Patient number | | | | | |

Date of visit | | month | | day | | year

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

NIH - BPH TRIAL

URINARY EVENT REPORT

This form should be completed if the patient experiences a urinary event listed in Section C.

Part I / IDENTIFICATION

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 Visit Information

1. Date of initial event visit **(NVSTDT)** | | month | | day | | year |
2. Week of initial event visit **(NVIWK)** | | |
3. Type of visit **(NVITYP)**
   - [1] Follow-up Visit
   - [2] Interim Visit

C. Urinary Event Identificaton

1. Type of event **(NSCEI)**
   - [1] Acute urinary retention event (Complete Part II)
   - [2] Recurrent urinary tract infection event (Complete Part III)
   - [3] Incontinence event (Complete Part IV)

Initials of person completing form **(FORMIN)** | | | | | first | last

Form entered in computer? [ ]

Signature of P.I. _____ Date _____

Patient number | | | | | |

Date of visit | | | | month day year

Part II / ACUTE URINARY RETENTION EVENT

A. Acute Retention Event

Complete this section if the patient is unable to urinate and requires a catheter.

1. Date of catheterization **(NARDTC)** | | | | month day year

2. Is there an obvious cause of urinary retention other than BPH (e.g. alpha sympathomimetic medications or anesthesia)? **(NAROBV)** YES [1] NO [2]

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

The catheter should be removed and the patient should try to void.

   a. Is the patient able to void with the catheter removed? **(NARVOID)** YES [1] NO [2]

If Question A.2.a is YES, this event should be recorded as an adverse event, but is not an acute urinary retention event. DO NOT STOP CODED MEDICATION.

If Question A.2 is NO or question A.2.a is NO, consultation with the Clinical Review Committee is required to declare an acute urinary retention event (i.e. discontinuation of coded medications)

3. Acute urinary retention event declared? **(NARDEC)** YES [1] NO [2]

   If YES, CONTINUE.

4. Date of confirmation by Clinical Review Committee **(NARCONF)** | | | | month day year

This documents an acute urinary retention event. If the patient is on coded medication, STOP ALL CODED MEDICATION.

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

   If YES, STOP ALL CODED MEDICATIONS AND CONTINUE.

6. Date coded medication discontinued **(NARDISC)** | | | | month day year

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

Part III / RECURRENT URINARY TRACT INFECTION EVENT

A. Documentation of Urinalysis Cultures

Complete this section if the patient has had 2 positive urinalysis cultures within 1 year.

1. Has the patient had two positive cultures within 1 year? **(NUT2CUL)** — YES [1] NO [2]

   If YES, CONTINUE.

   a. Date of first positive culture **(NUT1PC)** — month day year

   b. Date of negative culture **(NUTNC)** — month day year

   c. Date of second positive culture **(NUT2PC)** — month day year

Consultation with the Clinical Review Committee is required to declare a urinary tract infection event (i.e. discontinuation of coded medications).

2. Recurrent urinary tract infection event declared? **(NUTDEC)** — YES [1] NO [2]

   If YES, CONTINUE.

3. Date of confirmation by Clinical Review Committee **(NUTCONF)** — month day year

This documents a recurrent urinary tract infection event. If the patient is on coded medication, STOP ALL CODED MEDICATION.

4. Is the patient on coded medications? **(NUTMED)** — YES [1] NO [2]

   If YES, STOP ALL CODED MEDICATIONS AND CONTINUE.

5. Date coded medication discontinued **(NUTDISC)** — month day year

Patient number | | | | | |

Date of visit | month | day | year |

Part IV / INCONTINENCE EVENT

A. Documentation of Event

Complete this section if the patient has had an involuntary loss of urine that is socially or hygienically unacceptable.

1. Has the patient had an involuntary loss of urine that is socially or hygienically unacceptable? **(NINLU)** — YES [1] NO [2]

   If YES, CONTINUE.

Consultation with the Clinical Review Committee is required to declare an incontinence event (i.e. discontinuation of coded medications).

2. Incontinence event declared? **(NINDEC)** — YES [1] NO [2]

   If YES, CONTINUE.

3. Date of confirmation by Clinical Review Committee **(NINCONF)** — month | day | year

This documents an incontinence event. If the patient is on coded medication, STOP ALL CODED MEDICATION.

4. Is the patient on coded medications? **(NINMED)** — YES [1] NO [2]

   If YES, STOP ALL CODED MEDICATIONS AND CONTINUE.

5. Date coded medication discontinued **(NINDISC)** — month | day | year