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

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

NIH - BPH TRIAL

ADVERSE EVENT REPORT

This form is to be completed if the patient has had any adverse experiences, drug reactions, side effects, abnormal laboratory values, hospitalizations, discontinued coded medications, other complications or pre-existing conditions that worsened.

If this is a SERIOUS event or the patient discontinued coded medications, this form should be FAXED to the Biostatistical Coordinating Center IMMEDIATELY at (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

B. General Classification

1. Adverse experience (short description) **(ZGICAE)** **(ZGCOSTG)**

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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)**

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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)**

IF ANY ITEM IN QUESTION B.2 OR B.3 IS CHECKED, THIS DOCUMENTS A SERIOUS ADVERSE EVENT. 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

2. Was the patient on coded medication at the time of the adverse experience? **(ZEICMED)**

YES [1] NO [2]

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

a. Was the adverse experience related to coded medication? **(ZEICREL)**

- [1] no
- [2] possibly
- [3] probably
- [4] unknown

b. Were the coded medications interrupted or stopped? **(ZEICINT)**

YES [1] NO [2]

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

i. Which coded medication(s) was interrupted or stopped? (Check all that apply)

- [1] doxazosin **(ZEIINTD)**
- [1] finasteride **(ZEIINTF)**

ii. Was the adverse experience reversible when the coded medication(s) was withdrawn? **(ZEICREV)**

YES [1] NO [2]

iii. Was the coded medication(s) re-started? **(ZEICRST)** [1] [2]

Patient number | | | | | |

Date of report | month | day | year |

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

a) Which coded medication(s) was re-started? (Check all that apply)

[1] doxazosin **(ZEIRSTD)**

[1] finasteride **(ZEIRSTF)**

b) How long was the patient off coded medications?

(ZEIOFFN) | | [1] days | [2] weeks | [3] months **(ZEIOFFU)**

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

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

3. Was the patient taking any medication other than the coded medications within 14 days of the onset of the adverse experience? **(ZEIMED)** [1] [2]

If YES, list below:

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

4. Describe the adverse experience in detail:

_____

_____

_____

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

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

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 _____