Patient number [ ][ ][ ][ ][ ]

Date of visit [ ][ ] month [ ][ ] day [ ][ ] year

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

NIH - BPH TRIAL

INTERIM VISIT CHECKLIST

This form should be completed at any visits that are not scheduled follow-up visits.

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. Visit Information

1. Date of visit **(IVSTDT)** [ ][ ] month [ ][ ] day [ ][ ] year
2. Week of visit **(IVIWK)** [ ][ ][ ]

C. Reason for Interim Visit (Check all that apply)

Complete Parts II and III of this form for ALL reasons listed below.

1. AUA symptom score event **(IRAUA4)** [1] Complete AUA Symptom Score Event Report (Form E01)
2. Creatinine rise event **(IRCR)** [1] Complete Creatinine Rise Event Report (Form E02)
3. Acute urinary retention event **(IRUR)** [1]
4. Recurrent urinary tract infection event **(IRUTI)** [1]
5. Incontinence event **(IRINC)** [1]

   Complete Urinary Event Report (Form E03)
6. Adverse event **(IRAE)** [1] Complete Adverse Event Report (Form E05)
7. Blood pressure management **(IRBPM)** [1]
8. Dispense medication **(IRMED)** [1]

   Complete Parts II and III of this form ONLY
9. Intercurrent illness event **(IRII)** [1] Complete Part IV of this form

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

Part II / VITAL SIGNS

D. Blood Pressure Readings

1. Supine Blood Pressure (After lying 5 minutes)

a. Blood Pressure **(IBPLS)/(IBPLD)** ☐☐☐ / ☐☐☐ mmHg

b. Heart Rate **(IBPLHR)** ☐☐☐ bpm

2. Standing Blood Pressure (Immediately)

a. Blood Pressure Reading 1 **(IBPSS1)/(IBPSD1)** ☐☐☐ / ☐☐☐ mmHg

b. Heart Rate 1 **(IBPSHR1)** ☐☐☐ bpm

Wait 2 minutes

c. Blood Pressure Reading 2 **(IBPSS2)/(IBPSD2)** ☐☐☐ / ☐☐☐ mmHg

d. Heart Rate 2 **(IBPSHR2)** ☐☐☐ bpm

E. Orthostatic Hypotension

1. Did the patient have orthostatic hypotension? **(IORTHYP)** YES [1] NO [2]

Orthostatic hypotension is defined as a decrease of more than 20mmHg in supine to standing systolic blood pressure or a decrease of more than 10mmHg in supine to standing diastolic blood pressure (in either standing blood pressure reading) or the development of significant postural hypotension.

Part III / MEDICATION DISPENSING AND COMPLIANCE

F. Number of days since last visit **(IDDAYS)** ☐☐☐

G. Doxazosin Compliance

If doxazosin was dispensed at the last visit, returned and/or dispensed today, CONTINUE.
If not, SKIP to Section H.

1. Dose of doxazosin **(IDDDOSE)** 1 mg [1] 2 mg [2] 4 mg [3] 8 mg [4]

2. Number of doxazosin tablets dispensed at the last visit **(IDDDISL)** ☐☐☐

3. Number of doxazosin tablets returned today **(IDDRET)** ☐☐☐

4. Compliance **(IDDCOMP)**

$$\frac{\text{tabs dispensed (\#2) - tabs returned (\#3)}}{\text{days since last visit (question F)}} \times 100 = \square\square\square\square\ \%$$

NOTE: Counsel patient if less than 80% compliant with doxazosin.

5. Number of doxazosin tablets dispensed today **(IDDDIST)** ☐☐☐

H. Finasteride Compliance

If finasteride was dispensed at the last visit, returned and/or dispensed today, CONTINUE.
If not, SKIP to Section I.

1. Number of finasteride tablets dispensed at the last visit **(IDFDISL)** ☐☐☐

2. Number of finasteride tablets returned today **(IDFRET)** ☐☐☐

3. Compliance **(IDFCOMP)**

$$\frac{\text{tabs dispensed (\#1) - tabs returned (\#2)}}{\text{days since last visit (question F)}} \times 100 = \square\square\square\square\ \%$$

NOTE: Counsel patient if less than 80% compliant with finasteride.

4. Number of finasteride tablets dispensed today **(IDFDIST)** ☐☐☐

I. Concomitant Medications

	YES	NO
1. Is the patient currently taking coded doxazosin? **(IDDCODE)**	☐ 1	☐ 2
2. Is the patient currently taking coded finasteride? **(IDFCODE)**	☐ 1	☐ 2

Part IV / INTERCURRENT ILLNESS EVENT

J. Intercurrent Illness Information

1. Specify intercurrent illness: **(IIISPEC)**

_____

_____

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

	YES	NO
2. Is this a serious event? **(IIISE)**	1	2

3. Specify action taken: **(IIIACT)**

_____

_____

4. Intercurrent illness event declared? **(IIIDEC)**	1	2

Consultation with the Clinical Review Committee is required to declare an intercurrent illness stop point (i.e. discontinuation of coded medications).

If YES:

a. Date of confirmation by Clinical Review Committee **(IIICONF)** ☐☐ month ☐☐ day ☐☐ year

Signature of P.I. ____ Date _____

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

Form entered in computer? ☐