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

NIH - BPH CLINICAL TRIAL

MISSED BIOPSY REPORT

This form should be completed for a patient in the biopsy substudy on active follow-up, any time after randomization that a biopsy should be performed but is not performed. These visits are end-year 1 visit, primary endpoint declaration and end-of-study. Biopsies need not be performed if the patient has been diagnosed with prostate cancer, has crossed over to known invasive therapy or has had a biopsy within 3 months prior to the visit.

| 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. <u>Visit Information</u> | |
| 1. Date of follow-up visit (YVSTDT) | month day year |
| 2. Week of visit (YVIWK) | |
| 3. Type of visit (YVITYP) | End-year 1 Major Follow-up Visit Primary Endpoint Declaration End-of-Study |
| Reason biopsy was not performed (YVIREAS) | 1 |
| | |
| | |
| | |
| | |
| | |
| Initials of person completing form (FORMIN) | Form entered in computer? |