University of Florida Health Cancer Center

UFHCC Disease Site Group Charter

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Table of Contents

Overview ..............................................................................................................................................2
Disease Site Group Purpose ................................................................................................................3
Disease Site Group Structure ..............................................................................................................3
Membership Selection ..........................................................................................................................3
Meeting Agenda ...................................................................................................................................4
Responsibilities of the Lead/Co-lead .................................................................................................5
Responsibilities of CTO Support Staff ...............................................................................................6
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 appropriateness, feasibility, and scientific merit as defined by the UFHCC. The committees comprising UFHCC’s Research Oversight System (ROS) work together to provide a complementary review, but each has a distinct, and clearly defined role. The result of the various reviews is that each clinical trial is evaluated for its alignment with UFHCC overarching objectives. The likelihood of successful completion of each trial is maximized through an assessment of its feasibility, priority in the context of potentially competing trials, and scientific integrity.

The UFHCC ROS components involved in protocol selection and approval include:

*Disease Site Group (DSG):* The charge to the UFHCC DSGs is to provide an integrated, multidisciplinary approach to guide in the selection, prioritization and conduct of high quality cancer research studies. Each clinical DSG has at least one designated clinical and research leader while the Cancer Population Sciences DSG has research co-leaders. The DSGs routinely meet to review all new and ongoing studies under their purview. All new interventional trials must be reviewed and approved by the applicable group of record prior to SRMC submission (for example, any clinical trials conducted in breast cancer must be vetted through the breast DSG). DSGs are responsible for ensuring that adequate resources are available to conduct the study. 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, and overall endorsement of support from the group. In addition, the DSG leaders are responsible for evaluating the impact of proposed study on the patient population at UF Health and/or the UFHCC catchment area. The DSG leadership collectively engages with one another and with UFHCC leadership through the UFHCC DSG Leadership Group. This quarterly management group is a critical working component of the ROS.

*Investigator Initiated Trial Concept Development Group (CDG):* The UFHCC has a pre-review process for all cancer-relevant IITs categorized as “interventional treatment” or otherwise involving investigational drugs, devices or medical procedures. This review, performed through the CDG, is mandatory for any IITs planning to utilize UFHCC CRO resources including Project Management Office (PMO) services, research coordinator or data entry support, regulatory management, financial, or other in-kind support. Concepts not meeting these specifications are exempt from this mandatory pre-review, but may request this service. The aims of this comprehensive review are to 1) improve the feasibility, scientific merit and ultimate success in completing cancer-relevant IITs, 2) shorten the timeframe from concept approval to protocol activation and 3) maximize staff and investigator effort in protocol development.

*Feasibility Group (FG):* The UFHCC recognizes that a common barrier to successful trial completion is inadequate resource allocation. As a steward of limited resources, the UFHCC Feasibility Group (FG) is responsible for reviewing or providing feedback on the non-scientific aspects of a study being considered. The goal is to assist the PIs and DSGs in ensuring adequate institutional, financial, personnel and patient resources are available. The UFHCC FG provides this information as a required component of the UFHCC CRO-managed protocol development and as a consultant to other UFHCC investigators. The FG issues a recommendation of feasible or non-feasible for each study reviewed to supplement DSG decision making. The FG is also involved in corrective action plan development for all studies at risk for closure or being place on probation by the SRMC.

*Scientific Review and Monitoring Committee (SRMC):* SRMC provides the critical review of scientific merit, methodology, and validity of statistical analyses of cancer-relevant studies prior to activation. The committee will ensure proper prioritization of studies and the ability to monitor all cancer-related studies for expected progress relating to accrual goals and performance...
standards. The SRMC also has the authority and charge to close any study not meeting the expected accrual goals or trials that have become obsolete by new advances in the field and therefore whose scientific rationale has become superseded by clinical practice. For a protocol to be reviewed by the SRMC, both the sponsoring DSG/RP and UFHCC FC (for CTO managed protocols only) must provide endorsement.

Disease Site Group Purpose
The primary objective of each DSG is to provide an integrated, multidisciplinary approach to guide the selection and endorsement of high quality cancer clinical trials. Each DSG is charged with establishing priorities within the framework described below.

To meet these objectives, the DSG and their members are responsible for:

- Collaborating with UFHCC members and other UFHCC Research Programs to develop areas of research with potential impact in the field of study,
- Reviewing initial study concepts for UF investigator-initiated trials (IITs),
- Review and endorsement of all new trials which are to be opened, with attention to competing trials and impact to the UFHCC catchment area,
- Ongoing review and internal prioritization of interventional studies,
- Performing ongoing review of the DSG’s research portfolio, including a review of accrual rates and continued scientific merit for existing trials,
- Optimizing population subgroup recruitment, including increasing both gender and racial/ethnic diversity, with particular emphasis on the UFHCC catchment area,
- Maintaining a priority list of pending and active protocols for their research portfolio.

Disease Site Group Structure
Disease Site Groups have been formed to support the programmatic deployment of cancer-relevant clinical trials to the UFHCC catchment area and in conjunction with the UFHCC’s destination cancer programs. The list of DSGs, along with the UFHCC members serving as DSG leaders is maintained by UFHCC administration.

Membership Selection
The UFHCC Director is responsible for approval of the formation of each DSG. Each DSG is led by a physician team and includes a multidisciplinary membership roster. The DSG research leader is appointed by the UFHCC Associate Director for Clinical Investigation (ADCI) while the DSG clinical leader is appointed by the UFHCC Associate Director for Medical Affairs. Leadership terms are for three (3) years, renewable upon the Director’s reapproval. The remaining membership consists of disease-focused (or for CPS, thematically research-focused) members and may include:

- Investigators (Physicians, Pharmacists, PhDs, etc.) - voting members,
- Other clinical staff involved in the research (e.g. advanced practice providers, nurses, trainees) – non-voting attendees,
- Clinical Research Office staff – non-voting attendees,
- Clinical Research Administrators – non-voting attendees,
- Cancer Center Administrators – non-voting attendees.
To ensure a multidisciplinary perspective, the DSG composition includes a breadth in discipline, including, but not limited to personnel from the following departments (as appropriate): Basic Science, Medical Oncology/Hematology, Pathology, Radiation Oncology, Radiology, Interventional Radiology, Laboratory Research, and Surgery. DSG membership rosters are maintained by the DSG leaders in conjunction with CTO support staff. DSGs are required to meet at least quarterly (in person or virtually) to review new project proposals and the full portfolio of trials. Trials may also be reviewed on an ad hoc basis between meetings as is necessary based on their priority.

Meeting Agenda

LOI Review for UFHCC Investigator-Initiated Trials (IITs)

At the UFHCC, the review of UF IITs is a multi-step process, including review of a proposed concept followed by subsequent review of the full protocol assuming the concept is approved to move forward with protocol development. Concept review is an important step intended to reduce faculty and staff effort in developing protocols of lesser scientific merit or redundancies; therefore, investigators must first submit UFHCC IIT concepts to the DSG for comment, review and endorsement. This review provides an opportunity for the DSG to strengthen the proposed research by offering constructive feedback on the hypothesis, objectives, research design concepts, eligibility criteria, etc. IIT concepts that are determined to be of scientific importance to the DSG, that do not overlap with existing trials, and those which can reasonably be expected to complete accrual within the desired time frame, may be endorsed and will be submitted to the UFHCC IIT CDG.

Protocol Endorsement

The DSGs review potential protocols for endorsement, taking into account their overall study portfolio, potential competing studies, patient population, and likelihood of successfully accruing patients to the trial. Importantly, the DSG is required to confirm the PI’s assessment of the accrual goals and annual target enrollments. The DSG leaders are also responsible for ensuring that proposed studies align with clinical workflows and that all endorsed studies have the potential for a meaningful impact on the patient populations served by the UFHCC. This review process culminates with the submission of a DSG-endorsed protocol to the SRMC. This endorsement is documented on the SRMC submission form by a signature by the sponsoring DSG research leader or delegate. Any conflicts with a currently approved protocol must be explained in detail at the time of the submission. Note: protocol review by the UFHCC FG may also be required for a study to be placed on the SRMC agenda. Protocol reviews by the DSG and FG may occur simultaneously and endorsements are performed independently but in conjunction with each other.

Prioritization of Potential Trials

Each DSG reviews a list of active clinical trials to determine whether the proposed study competes with an existing trial. If a study is deemed to be in competition with an ongoing study, the DSG must determine whether 1) current accrual rates and the institution’s patient population justify keeping both studies open or 2) if any competing study or studies should be closed or are expected to close before the new trial is opened.

Competing studies at the UFHCC are not allowed, with the exception of the following: 1) early phase studies, 2) competing studies demonstrating maximized accrual rates and/or are anticipated to complete accrual before the new trial is opened, or 3) studies that do not have completely overlapping eligibility criteria.

Adequate accrual rates vary depending on the target accrual for each trial. All DSGs must prioritize their portfolio of studies and any new or proposed trials in accordance with the UFHCC SRMC manual. In general, the highest priority studies are UFHCC member IITs.

Inclusion of Women and Minorities or Population Subgroup Recruitment
It is expected that women and members of minority groups and their sub-populations be included in all UFHCC clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Accrual of women and minorities to interventional treatment, interventional non-treatment and non-interventional studies should be proportional to the patient population in the UFHCC’s primary catchment area. DSGs are responsible for identifying opportunities and strategies for recruitment and retention of women and minorities; periodic review of recruitment rates for women and minorities will be conducted to correct any deficiencies that are noted.

Regular Review of Research Portfolio and Trial Accrual

Ongoing review of the research portfolio is the responsibility of each DSG. This review should include accrual to their active trials as well as the analysis of continued scientific merit of ongoing studies. The DSGs must regularly discuss protocols that are not accruing as expected and preemptively make recommendations to address accrual issues. DSG self-correction is always preferred prior to review at SRMC.

Communication with other UFHCC committees

The DSGs are responsible for providing a coordinated response to any questions or concerns raised by the other committees of the UFHCC, including the SRMC, the Data Integrity and Safety Committee (DISC), the Feasibility Group (FG) and the Investigator Initiated Trial Concept Development Group (CDG), as is appropriate or warranted.

Responsibilities of the Lead/Co-lead

Each DSG leader is responsible for ensuring the DSG functions effectively as outlined in this Charter. Specifically, they:

- Contribute to the mission of NCI-designation and high-quality comprehensive cancer patient care;
- Support the integration of multidisciplinary coordinated care and research as the culture in clinical practice;
- Participate in UFHCC programs representing the respective DSG interests (i.e., educational meetings, industry partner summits, research program meetings, DSG Leadership committee meetings, etc.);
- Support and foster the training/educational needs of research staff assigned to the DSG;
- Chair each DSG meeting, ensure adequate investigator representation is present and that meeting minutes are generated and archived;
- Facilitate distribution of Cancer Center communications to DSG members;
- Facilitate any ad hoc meetings or communications (i.e., by email or teleconference) as needed.

In addition to the above general DSG leader responsibilities, specific further responsibilities include:

- Research Leader:
  - Establishes and maintains a comprehensive research portfolio that covers the key diagnoses seen within the DSG’s and UFHCC’s patient population (portfolio includes industry, IITs, and NCTN trials and emphasis on studies that serve the catchment area);
  - Reviews and analyzes monthly and annual accrual metrics for the active trial portfolio;
  - Oversees ongoing internal prioritization of the study portfolio;
  - Provides signing authority on behalf of DSG for SRMC submissions;
• Provides mentorship to junior faculty in the DSG, esp. in the development of IITs and support the translation of UF-based scientific discoveries to the clinic;
• Arbitrates discussions regarding priority of trials;
• Research leaders of clinical DSGs report to the Associate Director for Clinical Investigation.

- **Clinical Leader:**
  • Serves on Network Cancer Committee and/or support and perform quality improvement/quality assurance studies;
  • Maintains Commission on Cancer compliance with Tumor Board meetings and documentation;
  • Supports efforts to attain or maintain national external accreditation of cancer program (e.g., Quality Oncology Practice Initiative (QOPI), American College of Radiology (ACR), National Accreditation Program for Breast Cancer (NAPBC), etc.);
  • Clinical leaders of clinical DSGs report to the Associate Director for Medical Affairs.

### Responsibilities of CRO Support Staff
- Maintain membership rosters for DSGs,
- Create and distribute agendas and materials to the DSG for review,
- Record meeting attendance and meeting minutes,
- Prepare and route DSG meeting decisions (including endorsements, disapprovals, and voluntary study closure decisions) to the SRMC and other committees as needed,
- Maintain priority lists for workflow and patient accrual based on disease team discussions,
- Report up through to the CRO Administrative Director.