CONCEPT SHORT NAME (PI):_____

UF HEALTH CANCER

CENTER CLINICAL RESEARCH OFFICE (CRO)

I2T3 Concept Review Form

INSTRUCTIONS: This form is mandatory for all UFHCC Investigator-Initiated interventional trial concepts. To initiate the process, your concept must be reviewed and discussed at a meeting of the IIT Think Tank (I2T3) group and supported by the applicable DSG Research Leader. This form is to document review and peer-review feedback at I2T3, attain preliminary DSG leader support, and approval of a UFHCC study budget. If 12 months has elapsed between SRMC submission and the last I2T3 review, the concept must undergo a new review. Electronic signatures are preferred when possible.

1. **Principal Investigator**:

2. **Sponsoring DSG**: Select DSG

3. **Is this a re-review of a previously presented concept at I2T3?**
   - ☐ **Yes** - provide date this concept was first presented:
   - ☐ **No**, this is the first time this concept has been reviewed

4. Concept Information	
4.1 Concept Title	
4.2 Hypothesis	Clearly state the study hypothesis. This should be no more than 2 sentences.
4.3 Primary Objective/ Endpoint	Example: Objective Response Rate (ORR). The ORR is defined as the proportion of subjects achieving a best overall response of partial or complete response, according to RECIST from the start of treatment until disease progression.
4.4 Secondary Objectives/ Endpoints	Example: To estimate the median overall survival, defined as the time period from start of treatment until death or last follow-up.
4.5 Exploratory Aims / Correlative Studies proposed	Example: To examine tumor microenvironment before and after treatment with xyz
4.6 Study Phase	☐ I ☐ II ☐ I/II ☐ III ☐ IV ☐ Pilot ☐ N/A
4.7 Has this concept been discussed with an industry partner?	☐ If Yes, please specify: ☐ If No, please list some possible partnerships / sources of funding:

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4.8 Study Design	*Allocation*: ☐ Randomized ☐ Non-randomized ☐ N/A Single arm study *Intervention model:* ☐ **Single group**: single arm study ☐ **Parallel**: participants are assigned to one or more groups in parallel for the duration of the study ☐ **Cross-over**: participants receive one of two alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study. ☐ **Factorial**: two or more interventions, each alone and in combination, are evaluated in parallel against a control group

5.Background and Rationale	
5.1	Please describe the scientific rationale for this trial and what current gap in the scientific literature could be addressed with this trial?
5.2	Please describe the clinical relevance of this trial (i.e., how could results affect clinical management and/or patient experience at UFHCC)?
5.3	Insert a schematic of the proposed study flow for a subject from screening to follow-up (if space is not sufficient, attach separately and comment as such below).

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6. Study Population	
6.1 Diagnosis/Targeted Patient Population	
6.2 <u>Key/Major</u> Inclusion Criteria (no need to list all)	
6.3 <u>Key/Major</u> Exclusion Criteria (no need to list all)	

7.Intervention Details *(if more than two arms/cohorts, attach separately)*		
Arm/Cohort Label	***Intervention Administered***	***Comments / Details***

8. Statistical Considerations	
8.1 Name of Statistician ****IITs must include a biostatistician***	☐ I need statistical support. Please set up a meeting with BQS.
8.2 What is the proposed sample size (# of subjects)?	
8.3 Sample Size Justification	
8.4 Briefly describe the data analysis plan	

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9. Feasibility	
9.1 Accrual	Eligible number of patients per year seen at UF Health: Source of the above estimate:
	Projected accrual rate/subjects per month *(rule of thumb: 20% of those seen may enroll)*:
	Anticipated duration of study (in months):
	To your knowledge, are there any current UFHCC protocols that would complete with subject accrual? ☐ Yes (please specify): ☐ No
9.2 UFHCC resources requested	☐ **IIT Project Management** (Protocol and/or consent authoring, case report form creation, study meetings, data monitoring, publication assistance, study sponsor reports, DISC submissions, initial IND/IDE submission) ☐ **Protocol Start Up Assistance** (contracting, internal committee submissions) ☐ **Regulatory Management** (IRB submissions, Clinicaltrials.gov management, IND/IDE management) ☐ **Subsite Management** (budgeting, startup, regulatory maintenance, sample collection and tracking) ☐ **Sample Banking** (including research blood and/or microbiome) ☐ **Clinical Trial Coordination** (subject education and/or recruitment, study coordinator, data management, research lab processing) ☐ **Quality Assurance** (monitoring, education & training) ☐ **Citizen Scientist Engagement** throughout the life of the study (consultations, review of subject materials, recruitment/retention strategies, presentations)

10. Disease Site Group (DSG) Research Leader Endorsement of CONCEPT	
Instructions to the DSG Research Leader – Providing your signature acknowledges the above concept has been reviewed and has received your support to pursue further development within your group (**NOTE**: Formal DSG review and endorsement of a full protocol is still required prior to SRMC submission)	
DSG Research Leader Approval Signature and Date	

11. Citizen Scientist Feedback Feedback from I2T3 Review
Comments

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12. Budget	
Are there any study procedures that are not considered standard of care (SOC) for the trial population (if unknown, that is OK, these will be confirmed by PMO)?	☐ Yes ☐ No ☐ Not sure (PMO will assist)
If yes, please list what is not SOC, and the timepoints at which these procedures will be performed, if not listed in the schema (in 5.3):	
Is a subsite budget also requested at this time?	☐ Yes ☐ No
Budget Review Comments:	
Budget Review Signature and Date:	
Version Date of Approved Budget:	

13.0 ADCR Reviewer	
Scientific Review at I2T3 Details	
Date most recently presented at I2T3:	
Qualtrics summary (average) score (full report attached to this form):	Select Score
Comments (please describe any outlier scores or concerns reported by I2T3)	
Final Review by ADCR	
Comments	
Merit Score	Select Score
ADCR Signature	

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Any notes/comments about the concept or its development should be placed below. Provide all feedback provided during review of this study and outcomes, if not captured in other areas of this form: