### ACRIN – 6687 FORM COMPLETION INSTRUCTIONS

#### **Prior Therapies Form**

## TX Completion Instructions

The TX form is required for all participants. The form should be completed as part of the registration visit/eligibility assessment. It collects any prior cancer related therapy/treatment the participant has had in their lifetime.

Note: Ideally all prior therapy would be made available in the participants medical history, however it is understood that there may be unknowns to some of the listed therapies.

# 1. Did the participant ever receive any type of cancer treatment (chemotherapy, hormonal therapy, surgery, vaccine, etc.?

No: The participant has not had any prior cancer related treatment. Initial and date the form.

**Yes:** The participant has received some type of cancer related treatment. Complete the entire table **Note:** Any prior cancer treatment the participant may have received to make them eligible for this study should be reported on this form. (Eg., Nilutamide or Dasatinib)

#### **Completing the Prior Therapies Table**

#### NOS = Not Otherwise Specified

Therapy Type Please see table below for the definitions and examples of the listed therapy types

Any Therapy? No: Select if it is known that participant has not received the corresponding therapy type.
Yes: Select if it is known that the participant has received the corresponding therapy type. Note that yes can be selected for more than one type.
Unknown: Select if it is unknown whether the participant has ever had the corresponding therapy type.

**# Prior Chemo Regimens** A regimen is described as a distinctive planned collection of agent(s) and or modalitie(s) to be utilized together during a cycle or course of therapy. The total number should include chemotherapy that was discontinued for any reason. If a prior treatment was ABVD/CHOP, it should be coded as one chemotherapy regiment.

**Note:** The total number of other prior therapy types (e.g., surgery) is not required here and should not be included in this number.

Therapy Type	CDUS Meaning	Examples
Anti-Retroviral Therapy	Agents administered to control the replication and/or spread of viruses	TAT therapy for HIV-1
Antisense	Treatment with an agent that prevents or impairs the translation of the genetic message for production of a specific protein.	
Bone Marrow Transplant	High dose chemotherapy combined with transplantation of bone marrow cells	allogeneic, syngeneic, autologous bone marrow or periperhal blood stem cell transplantation
Chemotherapy (NOS)	Non-systemic chemotherapy treatment (e.g., intra- peritoneal, intra-cavitary, intra-thecal), or chemotherapy not described by Chemotherapy Single Agent Systemic or Multi- Agent Systemic.	
Chemotherapy multiple agents systemic	Systemic chemotherapy with a regimen containing multiple agents. A regimen is described as a distinctive collection of agent(s) and/or modalities to be utilized together during a cycle or course of therapy. All routes of administration are acceptable as long as the agent is intended for systemic therapy.	
Chemotherapy non- cytotoxic	Prior therapy with agents that are not known to cause damage to cycling cells	endostatin, mmpi, bevacizumad

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# **Prior Therapies Form**

Therapy Type	CDUS Meaning	Examples
Chemotherapy single agent systemic	Systemic chemotherapy with a single agent regimen. A regimen is described as a distinctive collection of agent(s)	F
agent systemic	and/or modalities to be utilized together during a cycle or	
	course of therapy. All routes of administration are	
	acceptable as long as the agent is intended for systemic	
	therapy.	
Drug and/or	Biologic cancer therapy. Manipulation of the body's immune	interferons, interleukins,
immunotherapy	system, either directly or indirectly, with therapeutic intent,	tumor necrosis factor
	e.g., tumor vaccines, monoclonal antibodies, cytokines . Do	
	not include biologic therapy as supportive care (e.g., G-CSF	
	for immuno-protection).	
Gene Transfer	Treatment of human disease by gene transfer	
Hematopoietic Stem	The intravenous infusion of autologous or allogeneic stem	
Cell Transplantation	cells collected from the bone marrow, peripheral blood, or	
-	umbilical cord blood to re establish hematopoietic function in	
	patients with damaged or defective bone marrow or immune	
	systems.	
Hormonal Therapy	Cancer therapy which incorporates hormonal manipulation	tamoxifen, androgen deprivation
Image directed local	A technique whereby an imaging method is used to	
therapy	diagnose, localize and/or treat a carcinogenic lesion, for	
	example, a breast lump. A non-palpable carcinoma may be	
	diagnosed by image directed biopsy or needle localization.	
	Breast conserving surgery can be conducted with pre	
	surgical localization with a guide wire using a diagnostic	
	imaging method.	
Oncolytic Virotherapy	Anticancer treatment with a live, replication-competent virus.	
Prior Therapy (NOS)	Prior therapy not otherwise specified	
Radiation Therapy	Targeted ionizing radiation therapy utilizing radioactive	
	implants or seeds. Radiation Therapy combines the	
	following therapies:	
	Extensive Rediction: Concer thereasy using ionizing rediction	(a.g. oranicaninal total
	<i>Extensive Radiation</i> : Cancer therapy using ionizing radiation to a significant (>50%) portion of the body.	(e.g., craniospinal, total body irradiation, or pelvic
	to a significant (>50%) portion of the body.	radiation)
	<i>Limited Radiation</i> : Cancer therapy using ionizing radiation to	
	a limited (<50%) portion of the body.	
Surgery	Surgical procedure, or operation, with therapeutic intent. Do	
	not include diagnostic procedures (e.g., biopsy).	
Therapy (NOS)	A therapy used prior for which none of these selections is	Cryotherapy, phototherapy
	appropriate.	
Vaccine	Substance or group of substances administered to induce	
	the immune system to recognize and destroy tumors or	
	microorganisms.	