Feasibility Discussion Date:

Cancer Center Clinical Research: Protocol Submission Form

Trial Information
Protocol Title & Study Number/Short name:
HSR number (if known) and NCT Number:
Sponsor Name:
PI & Title:
Sub-investigators & title (Individuals required on the 1572):
Please provide a brief summary of the study (If study is phase 1, describe if UVA will participate in dose escalation, expansion, or both.**):**

General	
Disease Team:	☐Breast ☐GI ☐GU ☐GYN ☐ H&N ☐ Cellular Therapies ☐ CALM ☐ Lymphoma ☐ Plasma/Benign/T-cell (PBT) ☐ Melanoma ☐ Neuro-Oncology ☐ Radiation Oncology ☐ Thoracic ☐ Other: _____
Disease Stage:	☐ I ☐ II ☐ III ☐ IV ☐ Other: _____
Phase of trial	☐ Pilot/feasibility ☐ I ☐ II ☐ III + ☐ Other:_____

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Prior Lines of Therapy	☐ First ☐ Second ☐ Third ☐ Adjuvant ☐ Neoadjuvant ☐ Other:_____
Is there a complete start-up package/budget/contract?	☐ Yes ☐ No ☐ Other: _____
Type of trial (select both Sponsor and Protocol type)	***Sponsor Type*** ☐ Investigator-initiated, UVA is lead site ☐ Confirm protocol has all required sections, including inclusion/exclusion criteria, study objectives and endpoints, safety assessments and reporting, statistical analysis plan, and sample size justification. For studies without formal hypothesis testing, precision analysis with confidence intervals for the primary endpoint should be provided for sample size justification. ☐ Investigator-initiated, other center is lead site: _____ ☐ Cooperative Group: _____ ☐ Pharmaceutical: _____ ☐ Other: _____ --- ***Protocol Type*** ☐ Treatment ☐ Basic science ☐ Device ☐ Other(Diagnostic/Prevention/Screening/Supportive care/Health services research): _____
UVA PI Role	☐ National PI, Study Chair, overall PI on multi-site study ☐ PI on single site study ☐ Co-Chair (e.g., for cooperative group studies) ☐ Study champion (e.g., NCTN collaborative role for intergroup studies) ☐ Role in study design for industry trial (e.g., Steering Committee Chair) ☐ Local PI for multi-site study
Review committees that will be utilized	☐ PRC ☐ UVA IRB ☐ Central IRB ☐ HIRE ☐ IBC ☐ CTO ☐ Other: _____

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Funding	☐ Industry ☐ Cooperative Group ☐ Foundation ☐ Consortium ☐ Seed/grant money ☐ Philanthropy ☐ Department ☐ Other:_____
Accrual	
Is this a sub-study of an NCI/NCTN basket, umbrella, or master protocol?	☐ No ☐ Yes
Number of competing protocols at UVA	☐ n ≥ 3 active or pending competing trials ☐ 1-2 competing active or pending trials ☐ 0 active or pending competing trials ☐ 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 a study of a rare cancer (<6 per 100,000 people per year) or molecular subset that would qualify as rare cancer? (All pediatric cancers qualify as a rare disease.)	☐ Yes (justification required): _____ ☐ No
Is this trial using competitive enrollment (slots awarded on a first-come first serve basis)?	☐ Yes ☐ 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	

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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)	☐ Yes ☐ No ☐ Other: _____
Does the study have international sites? (only for **industry** multi-site studies)	☐ Yes ☐ 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(if applicable)**
	IIT	
	Sponsor is external academic center	
	Trial has inpatient aspects. Indicate admitting team	
	Physician practices in non EC4 location	
	Non EC4 drug administration with drug expiration less than 2 hours	
	Treatment requires 6 or more hours of infusion time	
	More than 4 treatment arms	
	More than 2 nurse interactions per hour (i.e. multiple vitals, multiple EKGs)	
	Ophthalmology exams	
	Trial has a cell therapy component (e.g. CAR-T, BATs, lymphocyte infusion (TIL), Natural Killer cell therapy etc.)	
	IBC approval required (e.g.: cell therapy, live viral product)	
	Treatment involves nuclear medicine	
	Trial involves equipment/process that has never been used at UVA facilities before	
	Trial involves commercially supplied drug unavailable on UVA formulary for inpatient administration	

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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.