Patient number | | | | | |

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

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

NIH - BPH CLINICAL TRIAL: PILOT STUDY

TRUS AND BIOPSY INFORMATION

This form should be completed at Screening Visit 2 and Six -month or End of Study Visit.

Part I / IDENTIFICATION

A. Patient Identification

1. Clinic number **(CLINIC)** | | |

2. Patient Identification number

   a. If before randomization, Screening number **(SCREEN)** | S | | | | |

   b. If after randomization, Patient number **(PATID)** | | | | | | clinic | patient |

3. Patient's initials **(INITS)** | | | | | first | last |

4. Patient's date of birth **(DOB)** | | month | | day | | year |

B. Visit Information

1. Date of visit **(TVSTDT)** | | month | | day | | year |

2. Type of visit **(TVITYP)**

   [1] Screening Visit 2

   [2] 6-month or End of Study Visit

3. If 6-month or End of Study Visit, week of visit **(TVIWK)** | | | |

4. Sonologist's initials **(TVISONI)** | | | | | first | last |

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

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

Part II / TRUS INFORMATION

C. Ultrasound Measurements

1. Total Gland

a. Transverse view

i. Height [ ][ ][ ] cm **(TUGTH)**

ii. Width [ ][ ][ ] cm **(TUGTW)**

b. Longitudinal view

i. Height [ ][ ][ ] cm **(TUGLH)**

ii. Length [ ][ ][ ] cm **(TUGLL)**

c. Ellipsoid volume (machine read) [ ][ ][ ] cc **(TUGEV)**

2. Transition Zone

a. Transverse view

i. Height [ ][ ][ ] cm **(TUZTH)**

ii. Width [ ][ ][ ] cm **(TUZTW)**

b. Longitudinal view

i. Height [ ][ ][ ] cm **(TUZLH)**

ii. Length [ ][ ][ ] cm **(TUZLL)**

c. Ellipsoid volume (machine read) [ ][ ][ ] cc **(TUZEV)**

For each question in this section, please check all that apply.

3. The inner gland (transition zone) is:

- [1] Normal **(TUIGN)**
- [1] BPH **(TUIGB)**
- [1] Calculi **(TUIGC)**
- [1] Other **(TUIGO)**

4. The peripheral zone is:

- [1] Normal **(TUPZN)**
- [1] Hypoechoic **(TUPZH)**
- [1] Calculi **(TUPZCA)**
- [1] Cyst **(TUPZCY)**
- [1] Vascular **(TUPZV)**

5. The surgical capsule is:

- [1] Normal **(TUSCN)**
- [1] Calculi **(TUSCC)**
- [1] Distorted **(TUSCD)**

6. The capsule is:

- [1] Intact **(TUCINT)**
- [1] Penetrated **(TUCPEN)**
- [1] Suspicious **(TUCSUS)**

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

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

D. Biopsy Sites

Please mark biopsy sites with an "X".

Part III / DIAGNOSTIC CENTER MAILING INFORMATION

E. Mailing Information

1. Date tissue sent to the Diagnostic Center **(TMIDT)** [|][|][|]
month day year

Initials of person completing form **(FORMIN)** [ ][ ][ ][ ]
first last

Date form completed **(FORMDT)** [|][|][|]
month day year

Signature