

UF Health Cancer Center (UFHCC) THealth Disease Site Group (DSG) or Research Program Protocol Approval Form

Instructions: Before an interventional protocol may be submitted to the Scientific Review and Monitoring Committee (SRMC) the appropriate DSG must thoroughly review and approve the protocol. Please submit the completed form to the appropriate UFHCC Clinical Trials Unit Leader.

DSG/Program:		P	Principal Investigator:		
Protocol Number:		S	Sponsor:		
Protocol Title:					
		<u> </u>			
Sponsor Type:		L	JFHCC Priority Score:		
1.	Has this study received prior peer-review by an NCI approved organization? You can find a list of NCI-approved organizations at the following URL: click here (PDF).				
	Yes* No *Note: If yes, please attach supporting documentation.				
	_ 103	Note: If yes, please attach supporting t	documentation.		
2.	Is the trial scientifically s	ound?			
	☐ Yes ☐ No				
3.	· · · ———				
	☐ Yes ☐ No				
1	Is an adequate patient population currently available to support projected enrollment?				
4.	☐ Yes ☐ No	opulation currently available to supp	port projected emoliment:		
	_ 1C3 1NO				
5.	What is the projected number of subjects you plan to enroll at this site?				
	Total:	Annual:			
6.	What is the projected enrollment period? In Month(s):				
7.	List protocol number(s) for similar historical studies that have been activated at UF:				
٧.	List protocor number (s)	ioi siiillai ilistoricai stadies tilat ilav	re been activated at or.		
	a. If this study is a	in IIT, will additional sites be opened	d? □ Yes □ No		
		any site(s) and where?			
8.					
	, , ,	omment. Be specific to potential issue	es that may affect enrollment	(eligibility criterion, testing	
	windows, overn	night stays, etc.).			
9.	Does this study involve (Cellular Therapy and/or apheresis?	Cellular Therapy Ap	heresis Both No	
	a. If yes, additiona	al review is needed. Contact UFHCC-	BMTCellularTherapy@ufl.edu	I	
10	Will this study target a n	on-English speaking population?	Yes □ No		
10.	a. If yes, Which la		163 = 110		
11	•	ollment been adequately addressed	hy the DSG?		
11.		N/A	by the D3G:		
	If "No", explain:				
12.	2. If this is an early phase study, do you anticipate participating in the phase 1 portion of the trial?			e trial?	
☐ Yes ☐ No N/A					
		phase I portion involve the following			
	☐ Slot reg	gistration \Box Cohort-based accru	ıaı		

13.	Is this trial serving a rare disease? The UFHCC defines a rare case as one with an incidence of ≤ 3 newly diagnosed persons out of a population of 100,000 persons per year (<9,600 cases/year). Only cancer origin, histology and molecular profile are used to determine rare disease				
	status. Yes* No *Note: If yes, please attach supporting documentation.				
14.	. Will this trial be conducted using UFHCC Clinical Research Office (CRO) resources including Project Management Office (PMO) services, research coordinator or data entry support, regulatory management, financial, or other in-kind support? □ Yes □ No				
15.	Do the following individuals have more than 1+year of experience conducting trials? Principal Investigator: Yes No				
	Primary Study Coordinator:				
16.	Does this trial have the potential to accrue minorities or underrepresented patients? \Box Yes \Box No				
17.	Does this study exclude older adults (>65)? ☐ Yes ☐ No If "Yes", explain:				
18.	3. Does this trial specifically target any of the following populations or those that self- identify as (Check all that apply):				
	☐ Black ☐ Rural Residency (as defined by the RUCC codes) ☐ Hispanics ☐ Socially Vulnerable Community Member (Per the CDC) ☐ LGBTQIA+ ☐ Other (Please specify, " ") ☐ Elderly ≥65				
19.	Does this protocol target patients with advanced-stage or metastatic disease (cancer that is unlikely to be cured or controlled with treatment)? \Box Yes \Box No				
20.	Does this protocol target tobacco or a tobacco-related cancer? \Box Yes \Box No				
21.	Does this study address the following: ☐ Survivorship ☐ Palliative Care N/A				
22.	2. How does this study fulfill a need in the current DSG research portfolio?				
23.	3. How does this study fulfill a need in the UFHCC catchment area?				
24.	1. Additional Comments:				
Plea inve	UF Investigator-Initiated Trials: se ensure you have a fully executed I2T3Concept Review Form for all IITs utilizing CRO resources and categorized as interventional, or otherwise involving stigational drugs, devices or medical procedures, prior to submitting to the SRMC committee. I2T3 Concept Review should be obtained prior to full elopment of the trial. More information can be found within the UFHCC IIT Policy document.				
	our signature below provides assurance to UFHCC Clinical Trials Group Leader and the Scientific Review and Monitoring tee (SRMC) that the disciplines necessary to complete this protocol have read and agreed with the study.				
Signatur	re of the DSG or Research Program Leader Date				