

Patient number

Date of visit / /
month day year

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

NIH - BPH CLINICAL TRIAL: PILOT STUDY

CREATININE RISE EVENT REPORT

This form should be completed if the patient experiences a rise in creatinine of 1.5 times the baseline value.

A. Patient Identification

1. Patient number (PATID)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
clinic			patient		

2. Patient's initials (INITS)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
first		last	

3. Patient's date of birth (DOB)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
month	day	year			

B. Initial Creatinine Rise Event Visit

1. Date of initial event visit (CVSTDT)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
month	day	year			

2. Week of initial event visit (CIVWK)

<input type="text"/>	<input type="text"/>	<input type="text"/>
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3. Type of visit (CIVTYP)

¹ Follow-up Visit
 ² Interim Visit

4. Serum creatinine (CIVSC)

<input type="text"/>	<input type="text"/>	.	<input type="text"/>	mg/dl
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5. Is the value in question B.4 greater than or equal to 1.5 times the baseline serum creatinine (see label)? (CIVGRT)

YES	NO
<input type="checkbox"/> ¹	<input type="checkbox"/> 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.

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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 label)? (CCVGRT) YES NO

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

5. Creatinine rise event declared? (CCVDEC) YES NO

If YES, CONTINUE.

6. Is the patient on coded medications? (CCVMED) YES NO

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

Date form completed (FORMDT)
month day year

Signature _____