

UF Health Cancer Center (UFHCC)

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:		Principal Investigator:	
Protocol Number:		Sponsor:	
Protocol Title:			
Sponsor Type:		UFHCC Priority Score:	

Has this study received prior peer-review by an NCI approved organization? YES NO
<https://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf>
 (If yes, please attach supporting documentation for non-NCTN trials)

Is the trial scientifically sound? YES NO

Are all physical resources currently available to conduct the trial? YES NO

Is an adequate patient population currently available to support projected enrollment? YES NO

What is the projected number of subjects you plan to enroll at this site? **Total:** **Annually:**

What is the projected enrollment period? **In Month(s):**

List protocol number(s) for similar historical studies that have been activated at UF:

If this study is an IIT, will additional sites be opened? YES No
 If "YES" how many site(s) and where?:

Are there any protocol or eligibility requirements that may limit UF's ability to recruit patients? YES NO
 If yes, please comment. Be specific as to the potential issues that may affect enrollment (eligibility criterion, testing windows, overnight stays, etc.)

If applicable, have all barriers to enrollment been adequately addressed by the DSG? YES NO

If this is an early phase study do you anticipate participating in the phase 1 portion of the trial? YES NO

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 (If yes, please attach supporting documentation). YES NO

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

Do the following individuals have more than 1+year of experience conducting trials?

Principal Investigator: Y N Primary Study Coordinator: Y N N/A

Name of study coordinator:

Does this trial have the potential to accrue minorities or underrepresented patients? YES NO

Does this study exclude older adults (>65)? YES NO

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

Blacks	Rural Residency (As defined by the RUCC codes)
Hispanics	Socially Vulnerable Community Member (Per the CDC)
LGBTQIA	Other- Specify
Elderly \geq 65	

Does this protocol target patients with advanced-stage or metastatic disease (cancer that is unlikely to be cured or controlled with treatment)? YES NO

Does this protocol target tobacco or a tobacco-related cancer? YES NO

Does this study address the following: Survivorship Palliative Care

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

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

Additional Comments:

Please ensure you have received SRMC Pre-Review approval for all IITs categorized as interventional treatment or otherwise involving investigational drugs, devices or medical procedures prior to submitting to the SRMC committee. SRMC Pre-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 DSG or Research Program Leader

Date