If YES, CONTINUE.
If NO, SKIP to Question 3.

i. Which coded medication(s) was re-started? (Check all that apply)
- [1] doxazosin **(ZEIRSTD)**
- [1] finasteride **(ZEIRSTF)**

ii. How long was the patient off coded medications? | | |
- [1] days
- **(ZEIOFFN)** [2] weeks **(ZEIOFFU)**
- [3] months

If the patient was off doxazosin coded medications for more than 3 days, doxazosin must be re-titrated when rechallenging.

	YES	NO
iii. Did the symptoms recur? **(ZEISREC)**	[1]	[2]

Patient number [ ][ ][ ][ ][ ] Date of report [ ][ ] month [ ][ ] day [ ][ ] year

3. Was the patient taking any medication other than the coded medications within 14 days of the onset of the adverse experience? **(ZEIMED)**

YES [1] NO [2]

If YES, list below:

	Medication	Dose	Start Date	Stop Date
a.	**(ZEIMEDA) (ZEICODA)**	**(ZEIDOSA)**	**(ZEISRTA)**	**(ZEISTPA)**
b.	**(ZEIMEDB) (ZEICODB)**	**(ZEIDOSB)**	**(ZEISRTB)**	**(ZEISTPB)**
c.	**(ZEIMEDC) (ZEICODC)**	**(ZEIDOSC)**	**(ZEISRTC)**	**(ZEISTPC)**
d.	**(ZEIMEDD) (ZEICODD)**	**(ZEIDOSD)**	**(ZEISRTD)**	**(ZEISTPD)**
e.	**(ZEIMEDE) (ZEICODE)**	**(ZEIDOSE)**	**(ZEISRTE)**	**(ZEISTPE)**
f.	**(ZEIMEDF) (ZEICODF)**	**(ZEIDOSF)**	**(ZEISRTF)**	**(ZEISTPF)**
g.	**(ZEIMEDG) (ZEICODG)**	**(ZEIDOSG)**	**(ZEISRTG)**	**(ZEISTPG)**
h.	**(ZEIMEDH) (ZEICODH)**	**(ZEIDOSH)**	**(ZEISRTH)**	**(ZEISTPH)**
i.	**(ZEIMEDI) (ZEICODI)**	**(ZEIDOSI)**	**(ZEISRTI)**	**(ZEISTPI)**
j.	**(ZEIMEDJ) (ZEICODJ)**	**(ZEIDOSJ)**	**(ZEISRTJ)**	**(ZEISTPJ)**

4. Describe the adverse experience in detail:

5. Overall severity of adverse experience (Check only one) **(ZEIOSEV)**

[1] mild
[2] moderate
[3] severe

6. Duration of adverse experience (Check only one) **(ZEIDUR)**

[1] < 1day
[2] 1day - 1week
[3] > 1week

Patient number | | | | | | Date of report | | | | month day year

7. Treatment administered for the adverse experience (Check only one) **(ZEITRT)**

- [1] none
- [2] self-treatment / OTC drug
- [3] outpatient - changes in medication
- [4] outpatient procedure
- [5] inpatient hospitalization

8. Outcome (Check only one) **(ZEIOUTC)**

- [1] recovered, no residual effect
- [2] residual effect, no treatment
- [3] residual effect, being treated
- [4] persistent, no treatment
- [5] persistent, being treated
- [6] death

D. Conclusion

1. Additional comments:

_____

_____

_____

Initials of person completing form **(FORMIN)** | | | | | first last Form entered in computer? [ ]

Signature of P.I. _____ Date _____