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

                                                      YES   NO
5. Is the value in question B.4 greater than or equal to 1.5   ☐¹   ☐²
   times the baseline serum creatinine (see patient label) and
   greater than or equal to 1.5 mg/dL? **(CIVGRT)**

   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 _____