

Cancer Center Office of Clinical Research: Protocol Submission Form

Trial Information	
Protocol Title & Study Number/Short name:	
Sponsor Name:	
PI & Title:	
Sub-investigators & title (Individuals required on the 1572):	
Please provide a brief summary of the study:	
General	
Disease Team:	<input type="checkbox"/> BATS <input type="checkbox"/> Breast <input type="checkbox"/> GI <input type="checkbox"/> GU <input type="checkbox"/> GYN <input type="checkbox"/> H&N <input type="checkbox"/> SMACT <input type="checkbox"/> LCM <input type="checkbox"/> Melanoma <input type="checkbox"/> Neuro <input type="checkbox"/> Rad Onc <input type="checkbox"/> Thoracic <input type="checkbox"/> Other: _____
Disease Stage:	<input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> Other: _____
Phase of trial	<input type="checkbox"/> Pilot/feasibility <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III + <input type="checkbox"/> Other: _____

<p>Prior Lines of Therapy</p>	<input type="checkbox"/> First <input type="checkbox"/> Second <input type="checkbox"/> Third <input type="checkbox"/> Adjuvant <input type="checkbox"/> Neoadjuvant <input type="checkbox"/> Other: _____
<p>Is there a complete start-up package/budget/contract?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other: _____
<p>Type of trial (select both Sponsor and Protocol type)</p>	<p>Sponsor Type</p> <input type="checkbox"/> Investigator-initiated, UVA is lead site <input type="checkbox"/> Investigator-initiated, other center is lead site: _____ <input type="checkbox"/> Cooperative Group: _____ <input type="checkbox"/> Pharmaceutical: _____ <input type="checkbox"/> Other: _____ <p>-----</p> <p>Protocol Type</p> <input type="checkbox"/> Treatment <input type="checkbox"/> Basic science <input type="checkbox"/> Device <input type="checkbox"/> Other: _____
<p>UVA PI Role</p>	<input type="checkbox"/> National PI, Study Chair, overall PI on multi-site study <input type="checkbox"/> PI on single site study <input type="checkbox"/> Co-Chair (e.g., for cooperative group studies) <input type="checkbox"/> Study champion (e.g., NCTN collaborative role for intergroup studies) <input type="checkbox"/> Role in study design for industry trial (e.g, Steering Committee Chair) <input type="checkbox"/> Local PI for multi-site study
<p>Review committees that will be utilized</p>	<input type="checkbox"/> PRC <input type="checkbox"/> UVA IRB <input type="checkbox"/> Central IRB <input type="checkbox"/> HIRE <input type="checkbox"/> IBC <input type="checkbox"/> CTO <input type="checkbox"/> Other: _____
<p>Funding</p>	<input type="checkbox"/> Industry <input type="checkbox"/> Cooperative Group <input type="checkbox"/> Foundation <input type="checkbox"/> Consortium <input type="checkbox"/> Seed/grant money <input type="checkbox"/> Philanthropy <input type="checkbox"/> Department <input type="checkbox"/> Other: _____

Accrual	
Is this a sub-study of an NCI/NCTN basket, umbrella, or master protocol?	<input type="checkbox"/> No <input type="checkbox"/> Yes
Number of competing protocols at UVA	<input type="checkbox"/> $n \geq 3$ active or pending competing trials <input type="checkbox"/> 1-2 competing active or pending trials <input type="checkbox"/> 0 active or pending competing trials <input type="checkbox"/> N/A (for screening protocols or sub-studies of NCI/NCTN basket, umbrella, or master protocols) If competing protocols exist, provide justification for opening this trial: Please list this trial and competing trial IRB #s in order of prioritization:
Is this trial using competitive enrollment (slots awarded on a first-come first serve basis)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Anticipated enrollment end date	
Anticipated total enrollment duration	months/years
How many patients meet both the inclusion and exclusion criteria per year?	
Accrual estimate per year (PI-please provide conservative estimate)	
Total trial accrual estimate (full duration of study)	
Total study sample size	
Number of patients enrolled at all sites at the time this form is completed	
Total number of planned sites	
Number of sites currently active (only for industry multi-site studies)	
Competing sites w/in our region? (only for industry multi-site studies)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Other: _____
Does the study have international sites? (only for industry multi-site studies)	<input type="checkbox"/> Yes <input type="checkbox"/> No

Complex Trial Indicators

Place a checkmark in the box on left if the corresponding indicator is true for this study.

Indicator	Corresponding page number in the protocol
<input type="checkbox"/> Phase 1	
<input type="checkbox"/> IIT	
<input type="checkbox"/> Trial has inpatient aspects	
<input type="checkbox"/> Sponsor is external academic center	
<input type="checkbox"/> Physician practices at Pantops	
<input type="checkbox"/> Trial is centered at Pantops	
<input type="checkbox"/> Breast trial	
<input type="checkbox"/> More than 2 nurse interactions per hour (i.e. multiple vitals, multiple EKGs)	
<input type="checkbox"/> Drug administration is ultra sound guided	
<input type="checkbox"/> Drug compound has expiration time of less than one week	
<input type="checkbox"/> IBC approval required	
<input type="checkbox"/> Trial uses process that has never been performed at UVA facilities before	
<input type="checkbox"/> Trial uses equipment that has never been used at UVA facilities before	
<input type="checkbox"/> Treatment requires 6 or more hours of infusion time	
<input type="checkbox"/> More than 2 treatment arms	
<input type="checkbox"/> > 1 PK/PD in one day	
<input type="checkbox"/> Trial requires specialty equipment	

Comments: What is the rationale behind doing this study? Why is it important to you? Why is it important to our patients? Please explain the relationship between this trial and any competing protocols. Please assign risk category below. Does the trial translate UVA science, and is there authorship potential for the research team?

Risk Category:

- High risk:** sponsor-investigator INDs (regardless of phase), Phase 1 studies, gene therapy trials, and any other types of trials designated by NIH as high risk
- Medium risk:** all other therapeutic intervention (such as drugs, biologics or devices) trials not designated by NIH, PRC or IRB as high risk (typically Phase II and Phase III trials)
- Low risk:** non-therapeutic intervention trials (no therapeutic intention, such as nutritional or behavioral trials, biopsy or blood sample collection)
- Exempt:** non-intervention trials are exempt from providing a monitoring plan (such as epidemiology research, survey, imaging or functional assessment). Intervention trials may not be classified as exempt.