University of Florida Health Cancer Center

Disease Site Group

Policies and Procedures

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Contents

Overview

The University of Florida Health Cancer Center (UFHCC) has developed a systematic and organized process for the review and conduct of cancer-relevant clinical trials. This system supports multi-level reviews of all trials to ensure they receive appropriate consideration in the areas of clinical alignment, feasibility, scientific merit, and Catchment Area (CA) impact, as defined by the UFHCC. The groups and committees comprising UFHCC's Research Oversight System (ROS) work together to provide a complementary review, but each has a distinct and clearly defined role. These reviews result in a thorough evaluation for each clinical trial to determine alignment with overarching UFHCC strategic objectives. The likelihood of successful completion of each trial is maximized through the DSG review process.

A component of the UFHCC ROS are the Disease Site Groups (DSGs) that each provide an integrated, multidisciplinary approach to guide the selection and endorsement of high-quality cancer clinical trials. They are charged with establishing a portfolio of studies that serves the needs of individuals within the CA through deployment of the framework described in this document.

Each DSG has at least one designated clinical and research leader while the Cancer Control Population Sciences DSG and Experimental Therapeutics Group DSG have research co-leaders. DSG leaders are appointed by and serve at the discretion of the UFHCC Director. The DSGs routinely meet (minimum 6 times per year) to review all new and ongoing studies under their purview. All new interventional trials must be reviewed and endorsed by the applicable group of record prior to submission to the SRMC as a component of NCI required first-stage scientific review. For example, any clinical trials conducted in a breast cancer patient population must be vetted through the breast DSG.

These functional units of UFHCC clinical research are organized into 11 disease-specific groups and two disease-agnostic groups for a total of 13 DSGs. Disease-specific DSGs are defined as groups that target one disease area, while disease-agnostic DSGs are defined as groups that target to two or more disease areas OR target a combination of healthy subjects and cancer patients.

1. Breast
2. Cutaneous
3. Gastrointestinal
4. Genitourinary
5. Gynecologic
6. Head and Neck
7. Malignant Hematology
8. Neuro-Oncology
9. Pediatric
10. Sarcoma
11. Thoracic
12. Cancer Control and Population Sciences
13. Experimental Therapeutics Group

DSGs are responsible for ensuring that adequate resources are available to support proposed clinical research studies. The sponsoring DSG Research Leader must attest to the projected annual accrual, allocation of UFHCC Clinical Research Office (CRO) resources, presence or absence of competing studies, CA impact, and overall endorsement of support from the group. Metrics including, but not limited to, studies declined and endorsed, accruals, and attendance will be reviewed twice per year as a component of DSG productivity and effectiveness.

Scope of Application

All interventional cancer-relevant clinical trials at the UFHCC must be reviewed and approved by their respective primary DSG prior to initial review by the SRMC. UF uses the following definitions:

- Interventional study: A study where individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.
- Cancer-relevant study: A study that specifies enrolling patients with a known or suspected diagnosis of cancer as part of the eligibility criteria or includes research endpoints related to cancer, associated symptoms, or established cancer risk factors, which includes smoking and tobacco-associated studies, surveys, hepatitis or HPV vaccines, etc. Another way for a study to be cancer relevant is if the local

principal investigator (PI) plans to exclusively enroll current, former, or potential cancer patients into the study.

Non-interventional cancer-relevant clinical research can also be reviewed by a DSG to promote awareness of the study, but are not required to be endorsed by the DSG prior to SRMC submission.

DSG Leadership and Members

DSG Leadership

The UFHCC Director is responsible for approval of the formation of each DSG and leaders. Each DSG is led by a faculty team and includes a multidisciplinary attendee roster. The DSG research leader reports to the UFHCC Associate Director for Clinical Research (ADCR) while the DSG clinical leader reports to the UFHCC Associate Director for Medical Affairs (ADMA). DSG leadership positions are reviewed annually by the Director, Deputy Director, and ADCR. Leadership terms are for three years, renewable upon the Director's re-approval.

DSG Members

DSG members come from and represent various academic and clinical departments that are engaged in cancer research. To ensure a multidisciplinary perspective, the DSG composition includes a broad range of specialties, including but not limited to basic science, medical oncology and hematology, pathology, radiation oncology, radiology, interventional radiology, laboratory research, surgery, and population-based science. DSG member attendance is maintained by the DSG leaders in conjunction with CRO support staff.

DSG membership is voluntary, open and inclusive. All DSG members are expected to review and participate in the discussions related to proposed and ongoing trial activities. However, DSG leaders have the responsibility to identify key stakeholders who serve as voting members on topics related to clinical trial portfolio management. These key stakeholders are expected to attend the majority of meetings held throughout the year.

DSG attendees are disease-focused (or for CCPS, thematically research-focused) and may include:

- Clinical and Non-Clinical Investigators
- Clinical staff involved in research (e.g. advanced practice providers, nurses, navigators)
- CRO staff & administrators

Responsibilities

The DSGs have the responsibility to review all interventional cancer-relevant clinical trials at the UFHCC, or otherwise supported with institutional resources, prior to initial review by the SRMC.

All DSGs are responsible for the following:

- Creation and maintenance of a clinical research portfolio, tailored to the needs of individuals within our clinical and CA populations, that is capable of supporting the DSG's treatment accrual goals;
- Review and endorsement of initial study concepts for UF investigator-initiated trials (IITs);
- Review and endorsement of all new interventional trials which are proposed for activation prior to Scientific Review and Monitoring Committee (SRMC) submission;
- Collaboration with a multi-disciplinary team including individuals such as investigators within the DSG, UFHCC Research Program members, clinical teams, Community Outreach and Engagement (COE) staff and clinical research staff to assess trials for resource utilization, feasibility, CA impact, and ability to integrate the research components of each study with clinical algorithms or pathways;
- Ongoing review and internal prioritization of the interventional clinical research portfolio, including thorough assessment of accrual rates for existing trials;
- Optimization of population subgroup recruitment focusing on efforts to improve gender and racial/ethnic diversity and inclusion across the lifespan, with particular emphasis on the UFHCC CA;
- Maintenance of a priority list of pending and active protocols for their clinical research portfolio;
- Maintenance of a clinical research portfolio with diverse sponsorship so as to support sustainability of resource allocation.

DSG Research Leaders

The Research Leader for each DSG is charged with the following responsibilities:

1) Create and facilitate a collaborative and inclusive environment across all treatment modalities, specific to the diseases served by the assigned DSG.
2) Serve as the gatekeeper and authorizing signatory for study development and endorsement prior to SRMC submission of all disease-specific interventional research at the institution. The NCI requires that individuals with expertise in a disease or discipline be responsible for first-stage scientific review of concepts and protocols. DSG review and endorsement is intended to fulfill these expectations.
3) Establish priorities for clinical research topics that need to be investigated.
4) Understand the critical needs for our CA, and provide studies for high burden cancers or those that are otherwise priorities for the UFHCC's region.
5) Establish achievable action plans to meet annual targets and expectations for:
    - Accruals and enrollments to interventional clinical trials, with particular focus on treatment trials
    - Protocol selection in alignment with available resources
    - Letters of intent (LOIs) submitted and IIT concepts developed into full protocols
    - Protocols closed by the DSG and SRMC for poor enrollment
6) Be innovative and supportive of IITs that are our highest priority in clinical trials research, particularly those that are treatment in classification and translational.
7) Conduct/lead meetings amongst DSG members consistent with UFHCC policies (minimum 6 per year).
8) Report to the UFHCC Leadership semi-annually on the following items:
    - DSG makeup, membership, and attendance/participation
    - Accrual to interventional protocols within the review period
    - Demographic-based reporting (gender, age, race, ethnicity)
    - Portfolio mix (e.g., IIT, Industry, and National studies)
    - Strategic planning with regard to portfolio coverage, competing studies, low-accruing studies, barriers to accrual, prioritizing studies, and portfolio flowcharts
    - LOI tracking, withdrawn/abandoned study tracking, and studies the DSG decided to "pass" on.
9) Attendance is required at:
    - DSG meetings
    - DSG leadership meetings with UFHCC leaders
    - Assigned UFHCC Research Program meetings
    - At least 70% of either UFHCC Grand Rounds or UFHCC Research Seminar Series, per academic year

DSG Clinical Leaders

The Clinical Leader for each DSG is charged with the following responsibilities:

1) Create and facilitate a collaborative and inclusive environment across all treatment modalities, specific to the diseases served by the assigned DSG.
2) Define treatment pathways for the DSGs major diseases by stage in UF patients by doing the following:
    - Establish these pathways in light of national guidelines, such as the NCCN

- Foster more robust UF-specific guidelines
- Establish a mechanism to monitor adherence to these pathways

3) Facilitate multidisciplinary and coordinated care.
4) Facilitate incorporation of clinical and basic research in the assigned DSG's clinical pathways.
5) Lead and coordinate an effective multidisciplinary tumor board for the assigned DSG that complies with the guidelines of the Hospital Cancer Committee.
6) Serve as agents of the Hospital Cancer Committee to ensure UF compliance with the metrics determined by the various accrediting agencies (e.g., Commission on Cancer, National Accreditation Program for Breast Cancer, etc.).
7) Responsible for the development or delegation of quality metrics important to the assigned DSG outside of national agencies.
8) Identify a major group quality project to complete annually.
9) Identify a major group patient experience project to complete annually.
10) Work with stakeholders, business development, and marketing to improve market share.
11) Present bi-annually to the Cancer ICAP on quality, patient experience, clinical pathway development, and adherence.
12) Attendance is required at:
    - DSG meetings
    - DSG leadership meetings with UFHCC leaders
    - Assigned Cancer ICAP and/or UF Health Cancer committee meetings.
    - At least 70% of either UFHCC Grand Rounds or UFHCC Research Seminar Series, per academic year.

Meetings and Administrative Coordination

DSGs are scheduled to regularly meet *at least* every other month (6 times per year). Meetings should include new study discussion(s) and review of current studies within the DSG portfolio, with overview of trials that are actively accruing, status updates, or trials experiencing issues in the clinic that could impact research. Discussions should also include review of concepts/trials declined since the last meeting as well as gaps and opportunities within the research portfolio. Ad hoc meetings can also be called at the discretion of the DSG leaders to ensure protocol development is not impeded or to address urgent needs. Any DSG meeting or official communication can occur in-person, virtually, or through other electronic means.

In preparation for scheduled DSG meetings, meeting materials will be sent out to attendees approximately one week prior to the DSG meeting. These meeting materials may include the agenda, previous meeting minutes, the current DSG study portfolio, a summary of DSG performance, and new trial information, as applicable. Meetings where a new trial will be discussed (first-stage review) must have at least 2 DSG physician faculty members present who qualify as key stakeholders for voting purposes. Attendance will be noted during the meeting through sign-in sheet or electronic attendance indicators. A Qualtrics survey will be sent out to capture DSG endorsement or declination.

In addition to routine DSG meetings, UFHCC and DSG leaders meet quarterly, alternating between individual and group meetings. The Deputy Director, the ADCR, the ADMA, the Administrative Director of the CRO, and the Assistant Director of Regulatory Affairs and Compliance meet with each DSG leadership team to review its research portfolio performance, challenges, and strategic goals as part of these individual meetings. Alternating with these, the Deputy Director convenes the DSG Leadership Committee, which is comprised of the research program leaders, shared resource leaders, Center Director, Associate Director for Community Outreach and Engagement (COE), Director, Office of COE, Associate Director for Population Sciences, and the Associate

Director for Basic Sciences. The Committee monitors the progress and impact of UFHCC clinical research on the CA, identifies systemic obstacles to trial initiation and accrual, receives updates from the DSGs, discusses new UFHCC resource needs or best practices, and establishes and reviews policies. These quarterly individual and group meetings are critical working components of the ROS.

Review Process

The DSG does not require review of cancer-relevant clinical trials that are considered non-human or are student led projects initiated to fulfill degree requirements. The DSG research leader for each group can determine if a new study should be reviewed at the next regularly scheduled DSG meeting or through an ad hoc review process.

Concepts considered by investigators and new trials moved forward for first-stage review must be submitted to the DSG leaders and the DSG administrator prior to the meeting. The content of each submission depends on the type of review, which is detailed below.

Review Types

New Concept Review

Interventional trial concepts that necessitate use of CRO Coordinator, Data Management or Project Management Office resources should be reviewed by the IIT Think Tank Group (I2T3) prior to obtaining DSG endorsement of the concept. The aim of this review is to provide feedback to the investigator on study design, clinical impact, scientific merit, and feasibility prior to full development. The I2T3 group is comprised of investigators, statisticians, community members, and clinical research team members so that multiple perspectives contribute to the feedback collected. Feedback from this meeting is incorporated into the final concept pre-review form, which is then submitted to the PI for incorporation into their study plan.

The purpose of the DSG new concept review is to provide feedback to the study team and establish if the protocol concept has preliminary scientific merit and fulfills the current needs for the DSG research portfolio and the UFHCC catchment area. This is not a true first-stage review since a full protocol is not available and the next step is not SRMC submission. Feedback to the study team may be provided through formal, informal, written or verbal means.

Necessary submission components:

- Concept pre-review form, completed after I2T3 review

New Study (Full Protocol) Review

A two-stage review process is followed for all new clinical trial protocols proposed for activation at the UFHCC. The first stage is review of the protocol at the level of the DSG while the second stage is at the level of the SRMC. Prior to the initial review of a new study, the PI and/or study team should submit necessary submission materials to CRO Staff. These submission materials include a protocol synopsis OR full protocol. Upon intake of a new study, CRO Staff will confirm if the new study is disease specific or disease agnostic. The study will be forwarded to the appropriate DSG Research Leader for interest. If interest is confirmed, the DSG Research Leader for each group will determine if the study should be reviewed through an ad hoc review process or at the next scheduled DSG meeting.

For disease-agnostic studies, CRO staff will determine if endorsement from other DSGs is needed. If interest is confirmed, the primary DSG research leader will determine if the study should be reviewed through an ad hoc review process or at the next scheduled DSG meeting. If the study is endorsed and secondary DSG endorsements are determined to be needed, the DSG coordinator will facilitate the review and whether any secondary endorsements are provided from secondary contributing DSG's research leader(s) on behalf of their DSGs. If endorsement from secondary DSGs is not needed, the DSG coordinator will note as such.

For studies reviewed through an ad hoc review process, the DSG Research Leader will identify key stakeholders from the DSG for the DSG administrator to contact for their vote.

For studies reviewed at a meeting, it is expected for the PI or their delegate to present a short presentation during the DSG meeting. The short presentation should touch on the following:

- Scientific Rationale
- Prioritization
- Community Outreach and Engagement
    - Catchment Area Impact
    - Recruitment Strategies
- Competing trials
    - **Note:** It is a rare exception for a new trial to be acceptable if competing studies already exist
- Feasibility
- Enrollment expectations relative to study duration
- Staffing

Continuation/Status Update

The DSG will review the status of current trials at each DSG meeting. Information that should be discussed includes accrual and any difficulties experienced for the study. Any upcoming major amendments, major protocol revisions, or changes to clinical research resources can also be discussed during each DSG meeting.

Necessary submission components:

- Accrual status summary relative to target
- Next SRMC continuation review date
- Overall DSG portfolio of trials relative to diseases encountered

Decisions

After DSG (first-stage) review and discussion of a new trial, all key stakeholder members (identified by the DSG research leader) will cast their votes and have the opportunity to provide comments/feedback. Self-recusals for conflicts of interest are encouraged. Votes are compiled for the following decisions:

- Endorsement: The study is scientifically sound and fulfills a need in the current DSG research portfolio as well as in the UFHCC catchment area. After the study is endorsed, the DSG submission form will need to be completed and signed by the DSG Research Leader.
    - If the study has a primary DSG that is disease agnostic, such as the ETG or CCPS, and the study targets a patient population of another DSG, the primary DSG will conduct the DSG review while any other acknowledging DSGs will be provided the study protocol and opportunity to acknowledge within Qualtrics.
    - All comments will be provided to the DSG research leader who can summarize or include them in their endorsement to SRMC and/or provide feedback to the study leadership team.
- Tabled: The PI and study team will need to make changes to address the concerns of the group. These concerns could include scientific validity or fulfillment of the DSG research portfolio and the UFHCC catchment area. Once revisions are completed, the DSG leader(s) will make the final decision. The minutes will be updated to reflect the final decision.
- Declination: The study is not scientifically sound and does not fulfill a need in the current DSG research portfolio as well as in the UFHCC catchment area. Once the study is declined, the study will not move past the DSG.
    - If the study team chooses to re-work the concept, A new review may be conducted.

Appendices

Appendix 1: I2T3 Concept DSG Review Form

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**: Choose an item.

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

4. Concept Information	
4.1 Concept Title	
4.2 Hypothesis	*Please clearly state the hypothesis to be tested by this trial in no more than a few sentences:*
4.3 Primary Objective/ Endpoint	
4.4 Secondary Objectives/ Endpoints	
4.5 Exploratory Aims / Correlative Studies proposed	
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:
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

CONCEPT SHORT NAME (PI):_____

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).

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

CONCEPT SHORT NAME (PI):_____

8.4 Briefly describe the data analysis plan	

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

CONCEPT SHORT NAME (PI):_____

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:	Click or tap to enter a date.

13.0 ADCR Reviewer	
Scientific Review at I2T3 Details	
Date most recently presented at I2T3: Click or tap to enter a date.	
Qualtrics summary (average) score (full report attached to this form): Choose an item.	
Comments (please describe any outlier scores or concerns reported by I2T3)	
Final Review by ADCR	
Comments	
Merit Score	Choose an item.
ADCR Signature	

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:

Appendix 2: DSG Submission Form

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:	[Disease Site Group]	Principal Investigator:	[PI Last, First Name]
Protocol Number:	[Protocol Number]	Sponsor:	[Sponsor Name]
Protocol Title:	[Full Protocol Title]		
Sponsor Type:	[Sponsor Type]	UFHCC Priority Score:	[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.

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: [Total Accrual Goal] **Annual:** [Annual Accrual Goal]

6. What is the projected enrollment period? **In Month(s):** [Enrollment Period]

7. List protocol number(s) for similar historical studies that have been activated at UF:
   [Similar historical studies]
   a. If this study is an IIT, will additional sites be opened? ☐ Yes ☐ No
   b. If "yes," how many site(s) and where?
      [Additional Sites]

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.).
      [Potential issues that may affect enrollment]

9. Does this study involve Cellular Therapy and/or apharesis? ☐ Yes ☐ 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. If applicable, have all barriers to enrollment been adequately addressed by the DSG?
    ☐ Yes ☐ No

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

DSG Submission Form | Page 1

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: [Last Name, First Name]

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

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, "[Other - Specification]")

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

22. How does this study fulfill a need in the current DSG research portfolio?
    Click or tap here to enter text.

23. How does this study fulfill a need in the UFHCC catchment area?
    Click or tap here to enter text.

24. Additional Comments:
    Click or tap here to enter text.

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

Appendix 3: CCPS DSG Submission Form

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:	[Disease Site Group]	Principal Investigator:	[PI Last, First Name]
Protocol Number:	[Protocol Number]	Sponsor:	[Sponsor Name]
Protocol Title:	[Full Protocol Title]		
Sponsor Type:	[Sponsor Type]	UFHCC Priority Score:	[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.

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: [Total Accrual Goal] **Annual:** [Annual Accrual Goal]

6. What is the projected enrollment period? **In Month(s):** [Enrollment Period]

7. List protocol number(s) for similar historical studies that have been activated at UF:
   [Similar historical studies]
   a. If this study is an IIT, will additional sites be opened? ☐ Yes ☐ No
   b. If "yes," how many site(s) and where?
      [Additional Sites]

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.).
      [Potential issues that may affect enrollment]

9. Does this study involve Cellular Therapy and/or apharesis? ☐ Yes ☐ 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. If applicable, have all barriers to enrollment been adequately addressed by the DSG?
    ☐ Yes ☐ No

12. If this is an early phase study, do you anticipate participating in the phase 1 portion of the trial?
    ☐ Yes ☐ No
    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

CCPS DSG Submission Form | Page 1

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: [Last Name, First Name]

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

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, "[Other - Specification]")

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

22. How does this study fulfill a need in the current DSG research portfolio?
Click or tap here to enter text.

23. How does this study fulfill a need in the UFHCC catchment area?
Click or tap here to enter text.

24. Additional Comments:
Click or tap here to enter text.

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 Cancer Control and Population Sciences Research Leader Date

_____ _____
Signature of Acknowledging DSG Research Leader Date

Appendix 4: DSG Leadership List

Disease-Specific Groups	Research Leader(s)	Clinical Leader(s)
Breast	Karen Daily, DO	Lisa Spiguel, MD & Oluwadamilola T, Oladeru, MD
Cutaneous	Bently Doonan, MD, MS	Christiana Shaw, MD
Gastrointestinal	Thomas George, MD, FACP	Steven J. Hughes, MD
Genitourinary	Paul L. Crispen, MD	Jonathan Chatzkel, MD
Gynecologic	Merry Jennifer Markham, MD	TBD
Head and Neck	Kathryn Hitchcock, MD, PhD	Dennie Jones, Jr., MD
Hematologic Malignancies	Nosha Farhadfar, MD	Randy A. Brown, MD & Jack W. Hsu, MD
Neurology	David Tran, MD	Maryam Rahman, MD
Pediatrics	Elias Sayour, MD, PhD	William B. Slayton, MD
Sarcoma	Joanne Lagmay, MD	Andre Spiguel, MD
Thoracic	Frederic Kaye, MD & Aaron Franke, MD (Assoc)	Hiren Mehta, MD
Disease-Agnostic Groups	**Research Leader(s)**	**Clinical Leader(s)**
Cancer Control and Population Sciences	Dejana Braithwaite, PhD & Janice Krieger, PhD	N/A
Experimental Therapeutics Group	Thomas George, MD, FACP & David DeRemer, PharmD, FCCP, BCOP	N/A

Appendix 5: First-Stage Review Process

1. All interventional cancer-relevant concepts/protocols considered by any PI should be logged within the Study Intake Tracker located within the UFHCC CRO Microsoft TEAMS channel.

2. Study Intake Tracker within TEAMS is updated to track concept/protocol initial disposition during First-Stage Review.
    - For study teams outside of the UFHCC CRO, email DSG-Support@cancer.ufl.edu with below information and provide updates as they occur. Tracking these items is required to capture all PRMS activities of the UFHCC.

- Date Concept/Protocol Received
- Study Identifier
- Disease to be studied
- PI
- DSG(s) assigned
- Date Declined (if applicable)
    - Reason for declining
- Study Sponsor
- Sponsor Type (Nat'l, Industry, Institutional, EPR)
- Study entered into OnCore?
    - OCR#

3. If initial PI interest is confirmed, concept/trial is forwarded to the DSG for consideration and endorsement

4. Once full protocol is available, formal DSG vote is obtained via convened mtg or via Qualtrics

5. For studies declined by DSG, tracker is updated to reflect the vote with reason for declining.

6. For studies endorsed by DSG, OnCore study shell is built (See Guidance – UFHCC Protocol Creation document on UFHCC CRO website) and DSG endorsement reported as a "Other Committee" action within PC Console ->Details->Reviews.

7. Endorsed studies progress to stage 2 review (SRMC) via PAC.