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

NIH - BPH CLINICAL TRIAL

FINAL STATUS REPORT FOR INACTIVE PATIENTS

This form is completed for all patients who are inactive prior to death or the administrative censoring date of November 30, 2001. The purpose of this form is to document the final status of the aforementioned patients as of November 30, 2001.

A. Patient Identification

1. Clinic number **(CLINIC)** ☐☐

2. Patient Identification number **(PATID)** ☐☐☐☐☐ (clinic / patient)

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

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

B. Last Visit Information

The last completed follow-up visit includes all visits that the patient attended in person (i.e. this does not include Interim Visits for which medications were mailed.)

1. Date of last completed follow-up visit **(SVSTDT)** ☐☐ / ☐☐ / ☐☐ (month / day / year)

2. Specify the classification of this patient at the last completed follow-up visit. (check all that apply)

1	Initiated open-label medication (SKIP Section C) **(SLVCOL)**
1	Crossed over to invasive therapy (SKIP Section D) **(SLVCIT)**
1	Diagnosis of prostate cancer (SKIP Section E) **(SLVCPC)**
1	Diagnosis of bladder cancer (SKIP Section F) **(SLVCBC)**
1	None of the above **(SLVCNO)**

C. Open-label Medication Status

1. Did the patient initiate open-label medication since the last completed follow-up visit? **(SOLSTAT)**

YES	NO	Unknown
1	2	3

If NO or Unknown, SKIP to Section D, if applicable.
If YES, CONTINUE. Please answer the following questions for the first dispensing of open-label medications only.

a. Specify the medical therapy: (Check all that apply)

1	Alpha-1 blocker **(SOLMA1)**
1	5-alpha inhibitor **(SOLM5A)**
1	Hormonal therapy **(SOLMHT)**
1	Other medication, specify below **(SOLMO)**
	(SOLMOX)

b. Date open-label medications dispensed **(SOLDT)** | | | | month day year

D. Crossover to Invasive Therapy Status

1. Did the patient cross over to invasive therapy since the last completed follow-up visit? **(SITSTAT)** YES 1 NO 2 Unknown 3

If NO or Unknown, SKIP to Section E, if applicable.
If YES, CONTINUE. Please answer the following questions for the first invasive therapy performed.

a. Specify the invasive therapy: (Check one.) **(SITITS)**

1	TURP	7	Laser Therapy
2	TUIP	8	Stent
3	Radical prostatectomy	9	External Beam Radiation
4	Open prostatectomy	10	Radiation Seeds
5	TUNA	11	Other, specify below
6	Microwave Therapy		**(SITITSX)**

b. Date of crossover to invasive therapy **(SITDT)** | | | | month day year

E. Prostate Cancer Status

1. Has the patient been diagnosed with prostate cancer since the last completed follow-up visit? **(SPCSTAT)** YES 1 NO 2 Unknown 3

If YES, CONTINUE.
If NO or Unknown, SKIP to Section F.

a. Date of cancer diagnosis **(SPCDT)** | | | | month day year

b. Did the patient undergo an invasive therapy after diagnosis of prostate cancer that was not captured in Section D? **(SPCIT)** YES 1 NO 2 Unknown 3

If NO or Unknown, SKIP to Section F, if applicable.
If YES, CONTINUE.

i. Specify the invasive therapy: (Check one.) **(SPCITS)**

1	TURP	7	Laser Therapy
2	TUIP	8	Stent
3	Radical prostatectomy	9	External Beam Radiation
4	Open prostatectomy	10	Radiation Seeds
5	TUNA	11	Other, specify below
6	Microwave Therapy		**(SPCITSX)**

ii. Date of crossover to invasive therapy **(SPCITDT)** | | | | month day year

F. Bladder Cancer Status

1. Has the patient been diagnosed with bladder cancer since the last completed follow-up visit? **(SBCSTAT)** YES 1 NO 2 Unknown 3

Patient number ☐☐☐☐☐ Date form completed ☐☐ month ☐☐ day ☐☐☐☐ year

If question F.1 is answered YES, CONTINUE.
If question F.1 is answered NO or Unknown, SKIP to Section G.

a. Date of cancer diagnosis **(SBCDT)** ☐☐ month ☐☐ day ☐☐☐☐ year

b. Did the patient undergo an invasive therapy after diagnosis of bladder cancer that was not captured in Section D? **(SBCIT)** YES ☐ 1 NO ☐ 2 Unknown ☐ 3

If NO or Unknown, SKIP to Section G, if applicable.
If YES, CONTINUE.

i. Specify the invasive therapy: (Check one.) **(SBCITS)**

1	TURP	7	Laser Therapy
2	TUIP	8	Stent
3	Radical prostatectomy	9	External Beam Radiation
4	Open prostatectomy	10	Radiation Seeds
5	TUNA	11	Other, specify below
6	Microwave Therapy		**(SBCITSX)**

ii. Date of crossover to invasive therapy **(SBCITDT)** ☐☐ month ☐☐ day ☐☐☐☐ year

G. Mortality Status

1. Has the patient died since the last completed follow-up visit? **(SDESTAT)** YES ☐ 1 NO ☐ 2 Unknown ☐ 3

If YES, CONTINUE.
If NO or Unknown, SKIP to Section H.

a. Date of death **(SDEDT)** ☐☐ month ☐☐ day ☐☐☐☐ year

b. Probable cause of death **(SDECAUS)**

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H. Conclusion of Report

1. Additional comments:

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_____

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_____

Initials of person completing form **(FORMIN)** ☐☐☐☐ first last Form entered in computer? ☐

Signature of P.I. _____ Date _____