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

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.

2. Is the trial scientifically sound?
   ◯ Yes ◯ No

3. Are all physical resources **currently** available to conduct the trial?
   ◯ Yes ◯ No

4. Is an adequate patient population currently available to support projected enrollment?
   ◯ Yes ◯ No

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:

   a. If this study is an IIT, will additional sites be opened? ◯ Yes ◯ No
   b. If "yes," how many site(s) and where?

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

9. Does this study involve Cellular Therapy and/or apheresis? ◯ Cellular Therapy ◯ Apheresis ◯ Both ◯ No
   a. If yes, additional review is needed. Contact UFHCC-BMTCellularTherapy@ufl.edu

10. Will this study target a non-English speaking population? ◯ Yes ◯ No
    a. If yes, Which language: _____

11. Have all barriers to enrollment been adequately addressed by the DSG?
    ◯ Yes ◯ No ◯ N/A

    If "No", explain:

12. If this is an early phase study, do you anticipate participating in the phase 1 portion of the trial?
    ◯ Yes ◯ No ◯ N/A
    If yes, does the phase I portion involve the following?
    ◯ Slot registration ◯ Cohort-based accrual

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: ◯ 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):
    ☐ Black
    ☐ Hispanics
    ☐ LGBTQIA+
    ☐ Elderly ≥65
    ☐ Rural Residency (as defined by the RUCC codes)
    ☐ Socially Vulnerable Community Member (Per the CDC)
    ☐ Other (Please specify, " ")

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 I2T3Concept 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