Instructions: The Enrollment Form should be completed for each TCGA qualified case, upon qualification notice from the BCR. All information provided on this form should include activity from the date of initial diagnosis to the most recent date of contact with the patient ("Date of Initial Pathologic Diagnosis" and "Date of Last Contact" on this form).

Questions regarding this form should be directed to the Tissue Source Site's primary Clinical Outreach Contact at the BCR.

Please note the following definitions for the "Unknown" and "Not Evaluated" answer options on this form.

Unknown: This answer option should only be selected if the TSS does not know this information after all efforts to obtain the data have been

pı N	rovid ot Ev	ling a reason why the answer valuated: This answer option	is unknown. should only be selected by the TSS if it is known that	ed data set, the TSS must complete a discrepancy note the information being requested cannot be obtained. This ws that the information requested was never disclosed.	
Ti	ssue Source Site (TSS):TSS Identifier:TSS Unique Patient Identifier:				
Co	omp	leted By (Interviewer Name	in OpenClinica):	Completed Date:	
G	ene	ral Information			
L	#	Data Element	Entry Alternatives	Working Instructions	
	1	Is this a prospective tissue collection?	☐ Yes ☐ No	Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively. 3088492	
	2	Is this a retrospective tissue collection?	□ Yes □ No	Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively. 3088528	
P	atie	nt Information			
	#	Data Element	Entry Alternatives	Working Instructions	
	3*	Date of Birth	//	Provide the date the patient was born. 2896950 (month), 2896952 (day), 2896954 (year) Note: The day of Birth is not required.	
	4*	Race	☐ American Indian or Alaska Native ☐ Asian ☐ White ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander: ☐ Not Evaluated ☐ Unknown	Provide the patient's race using the defined categories. 2192199 American Indian or Alaska Native: A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment. Asian: A person having origins in any of the original peoples of the far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. White: A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa. Black or African American: A person having origins in any of any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." Native Hawaiian or other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. Not Evaluated: Not provided or available. Unknown: Could not be determined or unsure.	
	5	Ethnicity	☐ Not Hispanic or Latino ☐ Hispanic or Latino ☐ Not Evaluated ☐ Unknown	Provide the patient's ethnicity using the defined categories. 2192217 Not Hispanic or Latino: A person not meeting the definition of Hispanic or Latino. Hispanic or Latino: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race. Not Evaluated: Not provided or available. Unknown: Could not be determined or unsure.	

#	Data Element	Entry Al	ternatives	Working Instructions
6*	History of Other Malignancy	□ Yes □ No		Indicate whether the patient was, at any time in their life, diagnosed with a malignancy prior to the diagnosis of the specimen submitted for TCGA. If the patient has had a prior malignancy, an additional form (the "Other Malignancy Form") must be completed for each prior malignancy. If the OMF was completed and submitted with the Initial Case Quality Control Form, the OMF does not need to be submitted a second time. 3382736 If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA. If the patient has a history of multiple diagnoses of basal or
				squamous cell skin cancer, complete an OMF for the first diagnosis for each of these types.
7	History of Undescended Testis	☐ Yes, left testicle only ☐ Yes, right testicle only ☐ Yes, bilateral ☐ Yes, laterality unknow ☐ No ☐ Unknown		Indicate whether the patient had a history of undescended testis. 3896542
8	If the patient had a history of undescended testis, what was the level of non-descent?	□ Non-palpable – high □ Inguinal □ Unknown		If the patient had a history of undescended testis, indicate the level of non-descent. 3896671
9	If the patient had a history of undescended testis, was it corrected?	□ Yes □ No		If the patient had a history of undescended testis, indicate whether it was corrected. 3896672
10	If the patient had a history of undescended testis and it was corrected, what age was it corrected?	☐ 2-11 months ☐ 1-2 years ☐ 3-9 years	☐ 10-14 years ☐ ≥ 15 years ☐ Unknown	If the patient had a history of undescended testis and it was corrected, indicate the patient's age when it was corrected. 3896673
		Left Testicle	Right Testicle	If the patient had a history of undescended testis and it was corrected, indicate the method of correction.
11	If the patient had a history of undescended testis and it was corrected, what was the method of correction?	□ Spontaneous descent □ Orchiopexy □ Hormones □ Testis Removed □ Not Applicable (right only) □ Unknown	□ Spontaneous descent □ Orchiopexy □ Hormones □ Testis Removed □ Not Applicable (left only) □ Unknown	_4340449_(left), 4340450_(right)
12	History of Hypospadias	☐ Yes ☐ No ☐ Unknown		Indicate whether the patient had a history of hypospadias. 3896751
13	Fertility History (Prior to Diagnosis)	□ Did not attempt to reproduce □ Fathered ≥ 1 child by natural conception □ Fathered ≥ 1 child by assisted reproduction □ Fathered ≥ 1 child by unspecified method □ Did NOT achieve pregnancy following ≥ 12 months of unprotected intercourse □ Unknown		Using the options provided, indicate the patient's fertility history prior to diagnosis. 3896771
14a	Does the patient have a family history (blood relatives only) of testicular cancer?	☐ Yes ☐ No ☐ Unknown		Indicate whether the patient had a family history of testicular cancer. 3896777
14b	Relationship to Blood Relative(s) with Testicular Cancer (check all that apply)	☐ Great-Grandfather☐ Grandfather☐ Father☐ Brother☐ Nephew☐	☐ Uncle ☐ Cousin ☐ Son ☐ Unknown	Indicate whether the patient had a family history of testicular cancer. 3901751
15a	Does the patient have a family history (blood relatives only) of other cancer?	☐ Yes ☐ No ☐ Unknown		Indicate if the patient has a family history of cancer (all cancers other than testicular cancer). 3901752

#	Data Element	F	Entry	Alternatives	Working Instructions
		Family Membe	r	Cancer Type	Provide any first degree blood relatives with a known history
		Mother			of cancer.
		Father			2783641
1 F L	Blood Relative Other	Grandmother			Provide the cancer diagnosis of any known relatives with a
15b	Cancer History	Grandfather			history of cancer.
	-	Sister			<u>3613444</u>
		Brother			
		Child			
16*	History of Neo-adjuvant Treatment for Sample Submitted for TCGA	☐ Yes ☐ No			Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the collection of the sample submitted for TCGA. 3382737 Mitotane prior to surgery is an exclusionary criterion for this study. Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted tissue) given prior to the procurement of the sample submitted for TCGA are exclusionary.
17	Tumor Status (at time of last contact or death)	☐ Tumor free☐ With tumor☐ Unknown			Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550
	Vital Status	☐ Living			Indicate whether the patient was living or deceased at the date
18*	(at date of last contact)	☐ Deceased			of last contact.
19*	Date of Last Contact	(month)	(da	y) (year)	If the patient is living, provide the date of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897020 (month), 2897022 (day), 2897024 (year) Note: The day of Last Contact is not required.
<u>20</u>	Date of Death	(month)	(da	/	If the patient is deceased, provide the month of death. - <u>2897026</u> , (month) <u>2897028</u> (day), <u>2897030</u> (year) Note: The day of Death is not required.
21	Cause of Death		mancy Malig	l by Disease	Indicate the patient's cause of death. 2554674
22	Source of Death Information	☐ Death Certi☐ Medical Red☐ Autopsy Re☐ Social Secun☐ Physician☐ Relative or☐ Other	cord port rity D	eath Index	Indicate the source used to identify the patient's cause of death. 2390921
Trea	ntment Information				
23	Has additional therapy been given after surgery?	☐ Radiation ☐ Pharmaceu ☐ None ☐ Unknown	tical		Indicate whether the patient had therapy for the tumor submitted for TCGA, after surgery. 3913861 If the patient did have additional therapy, please complete the Radiation and/or Pharmaceutical Supplemental Form.
D - 41	ologia/DuograpatiaInform	- 1' PI FIACE I	OFF		

Pathologic/Prognostic Information PLEASE NOTE: Where applicable, the following questions should be answered for the entire tumor that yielded the sample submitted for TCGA.

#	Data Element	Entry Alternatives	Working Instructions
24*	Primary Site of Disease	☐ Testis	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor that yielded the sample submitted for TCGA. 2735776
25	☐ Unilateral, Right 25 Tumor Laterality ☐ Unilateral, Left ☐ Bilateral		Indicate the laterality of the tumor that yielded the sample submitted for TCGA. 827
Bilate	eral Tumor Information		
25a	If the tumor was bilateral, was it a synchronous or metachronous?	☐ Synchronous ☐ Metachronous	If the patient had bilateral testicular cancer, indicate whether the patient's diagnosis was at the same time as the tumor submitted for TCGA (synchronous), or after the diagnosis of the TCGA tumor (metachronous). 3901753

#	Data Element	Entry Alternatives		Working Instructions
	(check all that apply)			
051	Bilateral Tumor: Date of	//		If the patient had bilateral testicular cancer, provide the date
25b	Diagnosis	(month) (day) (yea	r)	of diagnosis of the bilateral tumor. 3901759 (month), 3901760 (day), 3901761 (year)
	_	Histologic Diagnosis	Percent	If the patient had synchronous bilateral testicular cancer,
	If the bilateral tumor	☐ Seminoma	%	provide the histologic diagnosis of the synchronous tumor.
	was synchronous,	☐ Non-Seminoma - Choriocarcinoma	%	3901762 (histology), 3913863 (percent)
	indicate the histologic	□ Non-Seminoma - Embryonal		
	diagnosis of the	Carcinoma	%	
26	synchronous tumor.	☐ Non-Seminoma – Yolk Sac Tumor	%	
	Check all that apply Note: If the bilateral tumor	■ Non-Seminoma – Teratoma		
	was metachronous, please	(Mature)	%	
	provide this information in	☐ Non-Seminoma – Teratoma	0/	
	the "New Tumor Event"	(Immature)	%	
	section.	Total	100%	
Subn	nitted Tumor Information			
		☐ Involves testis only		Indicate the macroextent of the entire tumor the yielded the
		□ Epididymis		TCGA submitted sample. 3901766
27	Testis Tumor	☐ Spermatic cord		3701700
27	Macroextent	☐ Tunica albuginea		
		☐ Other, please specify		
		☐ Unknown		
20	Other Testis Tumor			If the extratesticular anatomic site of macroextent is not listed,
28	Macroextent			specify the macroextent of the testis tumor. 3901768
		□ Epididymis		Indicate the microextent of the entire tumor the yielded the
		☐ Hilar fat		TCGA submitted sample.
	Testis Tumor	☐ Rete testis		<u>3901767</u>
29	Microextent	☐ Scrotum		
	The ocatem	☐ Spermatic cord		
		☐ Tunica vaginalis		
		Histologic Diagnosis	Percent	Indicate the confirmed histologic diagnosis of the tumor
		☐ Seminoma	%	submitted for TCGA.
		☐ Non-Seminoma - Choriocarcinoma	%	3081934 (histology), 3729998(percent)
		☐ Non-Seminoma - Embryonal		The listed histologies are the only histologic types being accepted for this TCGA study. Recurrent tumors are NOT accepted, unless
	Histologic Diagnosis of Tumor Submitted for	Carcinoma	%	they are accompanied by the primary tumor, as part of a triplet
30	TCGA	☐ Non-Seminoma – Yolk Sac Tumor	%	submission.
30	Check all that apply	☐ Non-Seminoma – Teratoma	%	
	oncon an onac apply	(Mature)	70	
		□ Non-Seminoma – Teratoma	%	
		(Immature)		
		Total	100%	In disable with out to our consequence of interest, builting consequence
	Intratubular Germ-cell	□ Present		Indicate whether there was a presence of intratubular germ- cell neoplasia.
31	Neoplasm	☐ Absent		<u>3901770</u>
	Neopiasiii	☐ Unknown		
		Dungant		Indicate whether there was a presence of lymphovascular
32	Lymphovascular	☐ Present☐ Absent		invasion.
32	Invasion	☐ Absent ☐ Unknown		<u>2008052</u>
		□ Olikilowii		Described and the second secon
				Provide the date the patient was initially diagnosed with the malignancy submitted for TCGA.
	Date of Initial Pathologic	, ,		2896956 (month), 2896958 (day), 2896960 (year)
33*	Diagnosis	(month) (day) (yea	r)	Note: The day of Initial Pathologic Diagnosis is not required.
		(month) (day) (year)		
				Provide the procedure used to initially diagnose the patient.
	Method of Initial	☐ Orchiectomy		<u>2757941</u>
34	Pathologic Diagnosis	☐ Incisional Biopsy		Please note that this method is referring to the procedure
	1 actionogic Diagnosis	☐ Other Method (please specify)		performed on the Date of Initial Pathologic Diagnosis, provided in the previous question.
				the previous question.

#	Data Element	Entry Alt	ernatives	Working Instructions
35	Other Method of Initial Pathologic Diagnosis			If the procedure used to initially diagnose the patient was not included in the list provided, please describe the method used. 2757948
AIC	C and IGCCG Staging			
	Staging			
36*	AJCC Cancer Staging Edition	2 nd Edition (1984-1988)		Please indicate use the AJCC Cancer Staging Edition used to answer the following pathologic staging questions. 2722309
		☐ 7 th Edition (2010-pres	Pathologic	Using the patient's medical records and/or pathology report,
37	AJCC Primary Tumor (T)	□ TX □ T2 □ T0 □ T3 □ Tis □ T4 □ T1	□ TX □ T2 □ T3 □ T3 □ T4	select the code for the clinical and/or pathologic T (primary tumor) defined by the American Joint Committee on Cancer (AJCC). 3440328 (clinical), 3045435 (pathologic)
38	AJCC Regional Lymph Nodes (N) See below for additional information regarding the lymph nodes.	Clinical NX N0 N1 N2 N3	Pathologic □ NX □ N0 □ N1 □ N2 □ N3	Using the patient's medical records and/or pathology report, select the code for the clinical and/or pathologic N (nodal) defined by the American Joint Committee on Cancer (AJCC). 3440330 (clinical), 3203106 (pathologic)
	AJCC Distant Metastasis	Clinical	Pathologic	Using the patient's medical records and/or pathology report, select the code for the clinical and/or pathologic M
39	(M) See below for additional information regarding the metastasis.	□ M0 □ M1 □ M1a □ M1b	□ M0 □ M1 □ M1a □ M1b	(metastasis) defined by the American Joint Committee on Cancer (AJCC). 3440331 (clinical), 3045439 (pathologic)
40	AJCC Overall Stage Group	Clinical Stage 0 Stage I Stage IA Stage IB Stage IS Stage II Stage II Stage II Stage IIA Stage IIB Stage IIC Stage III Stage IIIA Stage IIIA Stage IIIA Stage IIIA Stage IIIA Stage IIIA	Pathologic Stage 0 Stage I Stage IA Stage IB Stage IS Stage II Stage II Stage IIA Stage IIB Stage IIC Stage III Stage IIIA Stage IIIA Stage IIIA Stage IIIB Stage IIIB Stage IIIB	Using the patient's medical records and/or pathology report, select the stage defined by the American Joint Committee on Cancer (AJCC). 3440332 (clinical), 3203222 (pathologic)
41	AJCC Serum Tumor Markers (S)	□ SX □ S0 □ S1 □ S2 □ S3		Using the patient's medical records and/or pathology report, select the code for the serum tumor marker (S) defined by the American Joint Committee on Cancer (AJCC). Note: Serum tumor marker is only assigned from postorchiectomy levels 3901772
Seru	Serum Tumor Marker Information			
PRIO	R TO ORCHIECTOMY If tests we	re performed multiple times, ple	ease provide the results for the	tests performed closest to the date of the orchiectomy.
42	Date Serum Tumor Markers Tested	(month) (day)	(year)	Provide the date the serum markers were tested prior to the orchiectomy. 3901773 (month), 3901774 (day), 3901781 (year)
43	Lactate Dehydrogenase (LDH)			Provide the patient's LDH level if it was tested prior to the orchiectomy. 3113468
44	Human Chorionic Gonadotropin (HCG)			Provide the patient's HCG level if it was tested prior to the orchiectomy. 3901798
45	Alpha-Fetoprotein (AFP)			Provide the patient's AFP level if it was tested prior to the orchiectomy. 3901799

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#	Data Element	Ent	ry Altern	atives		Working Instructions
46	Luteinizing Hormone (LH)				Provide the patient's LH level if it was tested prior to the orchiectomy. 3901800	
47	Testosterone				Provide the patient's Testosterone level if it was tested prior to the orchiectomy. 3913864	
	R ORCHIECTOMY If tests were p by was not performed, provide th				ults for the test	s performed prior to the date of systemic therapy. If systemic
48	Date Serum Tumor Markers Tested		 day)		ear)	Provide the date the serum markers were tested after the orchiectomy. 3901840 (month), 3901841 (day), 3901844 (year)
49	Lactate Dehydrogenase (LDH)					Provide the patient's LDH level if it was tested after the orchiectomy. 3901823
50	Human Chorionic Gonadotropin (HCG)					Provide the patient's HCG level if it was tested after the orchiectomy. 3901824
51	Alpha-Fetoprotein (AFP)					Provide the patient's AFP level if it was tested after the orchiectomy. 3901825
52	Luteinizing Hormone (LH)					Provide the patient's LH level if it was tested after the orchiectomy. 3901836
53	Testosterone					Provide the patient's Testosterone level if it was tested after the orchiectomy. 3901839
Trea	tment and Outcome Inf	ormation				
54*	Post-Orchiectomy Radiation Therapy	☐ Yes ☐ No ☐ Unknown			Indicate whether the patient had post-orchiectomy radiation therapy. <i>IF the patient did have post-orchiectomy radiation, the Radiation Supplemental Form should be completed.</i> 2005312	
55*	Post-Orchiectomy Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown			Indicate whether the patient had post-orchiectomy pharmaceutical therapy. IF the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed. 3397567	
56*	Post-Orchiectomy Retroperitoneal Lymph Node Dissection	☐ Yes – prior to ☐ Yes – after che ☐ No ☐ Unknown				Indicate whether the patient had a retroperitoneal lymph node dissection. 3953323
57a *	Measure of Success of Outcome at the Completion of Initial First Course Treatment Including Orchiectomy, Radiation, Chemotherapy and RPLND	□ No Measureable Tumor or Tumor Markers □ Normalization of Tumor Markers, but Residual Tumor Mass □ Elevated Tumor Markers and Residual Mass □ Progressive Tumor Mass and Tumor Markers □ Unknown			but dual Mass	Provide the patient's response to their initial first course treatment (surgery and/or adjuvant therapies). 4030393
57b	Molecular Marker(s) Used to Determine Outcome at the Completion of Initial First Course Treatment	Marker Elevated Normal Progressed Lactate Dehydrogenase (LDH) Human Chorionic Gonadotropin (HCG) Alpha-Fetoprotein (AFP) Luteinizing Hormone (LH) Testosterone		Progressed	If the patient's outcome, at the completion of initial first course treatment, was measured by a tumor marker(s), indicate the tumor marker(s) measured and the result of each of the tests. 3953322	
IGCC	G Staging – Note: this info		ly be provi	ded for po	atients who i	
58	International Germ Cell Cancer Collaborative Group (IGCCG) Staging	mation should only be provided for patients who r Good Intermediate Poor				If the patient received chemotherapy, provide the patient's IGCCG Staging indicator. 3901822

New Tumor Event Information Complete this section if the patient had a new tumor event. If the patient did not have a new tumor event (or if the TSS does not know) indicate this in the question below, and the remainder of this section can be skipped.

#	Data Element	Entry Alternatives	Working Instructions
59*	New Tumor Event After Initial Treatment?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after the date of initial diagnosis. 3121376 If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.
60	Type of New Tumor Event	☐ Locoregional Recurrence ☐ Distant Metastasis ☐ Biochemical Evidence of Disease ☐ New Primary Tumor	Indicate whether the patient's new tumor event was a metachronous testicular tumor, locoregional recurrence, a distant metastasis or a new primary tumor. A new primary tumor is a tumor with a different histology as the tumor submitted to TCGA. 3119721
61	Anatomic Site of New Tumor Event	□ Bone □ Testis □ Lung □ Mediastinum □ Liver □ Lymph Node(s) □ RPLN □ Other, specify	Indicate the site of this new tumor event. $\frac{3108271}{1}$
62	Other Site of New Tumor Event		If the site of the new tumor event is not included in the provided list, describe the site of this new tumor event. 3128033
63	Date of New Tumor Event	//	If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (month), 3104042 (day), 3104046 (year)

Time Intervals: The following questions are only to be answered if the Tissue Source Site is unable to provide the dates requested on this form. Please 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.

i	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: The time intervals must be recorded in place of dates where designated throughout this form if you have selected "yes" in the box. Provided time intervals must begin with the date of initial pathologic diagnosis (i.e., biopsy or resection).
ii	Number of Days from Date of Initial Pathological Diagnosis to Date of Birth	days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of birth. 3008233
iii	Number of Days from Date of Initial Pathological Diagnosis to Date of Last Contact	days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of last contact. 3008273
iv	Number of Days from Date of Initial Pathological Diagnosis to Date of Death	days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of death 3165475
v	Number of Days from Date of Initial Pathological Diagnosis to Date of Bilateral Tumor Diagnosis	days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of Bilateral Tumor Diagnosis 3966995
vi	Age at Initial Diagnosis	days	Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed with the tumor submitted for TCGA. 2006657
vii	Number of Days from Date of Initial Pathological Diagnosis to Date of Serum Tumor Marker	days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date the serum markers were tested prior to the orchiectomy. 4348005

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	Testicular	

	Testing Prior to Orchiectomy		
viii	Number of Days from Date of Initial Pathological Diagnosis to Date of Serum Tumor Marker Testing After Orchiectomy	days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date the serum markers were tested after the orchiectomy. 4348007
ix	Number of Days from Date of Initial Pathological Diagnosis to Date of New Tumor Event After Initial Treatment	days	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of new tumor event after initial treatment. 3392464

I acknowledge that the above information provided by my institution is true and correct and has been quality controlled.		
Principal Investigator or Designee Signature	Print Name	Date