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

Patient number ☐☐☐☐☐

Date of visit ☐☐ month ☐☐ day ☐☐ year

NIH - BPH TRIAL

CREATININE RISE EVENT REPORT

This form should be completed if the patient experiences a rise in creatinine of 1.5 times the baseline value that is greater than or equal to 1.5 mg/dL.

A. Patient Identification

1. Patient number **(PATID)** ☐☐☐☐☐ clinic patient

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

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

B. Initial Creatinine Rise Event Visit

1. Date of initial event visit **(CVSTDT)** ☐☐ month ☐☐ day ☐☐ year

2. Week of initial event visit **(CIVWK)** ☐☐☐

3. Type of visit **(CIVTYP)**
   ☐ 1 Follow-up Visit
   ☐ 2 Interim Visit

4. Serum creatinine **(CIVSC)** ☐☐.☐ mg/dL

5. Is the value in question B.4 greater than or equal to 1.5 times the baseline serum creatinine (see patient label) and greater than or equal to 1.5 mg/dL? **(CIVGRT)**

YES	NO
☐ 1	☐ 2

If YES, CONTINUE.

The patient should be scheduled for a confirming visit within 4 weeks from initial creatinine rise visit.
The Interim Visit Checklist should also be completed during the confirming visit.

Patient number ☐☐☐☐☐ Date of visit ☐☐ ☐☐ ☐☐ (month day year)

C. Confirming Creatinine Rise Event Visit

1. Date of visit **(CCVDT)** ☐☐ ☐☐ ☐☐ (month day year)

2. Week of visit **(CCVWK)** ☐☐☐

3. Serum creatinine **(CCVSC)** ☐☐.☐ mg/dL

4. Is the value in question C.3 greater than or equal to 1.5 times the baseline serum creatinine (see patient label) and greater than or equal to 1.5 mg/dl? **(CCVGRT)** YES [1] NO [2]

If the serum creatinine in question C.3 is greater than or equal to 1.5 times the baseline serum creatinine and greater than or equal to 1.5 mg/dL, this documents a creatinine rise event. If the patient is on coded medication, STOP ALL CODED MEDICATION.

5. Creatinine rise event declared? **(CCVDEC)** YES [1] NO [2]

If YES, CONTINUE.

6. Is the patient on coded medications? **(CCVMED)** YES [1] NO [2]

If YES, STOP ALL CODED MEDICATIONS AND CONTINUE.

7. Date coded medication discontinued **(CCVDISC)** ☐☐ ☐☐ ☐☐ (month day year)

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

Signature of P.I. _____ Date _____