FORM TITLE: **After-Treatment Follow Up**
Relevant SOP: Treatment Assessment and Data Monitoring (SOP TA)

Instructions: *Complete this form for the time points indicated below and attach copies of all relevant documentation. Submit completed form and attachments to Sponsor.*

Protocol Case #: _____ **Date of Visit:** _____MM/_____DD/_____YY

Patient Name: _____ **or Initials and DOB:** _____MM/_____DD/_____YY

A. Time Points calculated from the completion of radiation

☐ 3 months*+
☐ 6 months
☐ 12 months+
☐ 18 months
☐ 24 months

Schedule prostate biopsy (22-26 months after radiation completion)
Date planned: _____ or
Date completed: _____
Send biopsy slides with PT form

☐ After 24 months visit (every 6 months)

After 5 years, use Long Term Follow Up form (form LT)

(If visit occurs before 3 months as standard of care, please provide a one-time Variance form for your institution)*
(+AT 3 and 12 months, also send BS form if participating in optional blood collection for immune studies)

(*Follow-up for patients with treatment failure or discontinuation please indicate the closest time point above and provide prostate cancer general health status data from SOC visits).*

B. Evaluations:

History and physical/clinical note attached: ☐ Yes ☐ No

Are there GI or urinary symptoms? ☐ Yes ☐ No If yes, complete page 3.

Are there *new* medical problems? ☐ Yes ☐ No If yes, complete page 2 or attach institutional form.

DRE performed (if standard of care)? ☐ Yes ☐ No

DRE result: ☐ normal or ☐ abnormal. If known, estimated dimensions (cm): _____x_____ or volume ____

Other details (if not in the clinical note): _____

PSA* (as per standard of care) result attached? ☐ Yes, If No, explain: _____

**If progression/recurrence suspected, required studies prior to declaring failure are listed on Form TF.*

Other if clinically indicated (e.g., imaging): ☐ Yes ☐ No If yes, specify: _____

QOL attached (required until the 24-month visit)**?** ☐ Yes ☐ No If no, explain: _____

C. Additional Treatment for Prostate Cancer

If the patient is thought to have developed recurrence since last visit, contact Sponsor prior to patient receiving additional therapy to discuss plan and decide whether a Treatment Failure form (TF) is needed.

Has patient developed recurrence/progression? ☐ Yes ☐ No

Has patient received additional treatment for prostate cancer since the last visit? ☐ Yes ☐ No

If yes, please indicate treatment received:

D. New Medical Problems

If patient has been diagnosed with any new medical problems, please describe below:

Diagnosis

Autoimmune/Rheumatological _____

Comments: _____

Cardiovascular _____

Comments: _____

Dermatologic _____

Comments: _____

Endocrine_____

Comments: _____

Gastrointestinal_____

Comments: _____

Hematologic/Oncologic _____

Comments: _____

Infection (chronic) _____

Comments: _____

Neurological_____

Comments: _____

Orthopedic/Musculoskeletal _____

Comments: _____

Pulmonary/Upper Respiratory _____

Comments: _____

Psychiatric_____

Comments: _____

Renal/Genitourinary _____

Comments: _____

Sexual/Reproductive _____

Comments: _____

Surgical _____

Comments: _____

Other: _____

General Comments:

E. Gastrointestinal & Urinary Symptom Grading: If present, check the grade.

ADL= Activities of daily living

	Symptom	CTC Grade 1	CTC Grade 2	CTC Grade 3	CTC Grade 4
Gastrointestinal	**Constipation**	☐ Occasional/intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema	☐ Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL	☐ Obstipation with manual evacuation indicated; limiting self-care ADL	☐ Life-threatening consequences; urgent intervention indicated
	Diarrhea	☐ Increase of <4 stools per day over baseline	☐ Increase of 4 – 6 stools per day over baseline	☐ ≥7 stools per day over baseline; incontinence; hospitalization indicated	☐ Life-threatening consequences; urgent intervention indicated
	Fecal incontinence	☐ Occasional use of pads required	☐ Daily use of pads required	☐ Severe symptoms; elective operative intervention indicated	-
	Hemorrhoids	☐ Asymptomatic; clinical or diagnostic observations only; intervention not indicated	☐ Symptomatic; banding or medical intervention indicated	☐ Severe symptoms; radiologic, endoscopic or elective operative intervention indicated	-
	Proctitis	☐ Rectal discomfort, intervention not indicated	☐ Symptoms (e.g., rectal discomfort, passing blood or mucus); medical intervention; limiting instrumental ADL	☐ Severe symptoms; fecal urgency or stool incontinence; limiting self-care ADL	☐ Life-threatening consequences; urgent intervention indicated
	Rectal hemorrhage	☐ Mild; intervention not indicated	☐ Moderate symptoms; medical intervention or minor cauterization indicated	☐ Transfusion, radiologic, endoscopic, or elective operative intervention indicated	☐ Life-threatening consequences; urgent intervention indicated
	Other, specify:	☐	☐	☐	☐
Renal/Urinary	**Hematuria**	☐ Asymptomatic; clinical or diagnostic observations only; intervention not indicated	☐ Symptomatic; urinary catheter or bladder irrigation indicated; limiting instrumental ADL	☐ Gross hematuria, transfusion, IV medication or hospitalization; elective endoscopic, radiologic or operative intervention; limiting self-care ADL	☐ Life-threatening consequences; urgent radiologic or operative intervention indicated
	Urinary frequency	☐ Present	☐ Limiting instrumental ADL; medical management indicated	-	-
	Urinary incontinence	☐ Occasional (e.g., with coughing, sneezing, etc.), pads not indicated	☐ Spontaneous; pads indicated; limiting instrumental ADL	☐ Intervention indicated (e.g. clamp, collagen injections, operation); limiting self-care ADL	-
	Urinary retention	☐ Catheter placement not indicated; able to void with some residual	☐ Placement of urinary, suprapubic or intermittent catheter or medication indicated	☐ Elective operative or radiologic intervention; substantial loss of affected kidney function or mass	☐ Life-threatening consequences; organ failure; urgent operative intervention indicated
	Urinary tract pain	☐ Mild pain	☐ Moderate pain; limiting instrumental ADL	☐ Severe pain; limiting self-care ADL	-
	Urinary urgency	☐ Present	☐ Limiting instrumental ADL; medical management indicated	-	-
	Other, specify:	☐	☐	☐	☐

Name and Signature of the person who completed this form _____