



University of Florida Health Cancer Center

**Scientific Review and Monitoring
Committee (SRMC)**

Policies and Procedures

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University of Florida Health Cancer Center

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Manual Updates

Version 4.0 replaces Version 3.0 dated 07/13/2017

- Clarified SRMC charges (pg.7)
- Updated Pre-review process requirements (pg. 10)
- Updated needed documents for Continuation Review Submissions (pg.12)
- Added SRMC intake policy for IRB approved studies (pg.13)
- Updated change reviews from full-committee to expedited review types (pg.14)
- Modified required review of study amendments for protocols from full committee to expedited (pg.14)
- Updated studies that are eligible for Administrative Review by the SRMC (pg.14)
- Added requirement that studies need to be opened within 1 year of SRMC initial approval (pg.15)
- Added requirement for Feasibility Group input and review of a CAP for a study not meeting at least 50% of their year accrual goal for any Continuation Review (pg.16)
- Added definition of a study accrual (pg.16)
- Updated Continuation Review Policy for studies defined as treating a rare disease (pg.17)
- Added Updated Zero Tolerance Policy (pg.17)
- Added PI/study team responsibilities for studies voted to be closed by SRMC (pg.18)
- Updated possible Risk Level Assessment choices (pg.19)
- Updated protocol reviewer responsibilities (pg.21)
- Updated SRMC core members roster (pg.24)
- Added DSMP evaluation question to SRMC Reviewer Forms (pg. 33 & 46)
- Added Change Review Form (pg. 51-56)
- Added Appendix K: SRMC Scientific Scoring Guidance (pg.57)
- Added Appendix L: SRMC Intake Policy for IRB Approved Studies (pg.58)

Abbreviations

ARC	Affiliate Research Consortium
BMT CTN	Blood and Marrow Transplant Clinical Trials Network
CAP	Corrective Action Plan
CCSG	Cancer Center Support Grant
CDG	Concept Development Group
CPCS	Cancer Prevention and Control Subcommittee
CR	Continuing Reviews
CRA	Clinical Research Associate
CRO	Clinical Research Office
CTEP	Cancer Therapy Evaluation Program
CTMS	Clinical Trials Management System
DCP	Division of Cancer Prevention
DHHS	Department of Health and Human Services
DSG	Disease Site Group
DSMB	Data and Safety Monitoring Board
DISC	Data Integrity and Safety Committee
EPR	Externally Peer Reviewed
ETCTN	Experimental Therapeutics Clinical Trials Network
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HM-BMT	Hematology - Blood and Marrow Transplant
HSR	Health Services Research
IDE	Investigational Device Exemption
IIT	Investigator Initiated Trial
IND	Investigational New Drug
IRB	Institutional Review Board
NCI	National Cancer Institute
NCTN	National Clinical Trials Network
NIH	National Institute of Health

PHS	Public Health Service
PI	Principal Investigator
PMO	Project Management Office
PRMS	Protocol Review and Monitoring System
RP	Research Program
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SRMC	Scientific Review and Monitoring Committee
UF	University of Florida
UFHCC	University of Florida Health Cancer Center

1.0 SRMC Committee Overview

A Protocol Review and Management System (PRMS), as defined by the Cancer Center Support Grant (CCSG), must be utilized by a cancer center to fulfill the requirements for National Cancer Institute (NCI) designation.

NCI Guidelines for a PRMS include the following:

- A qualified committee of adequate size and with the breadth of expertise necessary to conduct a critical and fair scientific review of all institutional clinical cancer protocols;
- A committee with sufficient authority and processes for initiating, monitoring and terminating all cancer clinical research protocols in the institution(s) comprising the Center;
- Clear criteria and processes for scientific review, taking into account the rationale and study design, potential duplication of studies elsewhere, adequacy of biostatistical input, and feasibility for completion within a reasonable time;
- Appropriate processes for ensuring prioritization of competing protocols from all sources and optimal use of the Center's scientific resources;
- Robust criteria for monitoring trials to ensure they are making sufficient scientific progress; and
- Adequate and appropriate criteria and process for terminating trials that do not meet scientific goals (qualifying trials involving rare diseases are excluded)

The University of Florida Health Cancer Center (UFHCC) incorporates the use of a Scientific Review and Monitoring Committee (SRMC) which serves as the scientific merit and resource monitoring arm of the PRMS. The SRMC is charged with: 1) reviewing all new research studies and selected amendments for ongoing trials for scientific merit, methodology, validity of statistical analysis, potential feasibility based upon anticipated accrual goals; 2) ongoing monitoring of accrual to active interventional protocols to ensure that studies are adequately making progress towards their stated accrual goals and requiring corrective actions related to recruitment when necessary; 3) evaluating competing studies with overlapping eligibility criteria; and 4) establishing each protocol's priority based on institutional priorities. The SRMC is also responsible for the ongoing annual scientific review of cancer center protocols. Particular scrutiny in all areas is placed upon investigator-initiated clinical trials (IITs) for which no prior peer review has been conducted.

Mechanisms within the UFHCC SRMC ensure proper prioritization of studies within the site and the ability to monitor all cancer-related studies for expected progress relating to accrual goals and performance standards. The SRMC has the authority and charge to close any study deemed as not meeting the expected accrual goals or scientific standards laid out within the initial and ongoing approvals. Interventional studies are initially evaluated for feasibility in terms of accrual and available resources within their home Disease Site Group (DSG) and subsequently submitted to the SRMC for review. These studies are then assessed for scientific merit, priorities, and progress through the SRMC. Protocols will not be reviewed by a UF Institutional Review Board (IRB) until SRMC approval has been received. The UF IRB will not release the approval letter for any cancer-relevant research prior to the study receiving final SRMC approval. The SRMC is not intended to duplicate, or overlap with, the responsibilities of the IRB. The committee is complementary to the IRB, and UF associated IRBs review all research involving human subjects to ensure that their welfare and rights are protected as mandated by federal

regulations. Approvals must be obtained from both SRMC and IRB prior to commencing any research study. Continuing reviews (CRs) are conducted independently by the SRMC at 6 or 12 month periods to affirm that accrual goals are being met and the scientific rigor is being upheld.

2.0 Scope of Application

All cancer-related studies conducted at the UFHCC or otherwise supported with institutional resources must be reviewed and approved by SRMC prior to initiation of the study. The University of Florida defines a “cancer relevant” study as one 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 (including smoking and tobacco-associated studies, surveys, hepatitis or HPV vaccines, etc.); or the local PI plans to exclusively enroll current, former or potential cancer patients into the study. Interventional studies, especially those that involve treatment, supportive care or diagnosis of cancer, must undergo full committee review while Non-Interventional studies may qualify for expedited or administrative review. In addition, major amendments for all full committee studies must be submitted for review for the duration of the study’s active accrual period. Major amendments are further defined in section 7.3.

Research studies that have already received peer review by an organization accepted by the NCI (<https://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf>) or by an NCI approved external PRMS do not require full SRMC committee review. Notable examples include the NCI’s National Clinical Trials Network (NCTN), Experimental Therapeutics Clinical Trials Network (ETCTN), and Blood and Marrow Transplant Clinical Trials Network (BMT CTN) sponsored studies. These previously reviewed studies still require entry into the UFHCC’s Clinical Trials Management System (CTMS) and expedited SRMC review to ensure feasibility, proper resource utilization, and that any competing trials have been appropriately prioritized.

Non-human cancer relevant studies do not require SRMC review and approval.

3.0 Membership

The Director of the UF Health Cancer Center appoints the chair of the SRMC. The Director, in consultation with the Chair of the SRMC and the UFHCC Associate Director of Clinical Investigation, appoints Vice Chairs, core, and administrative members of the committee. The Chair, Vice Chairs, and committee members represent various academic and clinical departments within the University of Florida that are engaged in cancer research. In selecting members, the UFHCC strives to engage faculty and staff with expertise in a broad range of specialty and treatment modality areas. Representatives include those from the fields of basic laboratory, clinical, cancer prevention and control, and population-based science. Members of the committee come from the departments of medical oncology, bone marrow transplant, surgery, radiation oncology, neuro-oncology, pediatrics, radiology, nursing, pathology, pharmacy, public health, biostatistics, as well as clinical research staff and a patient advocate. Having a diverse, multi-disciplinary committee affords the SRMC a satisfactory breadth of knowledge for the review of investigator-initiated and other studies proposed at the UFHCC.

Members are appointed for 3-year terms that are renewed at the discretion of the UFHCC Director. Members will receive an appointment letter and a copy of the UFHCC SRMC Policies and Procedures manual. Voting members include UFHCC biostatisticians, appointed representatives of academic units/departments/centers, and patient advocates. Non-voting members include non-appointed clinical research staff representatives and the SRMC Administrator. At-large or additional ad hoc members with specific expertise not already present on the SRMC may be designated by the SRMC Chair as necessary.

4.0 Meetings and Administrative Coordination

The SRMC meets twice monthly for initial and continuing study reviews. Meetings may only start once quorum is met. Quorum for the SRMC is defined as having at least 5 of the voting members (i.e., appointed core committee members in attendance) including a minimum of one Chair or Vice Chair and one biostatistician. Members will either volunteer or be assigned for review based on need and availability from the relevant areas of expertise. A Vice Chair executes the responsibilities of the Chair when the Chair is unavailable or as delegated by the Chair. When a tie vote occurs, the Chair or Vice Chair, in the Chair's absence, can cast the deciding vote.

Approximately one week prior to each SRMC meeting, reviewers from the committee will be assigned by the Chair or his delegate to review all necessary protocols. In most cases, at least one primary and biostatistician reviewer are assigned to initial protocol reviews (see Section 7.2.1), paying particular attention to assigning reviewers to topics most relevant to their field of expertise if possible.

Meeting agendas are sent out to Principal Investigators and committee members prior to the SRMC meeting. The SRMC meets twice per month, on the Second and Fourth Thursday of each month. Committee members are expected to attend at least one of these meetings. Overlapping participation between the SRMC membership and DSG leadership promotes consistency throughout the review process.

A research administrator is assigned to provide administrative support to the SRMC. The SRMC Administrator receives, tracks, and reviews all SRMC submissions for completeness. The SRMC Administrator also reviews study related information entered into the CTMS for accuracy. The Administrator assists the Chair with assigning reviewers for all accepted submissions, handles completed review forms and manages meeting agendas, documentation of meeting minutes and generation of formal review paperwork. In addition, the SRMC Administrator tracks committee member attendances, issues and closes queries in the CTMS, and generates reports for the SRMC Chair and UFHCC Director. The SRMC Administrator is responsible for maintaining all documentation related to SRMC reviews and actions within the CTMS in support of the UFHCC PRMS.

In addition to routine committee meetings, there is a SRMC Executive Committee that meets quarterly. This committee is comprised of the Chair, Vice Chairs, SRMC Administrator, Associate Director for Clinical Investigation, Clinical Research Director and other key members at the discretion of the Chair. This group reviews SRMC metrics and sets forth proposed revisions to SRMC policy and workflows to the full committee.

5.0 Cancer Prevention and Control Subcommittee

The Cancer Prevention and Control Subcommittee (CPCS) of the SRMC reviews non-treatment studies that do not involve investigational drugs, devices or medical procedures. Behavioral, communication, nursing, general population-science based studies that involve cancer as well as secondary analysis of patient data fall under the purview of the CPCS. This subcommittee provides appropriate expertise for the evaluation of protocols that focus on: implementation science, disparities, palliative care, communication/shared-decision making, biomedical informatics, tobacco prevention, symptom science and self-management. These scientific themes are not exclusive, however, and decision as to review assignment will ultimately be decided by the SRMC Chair and Vice-Chairs. The CPCS meets quarterly and on an ad hoc basis as needed. Meetings may be conducted electronically or in person and is led by a representative SRMC Vice-Chair. The CPCS makes recommendations to the SRMC regarding the studies it reviews. Final approval is provided by the parent committee. The appropriate NCI guidelines apply to both the SRMC and the CPCS.

6.0 SRMC Pre-Review Process

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 IIT Concept Development Group (CDG), is mandatory for any IITs planning to utilize UFHCC resources including Project Management Office (PMO) services, Clinical Research Office (CRO) services including research coordinator or data entry support, regulatory management, financial, or other in-kind support. Concepts not meeting these specifications are exempt from this pre-review, but can undergo pre-review if requested. The aims of this comprehensive, 2-stage 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. Protocols not having undergone first stage review and approval often suffer significant setbacks during the development and implementation phases of the study. This 2-stage review process enables institutional concepts, without a full protocol, to be reviewed for scientific merit and allows constructive feedback prior to significant investment of time and resources. Concepts approved in this first stage, which have secured adequate support, are then sent forward for full protocol development.

Further details regarding the SRMC Pre-Review process can be found within the “UFHCC Process for Investigator-Initiated Trial Review, Approval, Development and Activation” policy document.

7.0 SRMC Review Process

7.1 Protocol Prioritization

All interventional trials must be reviewed and approved by the home DSG (see Appendix B) of record prior to SRMC submission. DSGs are responsible for ensuring that adequate resources are available to conduct the study. The DSG research leader must attest to the projected annual accrual, requirements for CRO resources, presence or absence of competing studies, and overall support from the group on the “Disease Site Group (DSG) Protocol Approval Form” (Appendix E). In addition, a protocol flowchart that demonstrates where the proposed trial fits

into the DSG's active study portfolio must also be maintained in the CTMS by the DSG leader in conjunction with designated clinical research staff. When there are competing trials, the DSG leader is charged with determining if both studies can be open while achieving the defined accrual goals and must submit written justification for the proposed trial. In general, studies competing for the same patient population will be rejected by default in the absence of approved justification. The SRMC may consider competing studies when the proposed trials include 1) early phase studies, 2) when current studies have 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.

The SRMC will ensure the prioritization submitted by the DSG aligns with the overall priorities of the UFHCC. During the review process, all trials will be assigned a priority score which will be captured in the CTMS. The scoring system is based on protocol type, sponsorship, and potential for scientific impact. In general, institutionally sponsored or investigator initiated trials are given the highest priority. Where both studies are assigned the same score (per Appendix C), the priority will be given to the study that has been activated the longest. Scientific merit will also be scored by the SRMC committee as part of initial review.

Non-interventional studies are not required to be submitted to a DSG prior to SRMC submission. The SRMC will confirm protocol prioritization for these studies.

7.2 Submission Procedures

Prior to protocol submission to the SRMC, the PI reviews the study with their respective DSG for approval if applicable. This initial review determines feasibility, prioritization and overall interest in the study design and content. Further instructions for study prioritization are described in Appendix C. After the initial review and approval by the DSG, the protocol is then submitted to the SRMC.

As noted in section 7.1, non-interventional studies are exempt from DSG review.

The SRMC submission deadline is at 4PM two weeks prior to the next scheduled SRMC meeting for all interventional IITs. For all other submissions, the deadline is 4PM the Thursday prior to the next scheduled SRMC meeting, unless otherwise noted on the list of scheduled meetings and SRMC submission deadlines. A list of scheduled meetings and SRMC submission deadlines is available through the UFHCC CTO. All submissions to the SRMC must be made via the ePRMS Console within the CTMS.

Initial Submission

The PI or designee provides all necessary study documents to the SRMC through the CTMS submission console. The documents must include:

- SRMC Submission form (Appendix F; interventional studies only)
- DSG protocol approval form (Appendix E; interventional studies only)
- Complete study protocol with all appendices or investigational plan
- Investigator's Brochure, if applicable
- Feasibility Group recommendation letter (CRO supported studies only)
- Draft Informed Consent document (interventional IITs only)

- SRMC Pre-Review approval confirmation (qualifying IITs only; see section 6.0)
- Any other relevant study documentation

Submission of Amendments/Revisions

The PI or designee provides all necessary study documents to the SRMC through the CTMS submission console. The documents must include:

- Revised study protocol or investigational plan with tracked changes or revisions clearly marked
- Revised Investigator’s Brochure if applicable
- Revised Informed Consent document if applicable (interventional IITs only)
- Any other relevant study documentation

Submission of Continuation Reviews

The SRMC Administrator initiates all SRMC Continuation Reviews. Documents required include:

- Signed Protocol Activity Report form
- Corrective action plan (for studies not meeting accrual targets)
- Current Protocol
- Current Informed Consent document (interventional IITs only)
- Any other relevant study documentation

7.2.1 Review Team

The SRMC Administrator, in conjunction with the Chair, will assign committee members to review each new study or revision. In general, reviewers are chosen based on the credentialing and expertise required to provide an in-depth review of the assigned protocol. The number of reviewers and credentialing required for each type of study is noted below:

Committee	Type of Study	Reviewer Number & Type
Parent	UF Interventional IIT	Minimum of 4 including one physician, one biostatistician, and one patient advocate
CPCS	UF Interventional IIT	Minimum of 3 including one biostatistician
Parent	Industry or Other Externally Sponsored Interventional Trial	Minimum of 2 including one physician and one biostatistician
CPCS	Externally Sponsored Interventional Trial	Minimum of 2 including one biostatistician
Parent/CPCS	NCTN or EPR Interventional Trial	One reviewer
Parent/CPCS	Prospective, Non-Interventional Studies	Minimum of 2 including one biostatistician

Admin	Retrospective, Non-Interventional Studies	Administrative review only
Admin	IRB Exempt Studies	Administrative review only
Admin	Expanded Access or Single Patient INDs	Administrative review only
Admin	Banks/Registries	Administrative review only
Parent/CPCS	Study Amendments for Full Committee Protocols	Minimum of one. Physician review is required for amendments that alter the methods, procedures or study design, drug dosage or delivery, or eligibility of parent committee protocols. Biostatistician review is required for any changes that affect the statistical section of any protocol.

Additional reviewers may be assigned based on the complexity of the study and the disease or treatment regimen under consideration.

7.3 Review Types

Full reviews require a short summary to be presented by the assigned primary investigator or their delegate during the specified SRMC meeting time laid out in the agenda. Primary, secondary (if applicable) and biostatistician reviewers are presented with the full study protocol, Investigator’s Brochure if applicable, draft Informed Consent form and other supporting documentation (DSG approval, SRMC application, and any other relevant items). Reviewers submit comments and recommendations where applicable. Statistical concerns are addressed by the assigned statistician. Reviewers submit a completed and signed review form to the SRMC Administrator prior to the meeting (see Appendices G - J).

Full reviews are conducted for the following protocol types:

- All UF sponsored Interventional Investigator Initiated Trials (IITs)
- New industry, external academic or foundation-sponsored Interventional cancer research studies that have not previously undergone external peer review by one of the NCI approved groups (see section 2) or via a NCI-approved external PRMS.
- Annual renewal of interventional cancer studies that have not made adequate progress towards accrual goals.

Note for studies that have been IRB approved but never underwent an initial review by the SRMC (i.e., legacy studies), refer to Appendix K for the SRMC intake policy for IRB approved studies.

Expedited reviews must include the same documents as a full-review, but are only reviewed by the SRMC for confirmation of DSG approval (if applicable) and feasibility. Expedited reviews are conducted for the following submissions:

- NCI-approved National Clinical Trials Network and Experimental Therapeutics Clinical Trials Network studies.
- Other trials that have been peer-reviewed by one of the NCI approved groups (see Section 2) or via a NCI-approved external PRMS.

- Prospective, Non-Interventional studies (e.g. Observational or Ancillary/Correlative studies)
- Study amendments for protocols that were initially approved via a full committee review, which include: 1) addition/reduction of subject accrual goals; 2) changes in methods, procedures or study design; 3) modifications in drug dosage or delivery; 4) changes in exclusion or inclusion criteria; 5) addition of sub-site(s) for IITs; 6) change of Principal Investigator; or other major changes.
- Annual renewal of interventional cancer studies that have made adequate progress towards accrual goals.

Administrative reviews are conducted on studies that do not qualify for full committee or expedited review. It is the responsibility of the SRMC Administrator to review the study to confirm that a study meets the criteria for administrative review. Studies that qualify for administrative review are exempt from further SRMC review. An approval letter is not generated for these study reviews. Administrative reviews are conducted for the following submissions:

- Retrospective, Non-Interventional studies
- Tissue and/or data banks/registries
- Studies that meet criteria for IRB exempt status
- Expanded access studies that do not have a research hypothesis
- Single patient INDs

Continuation reviews (CRs) are performed to assess study progress, monitor subject accrual, evaluate for continued scientific merit, and confirm prioritization. CRs are conducted initially at six months (for non-rare disease studies) following activation (“Open to Accrual” status in the CTMS) and then, minimally, at 12 month intervals thereafter on all full committee and expedited interventional protocols that are active with ongoing enrollment. At CR, the committee will determine if there have been any developments affecting the study objectives or general study conduct. In addition, current accrual will be compared against initial accrual goals. If a study is shown to be below the target accrual, it will be the responsibility of the PI or DSG to give an explanation as to why it is below the target goal and provide a corrective plan of action.

CRs for protocols that have achieved the expected accrual goals at the appropriate intervals will be recognized in the SRMC meetings as having attained their goal and the study will have a status of approved until its next yearly evaluation. Protocols will continue to be evaluated against their declared accrual goals until the study is closed to further accrual. It will be the responsibility of the SRMC Administrator to notify the study team of an upcoming continuation review.

Chair reviews are conducted to ensure that proper correspondence has occurred for protocols that were previously approved with stipulations. The coordinator forwards all correspondence from the reviewers once the reviewer has confirmed whether or not their initial stipulation(s) had been properly addressed. The authority to provide the final approval lies with the Chair. Once the Chair approves that the proper correspondence was conducted, the Administrator then notifies the PI and study coordinator with the appropriate approval letter. The study is recorded as approved through prior stipulations on the next agenda. Chair reviews may also be conducted in situations where a study requires reclassification (i.e. downgrading of the data table 4 classification) or reassessment (risk level) subsequent to the initial review. These reviews result in the issuance of an updated approval letter reflecting the date of the chair review.

7.4 Possible Decisions

7.4.1 Full Review Decisions

After the assigned reviewers provide any concerns or recommendations for a study protocol, all voting members in attendance will cast their votes for the following decisions:

- Approval: The study is scientifically sound and acceptable as written. Full approval is given and the PI is notified.
- Approval with Stipulations: 1) the study is scientifically sound and acceptable if minor clarifications are provided. Full approval will be withheld until the necessary clarifications are made and approved by the SRMC Chair or Vice Chair, or 2) the study is scientifically sound and acceptable if the PI makes modifications to the protocol. Full approval is withheld until the protocol is revised to adequately incorporate the recommended modifications. The protocol must be re-reviewed and approved by the original SRMC reviewers or the SRMC Chair or Vice Chair.
- Tabled: The study must be re-submitted in its entirety to the SRMC for full-committee review with significant modifications and responses to the questions raised by the SRMC during its initial review.
- Disapproved: The study is neither scientifically sound nor ethical.

7.4.2 Expedited Review Decisions

Any review that is considered expedited as described in section 7.3, and approved through its respective DSG, shall be reviewed for prioritization, potential for successful progress and scientific merit if applicable. Reviewers may recommend the following decisions to the SRMC Chair:

- Approval: The study is scientifically sound and is acceptable as written. Expedited approval is granted and the PI is notified.
- Approval with Stipulations: 1) the study is scientifically sound and is acceptable if minor clarifications or modifications are provided. Expedited approval will be withheld until the necessary clarifications are made and approved by the SRMC Chair or Vice Chair.
- Recommended for Full Committee Review: The study must be reviewed in its entirety by the full-committee review. Requirements for full committee review as outlines in Sections 5.3 and 5.4.1 then apply.

7.4.3 Administrative Review Decisions

Any review that is considered administrative as described in section 7.3 shall be reviewed to ensure the study meets the criteria for administrative review. Reviewers may recommend the following decisions to the SRMC Chair:

- Approval: The study meets the requirements for administrative review.
- Returned: The study does not meet the requirements for SRMC review or approval.

All studies approved via full committee or expedited review must open to subject accrual within one year (365 days) of the date of the final SRMC decision. Studies that do not proceed to the "Open to Accrual" status in the CTMS within this time frame are subject to re-review by the SRMC.

7.5 Continuation Reviews

Continuation Reviews will be performed for all interventional trials that are open to accrual. CRs are not required for Non-Interventional studies or Interventional studies that are closed to accrual.

After the committee reviews the study accrual goals as compared to the confirmed subject accrual, one of the following decisions will be made:

- If a study is at less than 25% of its annual accrual goal (with at least one accrual) at 6-months, a justification for continued accrual and corrective action plan (CAP) must be submitted to the SRMC. This CAP must be generated by the study team in consultation with the UFHCC CRO Feasibility Group (as an investigator team resource).
- Upon acceptable review of the CAP by the SRMC, the study will be placed on probation and accrual activity for the first 12 months will be reviewed at the annual CR. Studies that are still under 25% of their annual target following this probationary extension will be subject to immediate closure to accrual.
- If a study is at less than 25% of its annual accrual goal at a subsequent CR, a justification for continued accrual and CAP must be submitted to the SRMC. This CAP must be generated by the study team in consultation with the UFHCC CRO Feasibility Group (as an investigator team resource). If the explanation and CAP is deemed satisfactory to the SRMC, the study may continue and be reviewed again in 6 months. Otherwise, the study will be subject to immediate closure to accrual.
- If accrual is greater than 25% but less than 50% of the study's annual target during any review period, a justification for continued accrual and CAP must be submitted to the SRMC. This CAP must be generated by the study team in consultation with the UFHCC CRO Feasibility Group (as an investigator team resource). If the explanation and CAP is deemed satisfactory to the SRMC, the study may continue and will be reviewed again in either 6 or 12 months per the discretion of the Chair.
- Studies that have accrued greater than 50% of their annual accrual goal at the 6-month or annual CR will be granted expedited approval and will be reviewed again in 12 months and then annually.

An accrual is defined as a subject that has consented (or has enrolled via waiver of consent), has been deemed eligible and has been formally registered/randomized to the study. A subject is considered accrued when an On Study date has been entered in OnCore.

Protocol suspensions of ≥ 3 continuous months may be taken into consideration at CR. Any suspension must be noted in OnCore (via a "suspended" study status) and documentation of the enrollment hold provided (e.g. holds due to drug supply, financial limitations, interim analyses, etc.) at the time of CR. Protocols continuously suspended for greater than 12 months may be subject to immediate closure by SRMC unless they qualify for special consideration as outlined below.

Special consideration will be given for rare diseases, IITs, national protocols where UF faculty serve in a leadership capacity as documented on the protocol cover sheet, and

NCTN/ETCTN/consortium studies not meeting accrual goals. The SRMC will make recommendations to enhance recruitment whenever possible.

7.5.1 Rare Disease Designation

A modification to the accrual requirements will be made for studies involving rare cancers as defined per the UFHCC's rare disease definition. The Division of Cancer Treatment and Diagnosis and the "International Rare Cancers Initiative" (IRCI) defines a rare cancer as one with an incidence of ≤ 3 newly diagnosed persons out of a population of 100,000 persons per year ($\leq 3/100,000$ per year). Rare cancer definition can be assigned to clinical trials targeting specific mutations in non-rare cancers as long as the cancer specific mutation is diagnosed in $\leq 3/100,000$ patients per year ($< 9,600$ total patients per year in the U.S.). Patient factors such as stage, performance status, line of therapy or treatment modality are not taken into consideration when defining rare cancer trials. Rare disease designation will be confirmed by the committee. *All pediatric oncology clinical trials will be considered rare disease studies.*

Trials designated as rare disease at the time of initial SRMC review will be subsequently reviewed every 12 months. Rare disease studies failing to accrue any subjects at 12 months will require a CAP. Studies may then be administratively closed at 24 months if there is still no accrual. However those trials that are NCTN, ETCTN, consortium studies, or represent the only treatment option for the disease state may remain open beyond 24 months. Justification including documentation of continued scientific merit will be reviewed annually by the SRMC in these scenarios.

7.5.2 Zero Tolerance Policy

A study which has zero enrollments after being open to accrual for 3 months has two options:

- (1) PI decides to close study immediately (diverting resources to another trial)
- (2) Study is administratively placed on probation for 3 months

If at 6 months after the open to accrual date, a study still has zero enrollments, it will be immediately closed to accrual by the SRMC (unless "rare").

There is a caveat for rare disease qualifying studies (see Section 7.5.1). The zero tolerance policy allowance can be extended to a maximum of 2 years after a study opens to accrual. If the study has zero enrollments at the 2 year open to accrual mark it will be administratively closed, unless one of the following items are met resulting in a waiver:

- Pediatric study
- Clear demonstration that trial represents only therapeutic option for disease state

In these latter situations where a Zero Tolerance Policy waiver has been issued at the 2 year SRMC review mark, CRs will be performed annually thereafter to ensure scientific merit and resources remain justifiable.

7.5.3 CR Review Decisions

- 12 Month Approval: The study continues to be scientifically sound and is making adequate progress toward accrual goals.
- 6 Month Probationary Approval: The study continues to be scientifically sound however the study is not meeting the minimum accrual requirements. Revisions to the recruitment plan or accrual targets may be required. A corrective action plan must be generated by the study team in consultation with the UFHCC CRO Feasibility Group (as an investigator team resource).
- Closure Required: Closure may be required for studies that are no longer scientifically sound or have inadequate accrual for continuation.

7.6 Suspension or Closure Recommendation

The SRMC may make the decision to suspend or close a clinical trial depending on the significance of the following issues:

- No accrual during the first 6 months or more or chronic low accrual
- Amendments or developments that render the study no longer scientifically sound
- Recommendations from the DISC

Suspension or termination of a clinical trial is thoroughly deliberated. Particular consideration is given to any corrective action(s) that were implemented by the PI. If closure is required by the SRMC, the study status must be updated to “Closed to Accrual” within one business day of notification by the PI or designee. It is the PI’s responsibility to notify the IRB and any other regulatory authorities of a study that is closed by the SRMC.

7.7 Adjustments to Accrual Goals

Lowering accrual goals will be reserved for special cases. The SRMC may recommend changing the accrual goal if it is determined that the initial accrual goal was set too high. The study team may also request an adjustment to their original accrual goal at the time of CR. Requests to increase accrual goals may be considered for any type of study.

7.8 Decision Results Reporting

The SRMC will communicate the results of all reviews to the study team in writing. Decision letters will be sent electronically following meeting proceedings. Minutes from the SRMC meetings are recorded by the SRMC Administrator and approved into record by SRMC vote at the subsequent meeting.

7.9 Appeals Process

There is no appeal process. The PI and study team are able to provide perspective and dialogue to the SRMC through written or oral responses to reviewer questions or concerns and via a Corrective Action Plan prior to and during study review. All written SRMC decisions are final.

8.0 Assessment of Risk and Complexity for IITs

All protocols will be classified by the SRMC into one of the following general categories of risk at the time of initial review. Per 45 C.F.R. § 46.102(i), “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

For all local interventional investigator initiated trials and other trials deemed by SRMC to be without an adequate data and safety monitoring board (DSMB), the SRMC will determine the appropriate level of monitoring required and refer such monitoring oversight to the UFHCC Data Integrity and Safety Committee (DISC). This determination will be made as a component of initial review and approval. This includes review of the protocol-specific data safety and monitoring plan provided in the protocol. Trials submitted without a satisfactory data safety and monitoring plan will not be approved. Study review frequency will be determined based upon the protocol’s phase, objectives, intervention under study, level of risk to subjects and overall complexity. The assigned level of risk will be reported back to the UFHCC DISC and the study PI by the SRMC Administrator. Please note that any Phase III study regardless of the level of risk requires oversight by DISC or an appropriate independent DSMB.

Level 1 – **Low risk** Investigator Initiated interventional trials.

- Diagnostic or screening trials involving minimal risk procedures
- Trials involving accepted doses of over-the-counter drug, or vitamins and supplements
- Behavioral or health services research (HSR) trials
- Trials involving diet or exercise involving minimal risk

Level 2 – **Moderate risk** Investigator Initiated or externally sponsored interventional (such as drug, biologic or device) trials using FDA approved or commercially available compounds or interventions.

- IND exempt phase II and III trials
- Trials involving delivery of radiation therapy
- Screening, diagnostic, behavioral, HSR, diet or exercise trials that involve invasive or greater than minimal risk procedures or interventions that ordinarily would be regarded as minimal or low risk but are being tested in a context where the risk might be perceived as higher.

Level 3 – **High risk** Investigator Initiated or externally sponsored interventional trials (such as investigator-sponsored INDs, Phase I trials, studies requiring biosafety approval, or other areas that may be designated by NIH as high risk).

- UF investigator as IND/IDE holder
- Phase I drug, device, bone marrow transplant, and surgical trials
- Any UF trials that requires UF biosafety committee approval
- UF multisite interventional trials

Level 4 – Complex trials involving **very high risk** to subjects and a high level of complexity such as first in human or gene transfer studies.

8.1 DISC Monitoring Frequency

The SRMC will decide how often the DISC should review and assess study data as part of the trial-specific monitoring plan generated at the time of initial SRMC review. The SRMC discusses the risk level assigned by the primary and secondary reviewers and determines the necessary intervals for the UFHCC DISC to review these studies. Upon initial DISC intake of the study, if the DISC disagrees with the SRMC-assigned risk level determination or monitoring requirements, a written correspondence will be submitted to the SRMC chair by the DISC chair. The SRMC chair may take such information under advisement and consider issuing a modification. However, all SRMC determinations regarding risk assessment and monitoring are otherwise final. The following are the recommended guidelines for how often the DISC should review studies per risk level assigned:

Level 1: No routine monitoring required by DISC

Level 2: Annual review by DISC

Level 3: Semiannual review by DISC

Level 4: Quarterly review by DISC

9.0 Responsibilities

9.1 SRMC Responsibilities

The SRMC has the responsibility to review all new cancer-related protocols. These reviews focus mainly on confirming scientific merit, methodology, prioritization, and accrual goal feasibility.

The charge of the SRMC includes the following:

- Evaluate scientific merit and progression of studies
- Determine if study goals are aligned with the UFHCC scientific priorities and are feasible in terms of expected subject accrual
- Confirming risk levels relating to study design
- Approving, disapproving or discontinuing studies

SRMC membership selection aims to include a diverse and extensive range of expertise across all areas of cancer specialties. This broad representation and communication between fields ensure that study protocols and progression are reliable, verifiable and of scientific merit.

9.2 SRMC Member Responsibilities

To promote consistency between every SRMC meeting, core members are expected to attend the majority of meetings held throughout the year. To be considered in “good standing” with the SRMC, members must have an attendance level of at least 51%. Core members of the CPCS must attend at least 51% of subcommittee meetings. In-person, videoconferencing, and teleconferencing will apply towards meeting attendance. Ad hoc committee members are not required but are encouraged to attend meetings.

Members are expected to complete accurate and in-depth reviewer assignments for protocols assigned to them by the SRMC Administrator. When assigned protocols are reviewed members are responsible for ensuring enhancement of research quality with constructive criticism as needed. Members who are identified as a sub-investigator, other study personnel on a protocol

or who self-declare a conflict of interest will be ineligible to vote or provide a review. Members who self-declare a conflict of interest for any reason will be noted by the SRMC Administrator. Their participation will be recorded as “abstain due to conflict”. Conflicted members who wish to remain during committee deliberations will be asked to abstain from making further comments on behalf of the principal investigator. Members who belong to the home DSG sponsoring the study, but are not identified as having a conflict as noted above can provide a scientific review.

9.2.1 Protocol Reviewer Responsibilities

For studies meeting the criteria for full committee or expedited review, protocol reviewers will evaluate the SRMC submission form, clinical protocol, and any other relevant documents provided in the initial submission. When applicable, reviewers will present an assessment of the protocol and any recommendations for change. A recommendation for committee action is given by the reviewer as well. Primary, secondary and biostatistician reviewers are responsible for written reviews and comments on the following:

- Objectives: Are the objectives and endpoints of the protocol clearly defined? For interventional protocols, do the objectives measure the impact of the proposed intervention?
- Scientific Rationale: Does the protocol address relevant scientific questions?
- Scientific Impact: What is the project’s likelihood of having a sustained, powerful influence on the research field(s) involved?
- Study Design: Does the proposed protocol design address the protocol’s objectives and scientific rationale? Can the proposed objectives be met with available resources of the UFHCC? Can the objectives be met within an acceptable time frame? Does the study design include appropriate stopping criteria?
- Methodology: Are the methods in the protocol adequate to answer the questions addressed in the objectives? Are there resources available within the UFHCC to conduct these methods? For treatment intervention protocols, is there a description of the agent’s activity, dose delivery and scheduling, and dose modification criteria?
- Statistics: Is the statistical design clearly described, well-defined, and statistically sound? Are the accrual goals clearly stated? Is the sample size adequate to answer the specific objectives of the protocol? For qualitative studies, are appropriate analytical design and decision criteria included?
- Data Collection: Will the data collected answer the objectives of the protocol? Are the data collection and analysis methods clearly described and sound? Data forms are considered an essential part of the protocol and must be submitted to the SRMC with the initial submission. The SRMC may withhold review and approval of a protocol pending submission and review of data collection forms.
- Data and Safety Monitoring: Does the protocol have an acceptable DSMP inclusive of any pre-defined stopping rules? For UF Interventional IITs and other Interventional studies, does the trial require DISC oversight and, if so, what level of risk should be assigned? All DSMPs must include the following: Description of oversight responsibilities, description of data and safety review processes, frequency of data and safety review, process for routine and serious adverse event

- reporting, and the process for determining if a study requires early stopping as applicable.
- Protocol Classification: Is the protocol and data table type correctly assigned within CTMS? Proper protocol classification is required to determine if the study meets eligibility criteria for full or partial academic points.
 - Other: Are all other components (e.g., eligibility criteria, required biospecimens, timing of interventions, etc.) consistent with the scientific rationale and objectives of the study?

For National Cooperative Group Trials and Other Externally Peer Reviewed submissions that have been previously peer reviewed by an approved organization, the reviewer is responsible for confirming the DSG reviews regarding accrual, prioritization and feasibility only.

Primary Reviewer for Change(s) in Protocol: Reviewers are responsible for written review and comments regarding all changes in protocol. It should be noted that whenever a change is necessary to better protect research subjects, (for example, one that is the result of a toxicity or adverse event report) the IRB is obligated to approve or disapprove that change immediately and IRB continuation will not therefore, be contingent upon SRMC approval. However, the investigator should understand that continuance of the study is dependent upon SRMC approval of the changes. The reviewer will provide a summary of the proposed change and make recommendations to the SRMC. Depending on the nature of the change, the SRMC may request that a biostatistician review the proposed revisions to the protocol.

Primary Reviewer Acceptance of Stipulations: In the event that questions have been posed to the study team or stipulations have been recommended that prevent a clear approval or disapproval committee action, the reviewer raising these points will provide follow-up acceptance or comments of whether the information meets their needs to issue a formal recommendation. In the event that a reviewer is unavailable to provide closure of such follow-up (i.e., vacation, medical leave), the Chair or a delegated Vice Chair may issue that response in their stead.

10.0 Affiliate Program

At the request of a UFHCC Affiliate Research Consortium (ARC) member, the UFHCC supports our collaborating center(s) through the provision of ad hoc study reviews by the SRMC consistent with the UFHCC SRMC policies and procedures. Under the execution of a Confidentiality Agreement between UF and the partner organization requesting such services, the processes for application, review and decision rendering is similar, but will be outlined in an individual SOP. Of note, continuing reviews will not be undertaken and all recommendations by the SRMC are non-binding in these scenarios. Support of the UFHCC ARC in this manner will not jeopardize SRMC function, role or effectiveness otherwise. Submission processes, reviewer expectations and communication of non-binding recommendations are further described in the ARC SRMC SOP.

The exception to this will be UFHCC IITs that are proposed to be conducted at a UFHCC ARC site. In these scenarios, feedback will be solicited from the ARC site regarding feasibility.

Continuing reviews, risk categorization and committee recommendations, including annual accrual monitoring, will be binding.

Appendices

- A. **Committee Membership List**
- B. **Disease Site Group List**
- C. **Prioritization Score**
- D. **Protocol Initial Submission Flowchart**
- E. **DSG Submission Form**
- F. **SRMC Submission Form**
- G. **SRMC Full Committee Protocol Reviewer Form**
- H. **SRMC Biostatistician Protocol Reviewer Form**
- I. **SRMC Patient Advocate Reviewer Form**
- J. **SRMC Expedited Protocol Reviewer Form**
- K. **Appendix K: SRMC Expedited Change Reviewer Form**
- L. **SRMC Scientific Scoring Guidance**
- M. **SRMC Intake Policy for IRB Approved Studies**
- N. **NCI Study Primary Purpose/Phase/Type Classification**

Appendix A: Committee Membership List

SRMC Members	Position	Specialty	Disease
Paul Crispen, MD	Chair	Surgery	GU
Randall Henderson, MD, MBA	Vice-Chair	Radiation Oncology	GU
Frederic Kaye, MD	Vice-Chair	Medical Oncology*	Thoracic
Elias Sayour, MD, PhD	Vice-Chair	Pediatrics*	Peds; Neuro
Michael Weaver, RN, PhD	Vice-Chair	Nursing	
Ryan Thomas, MD	Core	Surgery*	GI
Karen Daily, DO	Core	Medical Oncology	Breast
Anamaria Yeung, MD	Core	Radiation Oncology	GYN
Joseph Grajo, MD	Core	Radiology	
Coy Heldermon, MD, PhD	Core	Medical Oncology*	Breast
John Hiemenz , MD	Core	Medical Oncology	HM-BMT
Alison Ivey, RN	Core	Research	
Petr Starostik, MD	Core	Pathology	Molecular
David DeRemer, PharmD	Core	Pharmacy	ETI
Jatinder Lamba, PhD	Core	Pharmacy	HM
Biljana Horn, MD	Core	Pediatrics	HM-BMT
Ji-Hyun Lee, PhD	Core	Biostats	
Yu Wang, MS	Core	Biostats	
Carmen Allegra, MD	Core	Medical Oncology	GI
Karen Miller, JD	Core	Patient Advocate	
Cancer Prevention and Control Subcommittee			
Michael Weaver, RN, PhD	Vice-Chair	Nursing	
Janice Krieger, PhD	Core	Communication	
Deidre Pereira, PhD	Core	Clinical Health Psychology	
Yulia Strekalova, PhD	Core	Communication	
Yi Guo, PhD	Core	Biomedical Informatics	
Versie Johnson-Mallard, RN, PhD	Core	Nursing	
Yingwei Yao, PhD	Core	Biostats	

*Laboratory Scientist

A continuously updated list of Committee members is maintained by the Cancer Center Administrative Office and is available upon request.

Appendix B: Disease Site Group List

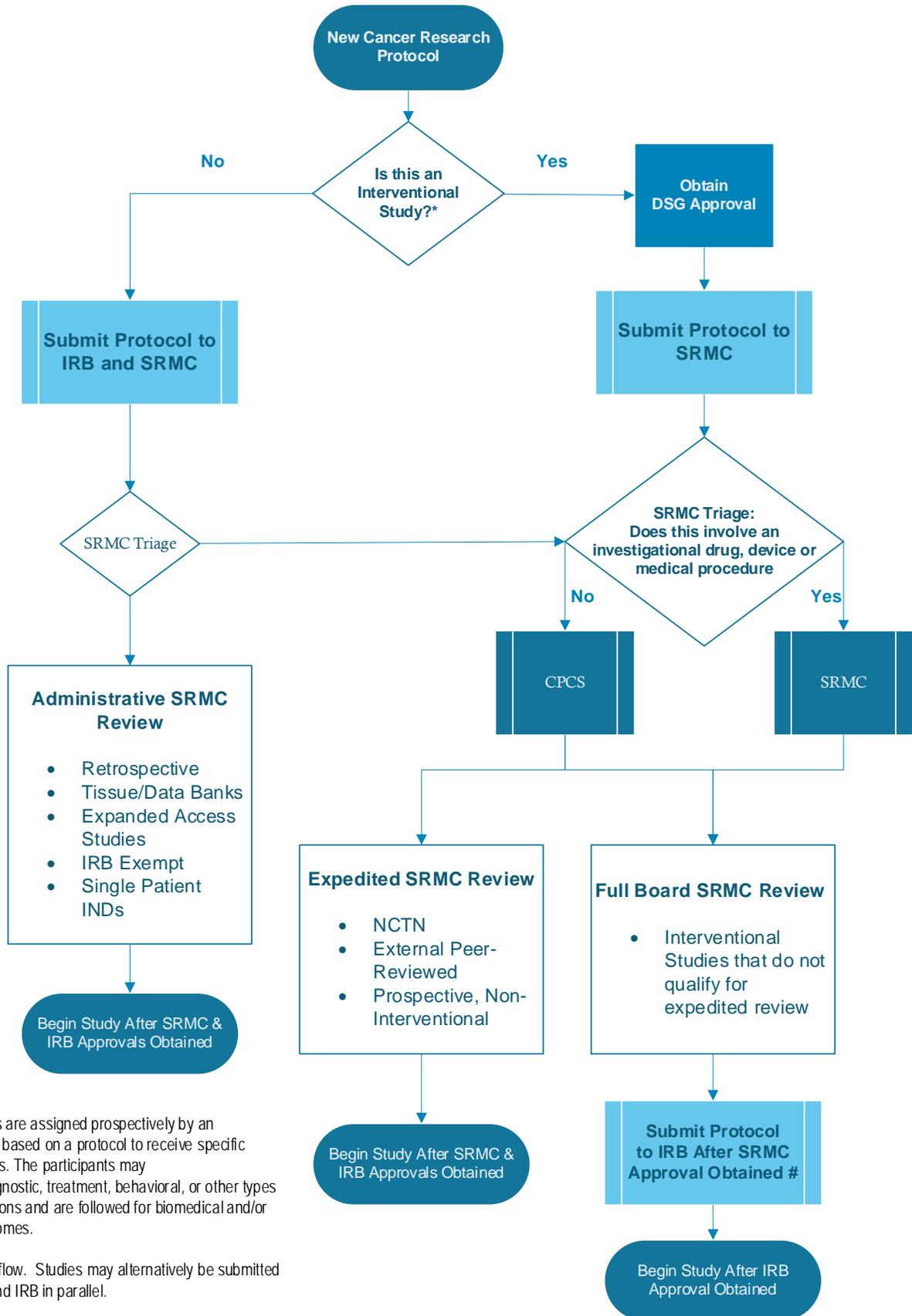
Disease Site Groups	Leaders
GI	Clinical – Steven Hughes, MD Research – Thomas George, MD
GU	Clinical – Long Dang, MD, PhD Research – Paul Crispen, MD
Thoracic	Clinical – Hiren Mehta, MD Research – Frederic Kaye, MD
Gyn Onc	Clinical – Jacqueline Castagno, MD Research – Merry Jennifer Markham, MD
Sarcoma/Melanoma	Clinical – Parker Gibbs, MD Clinical – Christiana Shaw, MD, MS Research – Stephen Staal, MD
Breast	Clinical – Lisa Spiguel, MD Research – Karen Daily, DO
Neuro	Clinical – Maryam Rahman, MD Research – David Tran, MD, PhD
Head and Neck	Clinical – Robert Amdur, MD Clinical – Peter Dziegielewski, MD Research – Natalie Silver, MD
Malignant Hematology	Clinical – Randy Brown, MD Research – Maxim Norkin, MD, PhD
Lymphoma	Clinical – Nam Dang, MD, PhD Research – Jack Hsu, MD
Pediatrics	Clinical – William Slayton, MD Research – Sridharan Gururangan, FRCP
Experimental Therapeutics Group	Research – Thomas George, MD Research – David DeRemer, PharmD
Cancer Population Sciences (CPS)	Research – Diana Wilkie, PhD, RN, FAAN Research – Janice Krieger, PhD

A continuously updated list of DSG Leaders is maintained by the Cancer Center Administrative Office and is available upon request.

Appendix C: Prioritization Scores

ORIGINATOR	STUDY TYPE	PRIORITIZATION SCORE
UFHCC Faculty Developed Studies	Treatment, Pilot/feasibility, Phase I	1
	Treatment, Phase I/II, II, III	2
	Interventional Non-Treatment, Any Phase	7
	Non-Interventional, Prospective	12
	Non-Interventional, Retrospective	13
NCI-NCTN Cooperative Group	Treatment, Any Phase	3
	Interventional Non-Treatment, Any Phase	8
	Non-Interventional	11
Foundation/ External Academic	Treatment, Any Phase	4
	Interventional Non-Treatment, Any Phase	9
	Non-Interventional	14
Industry	Treatment, Phase I, I/II, II	5
	Treatment, Phase III	6
	Interventional Non-Treatment, Any Phase	10
	Non-Interventional	15

Appendix D: Protocol Initial Submission Flowchart



Appendix E: DSG Submission Form

**UF Health Cancer Center (UFHCC)
Disease Site Group (DSG) 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? NO YES
<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 months)?

Is this trial serving a rare disease? The NCI has defined 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)* NO YES

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? If yes, your study may require CRO Feasibility Group review prior to SRMC submission. NO YES

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

Appendix F: SRMC Submission Form:

SRMC Submission Form will be pulled from the CTMS. Study teams can locate the SRMC Submission Report within OnCore under the “Reports” tab titled “[UF] SRMC Submission Form”

Appendix G: SRMC Full Protocol Reviewer Form:

University of Florida Health Cancer Center
Scientific Review and Monitoring Committee (SRMC)

Full-Committee Protocol Reviewer Form

Primary and Secondary Reviewers, complete this form for the upcoming SRMC meeting and record any necessary comments or clarifications regarding your decisions. The completed form will be kept on file in the UFHCC Clinical Research Office.

Protocol Number:

Protocol Title:

Principal Investigator:

Sponsor:

Phase:

New Application Revised Re-review Change Review

Reviewer: **SRMC Meeting Date:**

Primary Secondary

Note to Reviewers: *The Comment/Clarification section under each heading is used to describe the information you observe in the protocol that confirms your "Acceptable/Not Acceptable" decision. The protocol you are reviewing may not have the sections in the same order and some sections may not be present, but make your assessment of each section as noted, checking and commenting on the response you feel is appropriate. Add necessary notes, comments, or evaluations to be discussed by the SRMC.*

1. Title: Acceptable Not Acceptable

Add Comments/Clarifications:

2. Background:

Justification for conducting study and results of similar studies or pilot data.

Acceptable Not Acceptable

Add Comments/Clarifications:

3. Research Objectives:

Evaluate purpose of study and brief outline of therapy.

Acceptable Not Acceptable

Add Comments/Clarifications:

4. Eligibility and Study Requirements:

Specific inclusion/exclusion requirements which must be met.

Acceptable Not Acceptable

Add Comments/Clarifications:

5. Treatment or Study Plan:

Describes therapy: 1) Treatment doses/schedules, 2) any dose adjustment for first course of therapy, 3) duration of therapy and 4) schema.

Acceptable Not Acceptable

Add Comments/Clarifications:

6. Drug Information:

Description of drugs used in the study.

Acceptable Not Acceptable

Add Comments/Clarifications:

7. Toxicity Management:

Dose adjustments for each drug for toxicity (increases/decreases/delaying and/or withholding therapy) related to toxicity after initiation of therapy. Also outlines modifications due to toxicities from other medications and radiotherapy.

Acceptable Not Acceptable

Add Comments/Clarifications:

8. Definition of Outcomes:

Definitions of response/progression, relapse, and adequate trial (if necessary).

Acceptable Not Acceptable

Add Comments/Clarifications:

9. Statistical Section:

Identification of and plan for answering objectives (including patient accrual objectives and estimated duration of study), stopping rules and provision for interim analyses.

(This section has been evaluated by a biostatistician.) Add

Comments/Clarifications:

10. Adverse Event Reporting:

Requires a defined system for reporting and evaluating adverse events, including deadlines for reporting and parties responsible for reporting.

Acceptable Not Acceptable

Add Comments/Clarifications:

11. Data and Safety Monitoring:

All interventional clinical research protocols must include a data and safety monitoring plan. At a minimum the plan must describe the continuous review of data and subject safety. The plan may also describe the review of each dose level, subject accrual, significant toxicities, unanticipated problems, protocol or dose adjustments, and observed responses as applicable.

Does the study have a Data and Safety Monitoring Plan that includes the following: Description of oversight responsibilities, description of data and safety review processes, frequency of data and safety review, process for routine and serious adverse event reporting, and the process for determining if a study requires early stopping as applicable.:

Yes, no deficiencies

Yes, but clarifications/additions needed. Comment below:

No – This protocol may not be approved without a DSMP. Comment below:

For all studies: Does the study have an established independent Data and Safety Monitoring Board?:

Yes

No – Local interventional IITs must be under the oversight of DISC or an equivalent DSMB. For externally sponsored studies, DSMB oversight is only required for Phase III studies per the NCI.

For all studies without a DSMB: Will the study require monitoring by the UFHCC’s DISC?:

No, provide reason:

Yes, choose recommendation for assigned risk level: Per 45 C.F.R. § 46.102(i), “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” Note: Any Phase III UF IIT, regardless of risk (minimal vs greater than minimal risk), must be assigned risk level 2 or higher.

Level 1 – Low risk Investigator Initiated interventional trials.

- Diagnostic or screening trials involving minimal risk procedures
- Trials involving accepted doses of over-the-counter drug, or vitamins and supplements
- Behavioral or health services research (HSR) trials Trials involving diet or exercise involving minimal risk

Level 2 – Moderate risk Investigator Initiated or externally sponsored interventional (such as drug, biologic or device) trials using FDA approved or commercially available compounds or interventions.

- IND exempt phase II and III trials
- Trials involving delivery of radiation therapy
- Screening, diagnostic, behavioral, HSR, diet or exercise trials that involve invasive or greater than minimal risk procedures or interventions that ordinarily would be regarded as minimal or low risk but are being tested in a context where the risk might be perceived as higher.

Level 3 – High risk Investigator Initiated or externally sponsored interventional trials (such as investigator-sponsored INDs, Phase I trials, studies requiring biosafety approval, or other areas that may be designated by NIH as high risk).

- UF investigator as IND/IDE holder
- Phase I drug, device, bone marrow transplant, and surgical trials
- Any trial that requires UF biosafety committee approval
- UF multisite interventional trials

Level 4 – Complex trials involving very high risk to subjects and a high level of complexity such as first in human or gene transfer studies

Add Comments/Clarifications:

12. Inclusion of Women, if applicable:

Acceptable **Not Acceptable**

Add Comments/Clarifications:

13. Inclusion of Minorities, if applicable:

Acceptable **Not Acceptable**

Add Comments/Clarifications:

14. Inclusion of Children, if applicable:

Acceptable Not Acceptable

Add Comments/Clarifications:

15. Select One clinical research category below that best represents the protocol:

- Interventional**: 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.
- Observational**: Studies that focus on cancer patients and healthy populations and involve no prospective intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.
- Ancillary**: Studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported. **OR**
Correlative: Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.

16. Select One primary purpose classification below that best represents the protocol:

- Basic Science (BAS)**: Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.
- Diagnostic (DIA)**: Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition.
- Health Services Research (HSR)**: Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.
- Prevention (PRE)**: Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.
- Screening (SCR)**: Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).
- Supportive Care (SUP)**: Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease.
- Treatment (TRE)**: Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. Note: This equates to therapeutic trials in previous versions of the guidelines.
- Other (OTH)**: Not in other categories
-

17. Merit Score

Using the Merit descriptors (see below), please select one score below that you feel represents the scientific impact of the trial you reviewed:

- 1 - Exceptional exceptionally strong with essentially no weaknesses
- 2 - Outstanding extremely strong with negligible weaknesses
- 3 - Excellent Very strong with only some minor weaknesses
- 4 - Very Good Strong but with numerous minor weaknesses
- 5 - Good Strong but with at least one moderate weakness
- 6 - Satisfactory some strengths but also some moderate weaknesses
- 7 - Fair some strengths but with at least one major weakness
- 8 - Marginal A few strengths and a few major weaknesses
- 9 - Poor Very few strengths and numerous major weaknesses

18. Do the objectives truly evaluate the effect of the proposed intervention?

- Yes No, if no please outline your concerns below:

Reviewer Recommendation:

Scientific Merit:

- Approved
 Approved with stipulations
 Tabled
 Disapproved

Overall Assessment:

Reviewer Signature

Date

Appendix H: SRMC Biostatistician Protocol Reviewer Form

**Scientific Review & Monitoring Committee (SRMC)
Biostatistical Review Form**

Date sent for review:	Review due by 3 p.m. on:	
Protocol Number & Title:		
Sponsor:	UF Principal Investigator:	
Study Type:	Study Statistician:	
Statistical Reviewer:		
Review Type:		
<p>Trial Phase:</p> <p><input type="checkbox"/> Pilot / Feasibility</p> <p><input type="checkbox"/> Phase I</p> <p><input type="checkbox"/> Phase II</p> <p><input type="checkbox"/> Phase III</p> <p><input type="checkbox"/> Phase IV</p> <p><input type="checkbox"/> Non-Therapeutic</p> <p><input type="checkbox"/> Other:</p>	<p>Randomization:</p> <p><input type="checkbox"/> Randomized</p> <p><input type="checkbox"/> Not Randomized</p>	<p>Blinding:</p> <p><input type="checkbox"/> Open Label</p> <p><input type="checkbox"/> Single-Blinded</p> <p><input type="checkbox"/> Double-Blinded</p> <p><input type="checkbox"/> N/A</p>

Primary Goal(s):

Primary Outcome(s)/Primary Endpoint(s):

Evaluation Criteria

1. Are the study endpoints clearly and specifically defined and do they complement the study objectives?

Yes Partially No

Comment Below:

2. Is the proposed statistical analysis appropriately and sufficiently defined for the primary and secondary endpoints?

Yes Partially No

Comment Below:

3. Is the power / sample size calculation adequately described and is it reproducible?

- Yes Partially No

Comment Below:

4. Are there appropriate stopping rules / interim analysis plans for safety, futility, and/or efficacy?

- Yes Partially No

Comment Below:

5. Is there an adequate data collection and data management plans?

- Yes Partially No

Comment Below:

6. Additional items that *may* need to be addressed:

a. Is the patient population appropriate? Should any (or additional) stratifications be considered?

- Yes Partially No

b. If this is a randomized study, is the randomization procedure described?

- Yes Partially No

c. Are there any advocacy or ethical concerns?

- Yes Partially No

d. If there are multiple primary endpoints, has proper consideration been given to adjustment for multiple testing?

- Yes Partially No

Comment Below:

Score

The Reviewers should fill in any applicable comments or important information next to each category, then use the following scoring rubric to assign scores to each category:

Outstanding = 5, Acceptable = 3-4, Not Acceptable = 1-2

Category	Comments	Score
Adequacy of Sample Size/Power Evaluation		___ / 5
Statistical Analysis Plan, including Interim Analysis		___ / 5
Data Collection and Management Plan		___ / 5
TOTAL SCORE:		___ / 15

Overall Recommendation:

- Approve
- Approve with stipulations (clarification required)
- Table (mandatory revisions to protocol required)
- Disapprove

Additional Comments (i.e., concerns that must be addressed or any suggestions):

Signature

Date

Appendix I: SRMC Patient Advocate Reviewer Form

**UNIVERSITY OF FLORIDA HEALTH CANCER CENTER
SCIENTIFIC REVIEW AND MONITORING COMMITTEE (SRMC)**

Investigator-Initiated Trial Patient Advocate Reviewer Form

<u>Protocol Number:</u>		<u>Principal Investigator:</u>	
<u>Protocol Title:</u>			

New Application Revision Re-review Change Review

Reviewer:

SRMC Meeting Date: 7/26/2018

EVALUATION BY SECTION:

The protocol you are reviewing may not have the sections in the same order and some additional sections may be present.

Please make your assessment of each section by marking all items that are satisfactory by clicking the box to the left of the comment to create a "check mark". If a comment does not apply or is not addressed do not select it. In the comments section outline any comments that should have been addressed but are not. Do not hesitate to add notes, comments, evaluations, etc., as you feel necessary in the "Comments" field following each section.

(Each item should be confirmed as "Yes", "No", or "N/A")

1. Eligibility Criteria and Patient Selection

Choose Subject inclusion and exclusion criteria are listed separately.

Choose The extent or stage of disease required is described.

Choose A description of the prior therapies permitted and/or not allowed is included.

Choose A statement regarding the concomitant medications that are permitted or prohibited is included.

Choose A statement regarding the concurrent diseases that are permitted or prohibited is included.

Choose Any requirements regarding the allowance of concurrent and prior malignancies are included.

Choose Required laboratory parameters, scans, and tests are included.

Choose The study is age range appropriate (e.g. ≥ 18 years). If minors are permitted, please make note of this (a minor consent and parental assent form will be required).

Choose A statement advising women of childbearing potential and sexually active males and females to use effective contraception while on study is included (if applicable).

Choose A statement that the patient must have signed informed consent prior to registration on study is included.

Choose Randomization procedures are described and are adequate.

Choose A schema or schematic drawing of the treatment plan is included

Comments:

**2. Informed Consent Form
(According to the Code of Federal Regulations, an informed consent form must contain the following information. Please check to see that these elements are included in the consent and included in a manner that a patient could reasonably understand):**

Choose A statement that the study involves research is included.

Choose An explanation of the purposes of the research is included.

Choose The expected duration of the subject's participation is included.

Choose A description of the procedures to be followed is included.

Choose Any procedures which are experimental are identified as such.

Choose A description of any reasonably foreseeable risks or discomforts to the subject is included.

Choose A description of any benefits to the subject or to others which may be reasonably expected from the research is included.

Choose A disclosure of the appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject is included.

Choose A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained is included.

Choose An explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained is included.

Choose An explanation of whom to contact for answers to pertinent questions about the research.

Choose A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled is included.

Choose Overall, the consent accurately represents the protocol treatment. All treatment procedures detailed in the "treatment plan" section of the protocol are summarized in the consent form.

Choose Subject withdrawal criteria are included. (i.e., terminating investigational product treatment/trial treatment). There are procedures that specify:

- (a) When and how to withdraw subjects from investigational treatment.
- (b) Data collection procedures for withdrawn subjects.
- (c) Whether and how subjects are to be replaced.
- (d) The follow-up for subjects withdrawn from investigational product treatment/ trial treatment.

Choose Subject withdrawal criteria is clearly outlined on the informed consent form.

Choose If pathology materials are required, it is clear where these are to be sent.

Comments:

(These additional elements should be included, as is appropriate):

Choose A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable is included.

Choose A statement regarding the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent is included.

Choose A statement regarding any additional costs to the subject that may result from participation in the research is included.

Choose A statement regarding the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject is included.

Choose A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject is included.

Choose The approximate number of subjects involved in the study is stated.

Choose A statement that the subject agrees to participate in the research, and will receive a copy of the consent form is included.

Choose A statement about genetic testing or clarity on the use of genetic information obtained as part of this research study.

Comments:

OVERALL EVALUATION OF PROTOCOL - ACTION RECOMMENDED:

- (1) **Approved**
- (2) **Approved with Stipulations**
- (3) **Tabled**
- (4) **Reject**

Comments:

Reviewer Signature

Date

Appendix J: SRMC Expedited Protocol Reviewer Form

**University of Florida Health Cancer Center Scientific Review and
Monitoring Committee (SRMC)**

Expedited Protocol Reviewer Form

Protocol Number: Click here to enter text.

Protocol Short Title: Click here to enter text.

Principal Investigator: Click here to enter text.

Sponsor Type: Click here to enter text.

New Application

Re-review

Reviewer: Click here to enter text.

SRMC Review Date: _____

1. **Eligibility and Study Requirements: Do the inclusion/exclusion requirements, when compared to the available patient population allow study accrual goals to be feasible?**

Acceptable

Not Acceptable

Add Comments/Concerns:

2. **Select One clinical research category below that best represents the protocol:**

Interventional: 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.

Observational: Studies that focus on cancer patients and healthy populations and involve no prospective intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.

Ancillary: Studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported. **OR**

Correlative: Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.

3. Select One primary purpose classification below that best represents the protocol:

- Basic Science (BAS):** Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.
- Diagnostic (DIA):** Protocol designed to evaluate one of more interventions aimed at identifying a disease or health condition.
- Health Services Research (HSR):** Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.
- Prevention (PRE):** Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.
- Screening (SCR):** Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).
- Supportive Care (SUP):** Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease.
- Treatment (TRE):** Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. Note: This equates to therapeutic trials in previous versions of the guidelines.
- Other (OTH):** Not in other categories

4. Merit Score

Using the Merit descriptors (see below), please select one score below that you feel represents the scientific impact of the trial you reviewed:

- 1 - Exceptional exceptionally strong with essentially no weaknesses
- 2 - Outstanding extremely strong with negligible weaknesses
- 3 - Excellent Very strong with only some minor weaknesses
- 4 - Very Good Strong but with numerous minor weaknesses
- 5 - Good Strong but with at least one moderate weakness
- 6 - Satisfactory some strengths but also some moderate weaknesses

-
- 7 - Fair some strengths but with at least one major weakness
 - 8 - Marginal A few strengths and a few major weaknesses
 - 9 - Poor Very few strengths and numerous major weaknesses

5. Do the objectives truly evaluate the effect of the proposed intervention?

- Yes** **No, if no please outline your concerns below:**

6. Data and Safety Monitoring:

All interventional clinical research protocols must include a data and safety monitoring plan. At a minimum the plan must describe the continuous review of data and subject safety. The plan may also describe the review of each dose level, subject accrual, significant toxicities, unanticipated problems, protocol or dose adjustments, and observed responses as applicable.

Does the study have a Data and Safety Monitoring Plan that includes the following: Description of oversight responsibilities, description of data and safety review processes, frequency of data and safety review, process for routine and serious adverse event reporting, and the process for determining if a study requires early stopping as applicable.?:

- Yes, no deficiencies
- Yes, but clarifications/additions needed. Comment below:

- No – This protocol may not be approved without a DSMP. Comment below:

For all studies: Does the study have an established independent Data and Safety Monitoring Board?:

- Yes
- No – Local interventional IITs must be under the oversight of DISC or an equivalent DSMB. For externally sponsored studies, DSMB oversight is only required for Phase III studies per the NCI.

Please outline any of your concerns below:

Reviewer Recommendation

Scientific Merit:

- Approved
- Approved with stipulations
- Tabled
- Disapproved

Add Comments/Concerns

Reviewer Signature

Date

Appendix K: SRMC Expedited Change Reviewer Form

SRMC Change Review Form

Primary and Secondary Reviewers, complete this form for the upcoming SRMC meeting and record any necessary comments or clarifications regarding your decisions. The completed form will be kept on file in the Clinical Research Office.

Protocol Number:

Protocol Title:

Principal Investigator:

Sponsor:

Phase:

Risk Level Assessment:

Reviewer:

Review Date:

Primary

Secondary

Note to Reviewers: The Comment/Clarification section under each heading is used to describe the information you observe in the protocol that confirms your "Acceptable/Not Acceptable" decision. The protocol you are reviewing may not have the sections in the same order and some sections may not be present, but make your assessment of each section as noted, checking and commenting on the response you feel is appropriate. Add necessary notes, comments, or evaluations to be discussed by the SRMC.

1. Title: **Acceptable** **Not Acceptable**

Add Comments/Clarifications:

2. Background:

Justification for conducting study and results of similar studies or pilot data.

Acceptable

Not Acceptable

Add Comments/Clarifications:

3. Research Objectives:

Evaluate purpose of study and brief outline of therapy.

Acceptable **Not Acceptable**

Add Comments/Clarifications:

4. Eligibility and Study Requirements:

Specific inclusion/exclusion requirements which must be met.

Acceptable **Not Acceptable**

Add Comments/Clarifications:

5. Treatment or Study Plan:

Describes therapy: 1) Treatment doses/schedules, 2) any dose adjustment for first course of therapy, 3) duration of therapy and 4) schema.

Acceptable **Not Acceptable**

Add Comments/Clarifications:

6. Drug Information:

Description of drugs used in the study.

Acceptable **Not Acceptable**

Add Comments/Clarifications:

7. Toxicity Management:

Dose adjustments for each drug for toxicity (increases/decreases/delaying and/or withholding therapy) related to toxicity after initiation of therapy. Also outlines modifications due to toxicities from other medications and radiotherapy.

Acceptable **Not Acceptable**

Add Comments/Clarifications:

8. Definition of Outcomes:

Definitions of response/progression, relapse, and adequate trial (if necessary).

Acceptable **Not Acceptable**

Add Comments/Clarifications:

9. Statistical Section:

Identification of and plan for answering objectives (including patient accrual objectives and estimated duration of study), stopping rules and provision for interim analyses. (This section has been evaluated by a biostatistician.) Add Comments/Clarifications:

10. Adverse Event Reporting:

Requires a defined system for reporting and evaluating adverse events, including deadlines for reporting and parties responsible for reporting.

Acceptable **Not Acceptable**

Add Comments/Clarifications:

11. Data and Safety Monitoring:

All interventional clinical research protocols must include a data and safety monitoring plan. At a minimum the plan must describe the continuous review of data and subject safety. The plan may also describe the review of each dose level, subject accrual, significant toxicities, unanticipated problems, protocol or dose adjustments, and observed responses as applicable.

Do the changes in this study amendment constitute a change in the original risk level assessment score?

Yes, select an updated Risk Level Assessment below.

No.

Do the changes in the study amendment still contain a DSMP that meets UFHCC requirements: Description of oversight responsibilities, description of data and safety review processes, frequency of data and safety review, process for routine and serious adverse event reporting, and the process for determining if a study requires early stopping as applicable.:

Yes, skip to question 12.

No, confirm your recommendation below.

Yes, but clarifications/additions needed. Comment below:

No – This protocol may not be approved without a DSMP. Comment below:

For all studies: Does the study have an established independent Data and Safety Monitoring Board?:

Yes

No – Local interventional IITs must be under the oversight of DISC or an equivalent DSMB.

For externally sponsored studies, DSMB oversight is only required for Phase III studies per the NCI.

For all studies without a DSMB: Will the study require monitoring by the UFHCC's DISC?:

No, provide reason:

Yes, choose recommendation for assigned risk level: Per 45 C.F.R. § 46.102(i), “Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” Note: Any Phase III UF IIT, regardless of risk (minimal vs greater than minimal risk), must be assigned risk level 2 or higher.

Level 1 – Low risk Investigator Initiated interventional trials.

- Diagnostic or screening trials involving minimal risk procedures
- Trials involving accepted doses of over-the-counter drug, or vitamins and supplements
- Behavioral or health services research (HSR) trials Trials involving diet or exercise involving minimal risk

Level 2 – Moderate risk Investigator Initiated or externally sponsored interventional (such as drug, biologic or device) trials using FDA approved or commercially available compounds or interventions.

- IND exempt phase II and III trials
- Trials involving delivery of radiation therapy
- Screening, diagnostic, behavioral, HSR, diet or exercise trials that involve invasive or greater than minimal risk procedures or interventions that ordinarily would be regarded as minimal or low risk but are being tested in a context where the risk might be perceived as higher.

Level 3 – High risk Investigator Initiated or externally sponsored interventional trials (such as investigator-sponsored INDs, Phase I trials, studies requiring biosafety approval, or other areas that may be designated by NIH as high risk).

- UF investigator as IND/IDE holder
- Phase I drug, device, bone marrow transplant, and surgical trials
- Any trial that requires UF biosafety committee approval
- UF multisite interventional trials

Level 4 – Complex trials involving very high risk to subjects and a high level of complexity such as first in human or gene transfer studies

Add Comments/Clarifications:

12. Inclusion of Women, if applicable:

Acceptable **Not Acceptable**

Add Comments/Clarifications:

13. Inclusion of Minorities, if applicable:

Acceptable **Not Acceptable**

Add Comments/Clarifications:

14. Inclusion of Children, if applicable:

Acceptable **Not Acceptable**

Add Comments/Clarifications:

15. Do the objectives truly evaluate the effect of the proposed intervention?

Yes **No, if no please outline your concerns below**

Reviewer Recommendation:

Scientific Merit:

- Approved
- Approved with stipulations
- Tabled
- Disapproved
- Recommend Full-Board Review

Overall Assessment

Reviewer Signature

Date

Appendix L: SRMC Scientific Scoring Guidance

The [NIH scoring system](#) was adopted by the SRMC to assign of a scientific merit score for all applicable clinical research studies subject to SRMC review. This scoring system was selected as it is a widely utilized by other scientific review bodies for assessment of a study's potential impact.

The scientific scoring system uses a 9-point scale to evaluate the overall impact of the study.

- ***Overall impact, for purposes of clinical trials assessed by SRMC, is defined as the project's likelihood to have a sustained, powerful influence on the research field(s) involved***
- Scoring is assigned using whole numbers (no decimal ratings)
- There is an expectation that score of 1 or 9 to be used less frequently than the other scores
- 5 is considered an average score however the reviewers and committee are urged to use the full range of scoring to more accurately discriminate the potential impact between studies
- Scores should be based upon the current iteration of the protocol under review and not influenced by proposed modifications or the future plans not incorporated into the current study
- Assigned primary and secondary reviewers will each provide their individual assessment. These scores will be put forth to the committee for consideration. The final overall impact score will be assigned by the committee through a vote.
- The final overall impact score will be multiplied by 10 (range is 10 through 90) and will be recorded in the CTMS

Overall Impact on Field	Score	Descriptor
High	1	Exceptional
	2	Outstanding
	3	Excellent
Medium	4	Very Good
	5	Good
	6	Satisfactory
Low	7	Fair
	8	Marginal
	9	Poor

Appendix M: SRMC Intake Policy for IRB Approved Studies

MEMORANDUM

DATE: October 25, 2017

TO: Investigators and staff involved in cancer-relevant research

FROM: Alison Ivey, RN
UF Health Cancer Center CTO
Administrative Director

Alison Ivey
Digitally signed by Alison Ivey
Date: 2017.10.25 12:13:25 -04'00'

Thomas George, MD
UF Health Cancer Center
Associate Director for Clinical Investigation

Thomas J. George, Jr., MD,
FACP
2017.10.25 12:18:13 -04'00'

RE: Scientific Review and Monitoring Committee intake policy for IRB approved studies

The Scientific Review and Monitoring Committee (SRMC) is responsible for the review of all cancer-relevant studies (including but not limited to retrospective, observational, ancillary/correlative, and interventional) conducted at the University of Florida. Effective July 20, 2017 all new studies that are considered cancer-relevant must be reviewed and approved by the SRMC prior to obtaining final IRB approval. Studies that were IRB approved prior to this date will still require initial SRMC review however, the level of review will be limited to administrative or expedited per the table below. The submission documents noted as being required for each study type within the SRMC Policies and Procedures manual are still required. Full scientific review will not occur for these existing studies that are already IRB-approved and enrolling patients. However, annual accrual monitoring and submissions of protocol revisions will still be conducted per the SRMC Policies and Procedures following initial review and approval.

Study Type	Regular Review Level	Policy Exemption Level
<ul style="list-style-type: none"> UF Interventional Investigator Initiated Trial Industry, External Academic or Foundation Interventional Trials (non-external peer-reviewed) 	Full	Expedited
<ul style="list-style-type: none"> National Clinical Trials Network Trials External Peer-Reviewed Trials (NCI approved groups) Prospective, Non-Interventional Studies 	Expedited	Expedited
<ul style="list-style-type: none"> Retrospective, Non-Interventional studies Studies that meet criteria for IRB exempt status Single patient INDs Any cancer-relevant study that is permanently closed to accrual 	Administrative	Administrative

This policy exemption applies to initial SRMC approval only and was effective as of August 2017. Additional clarifications regarding documents required prior to review of IRB approved studies have been incorporated into this policy with this update.

Appendix N: NCI Definitions/Research Categories/Primary Purpose Classification

Definition of Clinical Research

Clinical Research includes:

- **Patient-oriented research:** This type of research is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual, tissue banking, and studies that do not require patient consent (e.g., retrospective chart reviews). Patient-oriented research includes:
 - Studies of mechanisms of human disease
 - Studies of therapies or interventions for disease
 - Clinical trials, and
 - Studies to develop new technology related to disease
- **Epidemiological and behavioral studies:** Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g. surveillance, risk assessment, outcome, environmental, and behavioral studies.
- **Health services research:** Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.

Investigator Initiated Trials

Investigator-initiated trials are those in which the primary intellectual contribution (conception, design, implementation, etc.) originated with a cancer center member. For study source, they may be classified as Institutional, Externally Peer Reviewed, or even Industrial, if the center member was the intellectual source of the trial. Investigator-initiated trials can also include multi-institutional trials in which the center member had a significant intellectual contribution, even if the trial originated with another institution.

Clinical Research Categories

Interventional: 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.

Observational: Studies that focus on cancer patients and healthy populations and involve no prospective intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may

receive diagnostic, therapeutic, or other interventions, but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.

Ancillary or Correlative:

- Ancillary: Studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported.
- Correlative: Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, *etc.* Only studies that can be linked to individual patient or participant data should be reported.

Primary Purpose Classification

Basic Science (BAS): Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.

Diagnostic (DIA): Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition.

Health Services Research (HSR): Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.

Prevention (PRE): Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.

Screening (SCR): Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).

Supportive Care (SUP): Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease.

Treatment (TRE): Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. **Note:** This equates to therapeutic trials in previous versions of the guidelines.