



DSG/Program:		Principal Investigator:	
Protocol Number:		Sponsor:	
Protocol Title:			
Sponsor Type:		UFHCC Priority Score:	

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Version 2/22/2024

13. Is this trial serving a rare disease?

The UFHCC defines a rare case as one with an incidence of  $\leq 3$  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: ☐ Yes ☐ No ☐ N/A

Name of Study Coordinator:

16. Does this trial have the potential to accrue minorities or underrepresented patients?

☐ Yes ☐ No

17. Does this study exclude older adults ( $>65$ )?

☐ Yes ☐ No If "Yes", explain:

18. Does this trial specifically target any of the following populations or those that self- identify as (Check all that apply):

- |  |  |
|--|--|
| <input type="checkbox"/> Black             | <input type="checkbox"/> Rural Residency (as defined by the <a href="#">RUCC codes</a> )     |
| <input type="checkbox"/> Hispanics         | <input type="checkbox"/> Socially Vulnerable Community Member (Per the <a href="#">CDC</a> ) |
| <input type="checkbox"/> LGBTQIA+          | <input type="checkbox"/> Other (Please specify, “ ”)   |
| <input type="checkbox"/> Elderly $\geq 65$ |  |

19. Does this protocol target patients with advanced-stage or metastatic disease (cancer that is unlikely to be cured or controlled with treatment)?

☐ Yes ☐ No

20. Does this protocol target tobacco or a tobacco-related cancer?

☐ Yes ☐ No

21. Does this study address the following:

☐ Survivorship ☐ Palliative Care ☐ N/A

22. How does this study fulfill a need in the current DSG research portfolio?

23. How does this study fulfill a need in the UFHCC catchment area?

24. Additional Comments:

**For UF Investigator-Initiated Trials:**

Please ensure you have a fully executed I2T3 Concept Review Form for all IITs utilizing CRO resources and categorized as interventional, or otherwise involving investigational drugs, devices or medical procedures, prior to submitting to the SRMC committee. I2T3 Concept Review should be obtained prior to full development of the trial. More information can be found within the UFHCC IIT Policy document.

**Note:** Your signature below provides assurance to UFHCC Clinical Trials Group Leader and the Scientific Review and Monitoring Committee (SRMC) that the disciplines necessary to complete this protocol have read and agreed with the study.

\_\_\_\_\_  
Signature of the DSG or Research Program Leader

\_\_\_\_\_  
Date