Follow Up: Prostate

V4.5

Tissue Source Site (TSS) Name: _____ TSS Identifier: _____ TSS Unique Patient #: _____

Completed By: _____ Completion Date (MM/DD/YYYY):_____

Form Notes: *A Follow-up Form is to be completed for any of the following reasons: 1) For each additional new tumor event identified at the time of enrollment or follow-up submission; or 2) 12 months after a case is shipped to the Biospecimen Core Resource (BCR) for cases that have qualified. All information provided on this form includes activity from the "Date of Last Contact" provided on the TCGA Enrollment Form to the most recent date of contact with the patient. This form should only be completed by the Tissue Source Site if updated information can be provided to TCGA. Questions regarding this form should be directed to the Tissue Source Site's (TSS) primary Clinical Outreach Contact at the BCR.*

The following definitions for the use of "Unknown" and "Not Evaluated" on this form are as follows:

Unknown: This answer option should only be selected if the TSS cannot answer the question because the answer is not known at the TSS. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing the reason why the answer is unknown.

Not evaluated: This answer option should be selected by the TSS if it is known that the information being requested cannot be obtained due to the test not being performed.

Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
1	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	☐ Yes ☐ No	Please note that time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box to the left. ***Note 1: Provided time intervals must begin with the date of initial pathologic diagnosis. (i.e., biopsy or resection)*** ***Note 2: Only provide interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.***
2	Reason For Follow-up Form Submission	☐ Scheduled (Routine) Follow-up Submission ☐ Additional New Tumor Event	3233305 Indicate the reason for submission of this follow-up form. If scheduled follow-up, complete entire form. If additional new tumor event, complete only questions pertaining *to new tumor*.
3	Is This Patient Lost to Follow-up?	☐ Yes ☐ No	61333 Indicate whether the patient is lost to follow-up as defined by the ACoS Commission on Cancer. This only includes cases where updated information has not been collected within the last 15 months. If the patient is lost to follow-up, the remaining questions may be left unanswered. ***Note: If the patient is deceased and a TCGA Follow-up Form has not yet been completed, the answer to this question should be "No" and the remaining applicable questions should be completed.***
4	Adjuvant Post-operative Radiation Therapy	☐ Yes ☐ No ☐ Unknown	2005312 Indicate whether the patient had adjuvant/ post-operative radiation therapy. ***Note: If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.***
5	Adjuvant Post-operative Pharmaceutical Therapy (Includes Hormonal Therapy)	☐ Yes ☐ No ☐ Unknown	2785850 Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. ***Note: If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.***
6	Measure of Success of Outcome at the Completion of Initial First Course Treatment (surgery and adjuvant therapies)	☐ Progressive Disease ☐ Stable Disease ☐ Partial Response ☐ Complete Response ☐ Not Applicable ☐ Unknown	2786727 Provide the patient's response to their initial first course treatment.
7	Vital Status(at time of last contact)	☐ Living ☐ Deceased	5 Indicate whether the patient was living or deceased at the date of last contact.

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Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
Date Of Last Contact(or date of death, if deceased)			
8	Month Of Last Contact	☐☐ (MM)	2897020 Provide the month of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). ***Note: Do not answer this question if the patient is deceased***
9	Day Of Last Contact	☐☐ (DD)	2897022 Provide the day of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). ***Note: Do not answer this question if the patient is deceased.***
10	Year Of Last Contact	☐☐☐☐ (YYYY)	2897024 Provide the year of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). ***Note: Do not answer this question if the patient is deceased.***
11	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____	3008273 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of Last Contact. ***Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.***
Date of Death		☐ Not Applicable (Patient is Alive)	
12	Month of Death	☐☐ (MM)	2897026 If the patient is deceased, provide the month of death.
13	Day of Death	☐☐ (DD)	2897028 If the patient is deceased, provide the day of death.
14	Year of Death	☐☐☐☐ (YYYY)	2897030 If the patient is deceased, provide the year of death.
15	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____	3165475 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of Death. ***Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.***
16	Tumor Status	☐ Tumor Free ☐ With Tumor ☐ Unknown Tumor Status	2759550 Indicate whether the patient was tumor/disease free from the tumor submitted for TCGA at the date of last contact or death.
17	Cause of Death	☐ Prostate Cancer ☐ Other Malignancy (not prostate cancer related) ☐ Other Non-Malignant Disease ☐ Unknown Cause of Death	2554674 Indicate the patient's cause of death.
18	Source of Death Information	☐ Death Certificate ☐ Medical Record ☐ Autopsy	2390921 Indicate the source used to identify the patient's cause of death.
19	New Tumor Event After Initial Treatment?	☐ Yes ☐ No ☐ Unknown	3121376 Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after their initial treatment for the tumor submitted to TCGA. ***Note: If the patient had multiple new tumor events, a follow-up form should be completed for each new tumor event.***

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Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
20	Type of New Tumor Event After Initial Treatment	☐ Biochemical Evidence of Disease (*Defined as two or more consecutively elevated PSA results greater than 0.2ng/ml.)* ☐ Locoregional Recurrence ☐ Distant Metastasis ☐ New Primary Tumor (Non-Prostatic)	3119721 Indicate whether the patient's new tumor event was a biochemical recurrence, a locoregional recurrence or a distant metastasis of the tissue submitted for TCGA; or a new primary tumor. ***Note: If there are additional documented biochemical recurrences during this time period, a follow-up form must be completed to capture the second and/ or third biochemical recurrences as each is considered to be a "New Tumor Event".***
Date of First Biochemical Recurrence		☐ Not Applicable (Patient has not had Biochemical Recurrence or the recurrence is not the first recurrence) ***Note: Documentation of Type of Hormonal Therapy Given as well as Start and End Dates Should be Provided by Completing the Supplemental Pharmaceutical Therapy Form***	
21	Month of First Biochemical Recurrence	☐☐ (MM)	3351905 Provide the month of the first biochemical recurrence, as reported by the patient's physician or medical record. ***Note: Do not answer this question if the patient has not had a biochemical recurrence.***
22	Day of First Biochemical Recurrence	☐☐ (DD)	3351906 Provide the day of the first biochemical recurrence, as reported by the patient's physician or medical record. ***Note: Do not answer this question if the patient has not had a biochemical recurrence.***
23	Year of First Biochemical Recurrence	☐☐☐☐ (YYYY)	3351907 Provide the year of the first biochemical recurrence, as reported by the patient's physician or medical record ***Note: Do not answer this question if the patient has not had a biochemical recurrence.***
24	Number of Days from Date of Initial Pathologic Diagnosis to Date of First Biochemical Recurrence	_____	3414609 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of first biochemical recurrence. ***Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.***
Date of New Tumor Event After Initial Treatment		☐ Not Applicable	
25	Month of New Tumor Event After Initial Treatment	☐☐ (MM)	3104044 If the patient had a new tumor event, provide the month of diagnosis for this new tumor event.
26	Day of New Tumor Event After Initial Treatment	☐☐ (DD)	3104042 If the patient had a new tumor event, provide the day of diagnosis for this new tumor event.
27	Year of New Tumor Event After Initial Treatment	☐☐☐☐ (YYYY)	3104046 If the patient had a new tumor event, provide the year of diagnosis for this new tumor event.
28	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment	_____	3392464 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of new tumor event. ***Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.***
29	Site of New Tumor Event (Metastases)	☐ Bone ☐ Liver ☐ Peritoneal Surfaces ☐ Lung ☐ Other (please specify) ☐ Non-Regional / Distant Lymph Nodes	3108271 Indicate the site of this new metastatic tumor event, as it relates to the tissue submitted for TCGA.

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Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
30	Other Site of New Tumor Event – (Metastasis) (please specify)	_____	3128033 If the metastatic site is not included in the list for the question above, designate the site of this new metastatic tumor event.
31	Progression of Disease After Hormonal Therapy	☐ Yes ☐ No ☐ Unknown	3158820 Indicate whether the patient has had a progression or relapse of his prostate cancer following administration of a planned course of hormonal therapy.
32	Type of Progression After Hormonal Therapy	☐ Biochemical Recurrence (*Defined as two or more consecutively elevated PSA results greater than 0.2ng/ml.)* ☐ Distant Metastasis	3241479 If the patient had progression or relapse of his prostate cancer after hormonal treatment, indicate the type of progression.
Date of Second Biochemical Recurrence		☐ Not Applicable (Patient has not had Second Biochemical Recurrence or the recurrence is not the second recurrence) ***Note: Documentation of Type of Hormonal Therapy Given as well as Start and End Dates Should be Provided by Completing the Supplemental Pharmaceutical Therapy Form***	
33	Month of Second Biochemical Recurrence	☐☐ (MM)	3351908 Provide the month of the second biochemical recurrence, as reported by the patient's physician or medical record. ***Note: Do not answer this question if the patient has not had a second biochemical recurrence.***
34	Day of Second Biochemical Recurrence	☐☐ (DD)	3351911 Provide the day of the second biochemical recurrence, as reported by the patient's physician or medical record. ***Note: Do not answer this question if the patient has not had a second biochemical recurrence.***
35	Year of Second Biochemical Recurrence	☐☐☐☐ (YYYY)	3351916 Provide the year of the second biochemical recurrence, as reported by the patient's physician or medical record. ***Note: Do not answer this question if the patient has not had a second biochemical recurrence.***
36	Number of Days from Date of Initial Pathologic Diagnosis to Date of Second Biochemical Recurrence	_____	3414617 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of second biochemical recurrence. ***Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.***

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Question#	Data Element Label	Data Entry Alternatives	CDE ID With Working Instructions
Date of Third Biochemical Recurrence		☐ Not Applicable (Patient has not had Third Biochemical Recurrence or the recurrence is not the third recurrence) ***Note: Documentation of Type of Hormonal Therapy Given as well as Start and End Dates Should be Provided by Completing the Supplemental Pharmaceutical Therapy Form***	
37	Month of Third Biochemical Recurrence	☐☐ (MM)	3351910 Provide the month of the third biochemical recurrence, as reported by the patient's physician or medical record. ***Note: Do not answer this question if the patient has not had a third biochemical recurrence.***
38	Day of Third Biochemical Recurrence	☐☐ (DD)	3351913 Provide the day of the third biochemical recurrence, as reported by the patient's physician or medical record. ***Note: Do not answer this question if the patient has not had a third biochemical recurrence.***
39	Year of Third Biochemical Recurrence	☐☐☐☐ (YYYY)	3351917 Provide the year of the third biochemical recurrence, as reported by the patient's physician or medical record. ***Note: Do not answer this question if the patient has not had a third biochemical recurrence.***
40	Number of Days from Date of Initial Pathologic Diagnosis to Date of Third Biochemical Recurrence	_____	3414621 Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of third biochemical recurrence. ***Note: Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.***
41	Additional Treatment of New Tumor Event Radiation Therapy	☐ Yes ☐ No ☐ Unknown	3008761 Indicate whether the patient received radiation treatment for this new tumor event. ***Note: If the patient did have radiation for this new tumor event, the Radiation Supplemental Form should be completed.***
42	Additional Treatment of New Tumor Event Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	2650646 Indicate whether the patient received pharmaceutical treatment for this new tumor event. ***Note: If the patient did have radiation for this new tumor event, the Radiation Supplemental Form should be completed.***
43	Measure of Success of Outcome at the Completion of This Follow-up Submission	☐ Not Applicable ☐ Partial Response ☐ Progressive Disease ☐ Complete Response ☐ Stable Disease ☐ Unknown	3104050 Provide the patient's outcome of treatment up to the point of the current follow-up data submission.

Comments:

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_____

Principal Investigator Name: _____ Principal Investigator Signature: _____

Date Signed (MM/DD/YYYY): _____