



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 3.0 replaces Version 2.0 dated 03/23/2017

- Updated Abbreviation table to include ARC and CPCS (pg. 5)
- Added option to submit all protocols to SRMC and IRB in parallel (pg. 6 & 22)
- Added description of Cancer Prevention and Control Subcommittee (pg. 8)
- Added pre-review process for IITs (pg. 9)
- Removed the requirement for all studies to obtain DSG/RP approval prior to SRMC submission
- Updated submission flowchart (pg. 22)
- Deleted DT4 Decision Matrix
- Updated DSG Submission Form (pg.23)
- Updated full-board SRMC reviewer form (pg. 25-30)
- Added patient advocate reviewer form (pg. 32-35)

Abbreviations

| | |
|-------|--|
| ARC | Affiliate Research Consortium |
| CCSG | Cancer Center Support Grant |
| CTO | Clinical Trials Office |
| CPCS | Cancer Prevention and Control Subcommittee |
| CR | Continuing Reviews |
| CRA | Clinical Research Associate |
| CTEP | Cancer Therapy Evaluation Program |
| DCP | Division of Cancer Prevention |
| DHHS | Department of Health and Human Services |
| DSG | Disease Site Group |
| DISC | Data Integrity and Safety Committee |
| FDA | Food and Drug Administration |
| GCP | Good Clinical Practice |
| 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 |
| PRMS | Protocol Review and Monitoring System |
| RP | Research Program |
| SAE | Serious Adverse Event |
| SOP | Standard Operating Procedure |
| SRMC | Scientific Review and Monitoring Committee |
| 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 (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 provides the initial review for scientific merit, methodology, validity of statistical analysis, potential feasibility based upon anticipated accrual goals and scientific priority for appropriate studies. Studies that are evaluated include, at a minimum, all research protocols that involve diagnosis, therapy, prevention and control of cancer that have not received traditional peer review for scientific merit. Particular scrutiny 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 our 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, ancillary and correlative protocols are initially evaluated for resource feasibility within their home Disease Site Group (DSG) or Research Program and subsequently submitted to the SRMC for review. These studies are then assessed for scientific merit, priorities, and progress through the SRMC. Protocols may be submitted to the SRMC and Institutional Review Board (IRB) in parallel however sequential submission to the SRMC followed by IRB is strongly encouraged for interventional trials. 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. Cancer-related studies are those that have a known or suspected diagnosis of cancer as part of the eligibility criteria. For studies that may enroll cancer and non-cancer patients, review of the study is only required if the objective of the trial is to study cancer, related symptoms or risk factors, or if the PI only plans on enrolling current, former or suspected cancer patients. Interventional studies, especially those that involve treatment, supportive care or diagnosis of cancer, must undergo full board review while Non-Interventional studies may qualify for expedited or administrative review. In addition, major amendments for all full board studies must be submitted for review for the duration of the study's active accrual period. Major amendments are further defined in section 5.2.

Research studies that have already received peer review and approval 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 board review. Notable examples are National Clinical Trials Network (NCTN) 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, alternate and ad hoc 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 the UFHCC Clinical Trials Office 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 Standard Operating Procedures (SOPs). Voting members include UFHCC biostatisticians, appointed representatives of academic units/departments/centers, and patient advocates. Non-voting members include non-appointed Clinical Trials Office 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 or alternate 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.

At least one week prior to each SRMC meeting, reviewers from the committee will be assigned to review all necessary protocols. At least one primary and biostatistician reviewer are assigned to initial protocol reviews, paying particular attention to assigning reviewers to topics most relevant to their field of expertise if possible.

Meeting agendas are sent out to PIs and committee members the end of the week 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 membership between the SRMC membership and DSG leadership promotes consistency throughout the review process.

A research administrator from the UFHCC Clinical Trials Office will be assigned to provide administrative support to the SRMC. The SRMC Coordinator receives, tracks, and reviews all SRMC submissions for completeness. The SRMC Coordinator will also review study related information entered into the CTMS for accuracy. The Coordinator 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 Coordinator tracks committee member attendances, issues and closes queries in the CTMS, and generates reports for the SRMC Chair and UFHCC Director. The SRMC Coordinator is responsible for maintaining all documentation related to SRMC reviews and actions within the Clinical Trials Office in support of the UFHCC PRMS.

5.0 Cancer Prevention and Control Subcommittee

The Cancer Prevention and Control Subcommittee (CPCS) of the SRMC reviews non-therapeutic 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. 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 interventional treatment IITs. The PI is required to submit their concept to the pre-review team for initial feedback prior to full protocol development. This 2-stage review process supports institutional concepts, without a full protocol, to be reviewed for scientific merit and allows constructive feedback prior to significant investment of resources. Concepts approved in this stage are then sent forward for full protocol development. Analysis of the full protocol occurs during the regular SRMC review process as described in section 7. The aims of this 2-stage review are to reduce effort in developing protocols of lesser scientific merit, and shorten the timeframe from concept approval to protocol activation.

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

7.0 SRMC Review Process

7.1 Protocol Prioritization

All interventional trials must be reviewed and approved by the home DSG or Research Program (see Appendix B) of record prior to SRMC submission. DSG/RPs are responsible for ensuring that adequate resources are available to conduct the study. The DSG/RP leader must attest to the projected annual accrual, requirements for Clinical Trials Office (CTO) resources, presence or absence of competing studies, and overall support from the group on the “Disease Site Group (DSG) or Research Program Protocol Approval Form” (Appendix E). In addition, a protocol flowchart that demonstrates where the proposed trial fits into the DSG/RP’s active study portfolio must also be maintained in the CTMS by the DSG leader in conjunction with designated CTO 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 will ensure the prioritization submitted by the DSG/RP 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.

Non-interventional studies are not required to be submitted to a DSG or RP 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/RP 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/RP, the protocol is then submitted to the SRMC.

As noted in section 7.1, non-interventional studies are exempt from DSG/RP 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 UFHCC CTO through the CTMS submission console. The documents must include:

- SRMC Submission form (Appendix F)
- DSG/RP protocol approval form (Appendix E; interventional studies only)
- Complete study protocol with all appendices or investigational plan
- Investigator’s Brochure if applicable
- Draft Informed Consent document (interventional IITs only)
- SRMC Pre-Review approval confirmation (interventional IITs only)
- Any other relevant study documentation

Submission of Amendments/Revisions

The PI or designee provides all necessary study documents to the UFHCC CTO 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

7.2.1 Review Team

The SRMC coordinator, 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 | Investigator Initiated Interventional Trial | Minimum of 3 including one physician and one biostatistician |
| CPC | Investigator Initiated Interventional Trial | Minimum of 3 including one biostatistician |
| Parent | Industry or Other External Sponsored Interventional Trial | Minimum of 2 including one physician and one biostatistician |
| CPC | Externally Sponsored Interventional Trial | Minimum of 2 including one biostatistician |
| Parent/CPC | NCTN or Other Peer-Reviewed Interventional Trial | One reviewer |

| | | |
|------------|---|--|
| Parent/CPC | 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 | Single Patient INDs | Administrative review only |
| Parent/CPC | Study Amendments for Full Board 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/RP 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 coordinator prior to the meeting (see Appendices G - I).

Full reviews are conducted for the following protocol types:

- All 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.
- Study amendments for **full board** protocols, 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 not made adequate progress towards accrual goals.

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 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)
- 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 board or expedited review. It is the responsibility of the SRMC coordinator 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. Administrative reviews are conducted for the following submissions:

- Retrospective, Non-Interventional studies
- Studies that meet criteria for IRB exempt status
- Single patient INDs

Continuation reviews (CRs) are conducted initially at six months following activation (“Open to Accrual” status in the CTMS) and then, minimally, at 12 month intervals thereafter on all full board and expedited interventional protocols that are active with ongoing enrollment. CRs will monitor the accruals for specific studies and compare them to initial accrual goals. If a study is shown to be below the target accrual, it will be the responsibility of the PI or DSG/PR 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 coordinator 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 that their initial stipulation(s) had been properly addressed. Once the Chair approves that the proper correspondence was conducted, the coordinator 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.

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-board 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 5.3, 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 Board Review:** The study must be reviewed in its entirety by the full-board review. Requirements for full board review as outlines in Sections 5.3 and 5.4.1 then apply.

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 at the initial 6-month CR, a justification for continued accrual and corrective action plan (CAP) must be submitted to the SRMC. The study will be placed on a 6-month probation period. Studies that are still under 25% of their annual target following the 6-month probationary extension may 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. 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 may 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. 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.

Special consideration will be given for IITs, including national protocols where UF faculty serve in a leadership capacity, and NCTN studies not meeting accrual goals. The SRMC will make recommendations to enhance recruitment whenever possible.

An exception to the accrual requirements will be made for studies involving rare cancers as defined per the NCI 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.

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 12 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.

7.7 Adjustments to Accrual Goals

Lowering accrual goals will be reserved for special consideration cases. The SRMC may recommend changing the accrual goal if it is determined that the initial accrual goal was set too high. 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 coordinator 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

For local interventional investigator initiated trials and other trials without established data safety and monitoring plans, SRMC will review the protocol and determine the appropriate level of monitoring required. 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 Data Integrity and Safety Committee and the study PI by the SRMC coordinator.

Protocols will be classified into one of the following categories of risk:

Level 1 – Low risk Investigator Initiated interventional trials.

- UF diagnostic, screening and behavioral IITs
- UF IITs involving diet and/or exercise, accepted doses of over-the-counter drug, or vitamins and supplements

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.

- UF IND exempt phase II and III IITs
- UF investigational radiation IITs

Level 3 – High risk Investigator Initiated or externally sponsored interventional trials

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

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. 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. The following are the recommended guidelines for how often the DISC should review studies per risk level assigned:

Level 1: Ad hoc review

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. Alternate members of the parent and subcommittee must have an attendance level of at least 34% of their respective 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 coordinator. 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 coordinator. 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/RP 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 board 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?
- **Scientific Rationale:** Does the protocol address relevant scientific questions?
- **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.
- **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.

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 Affiliate Research Consortium (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 & Research Program List
- C. Prioritization Score
- D. Protocol Submission Flowchart
- E. DSG/RP Submission Form
- F. SRMC Submission Form
- G. SRMC Full Board Protocol Reviewer Form
- H. SRMC Biostatistician Protocol Reviewer Form
- I. SRMC Patient Advocate Reviewer Form
- J. SRMC Expedited Protocol Reviewer Form
- K. 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 |
| Michael Weaver, RN, PhD | Vice-Chair | Nursing | CPCS |
| 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 | |
| Leslie Pettiford, RN, MS | Core | Research | |
| Petr Starostik, MD | Core | Pathology | Molecular |
| Larisa Cavallari, PharmD | Core | Pharmacy* | |
| Fei Zou, PhD | Core | Biostats | |
| Susan McGorray, PhD | Core | Biostats | |
| Carmen Allegra, MD | Alternate | Medical Oncology | GI |
| Priya Gopalan, MD, PhD | Alternate | Medical Oncology | Thoracic |
| Karen Miller, JD | Advocate | Patient Advocate | |

*Laboratory Scientist

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

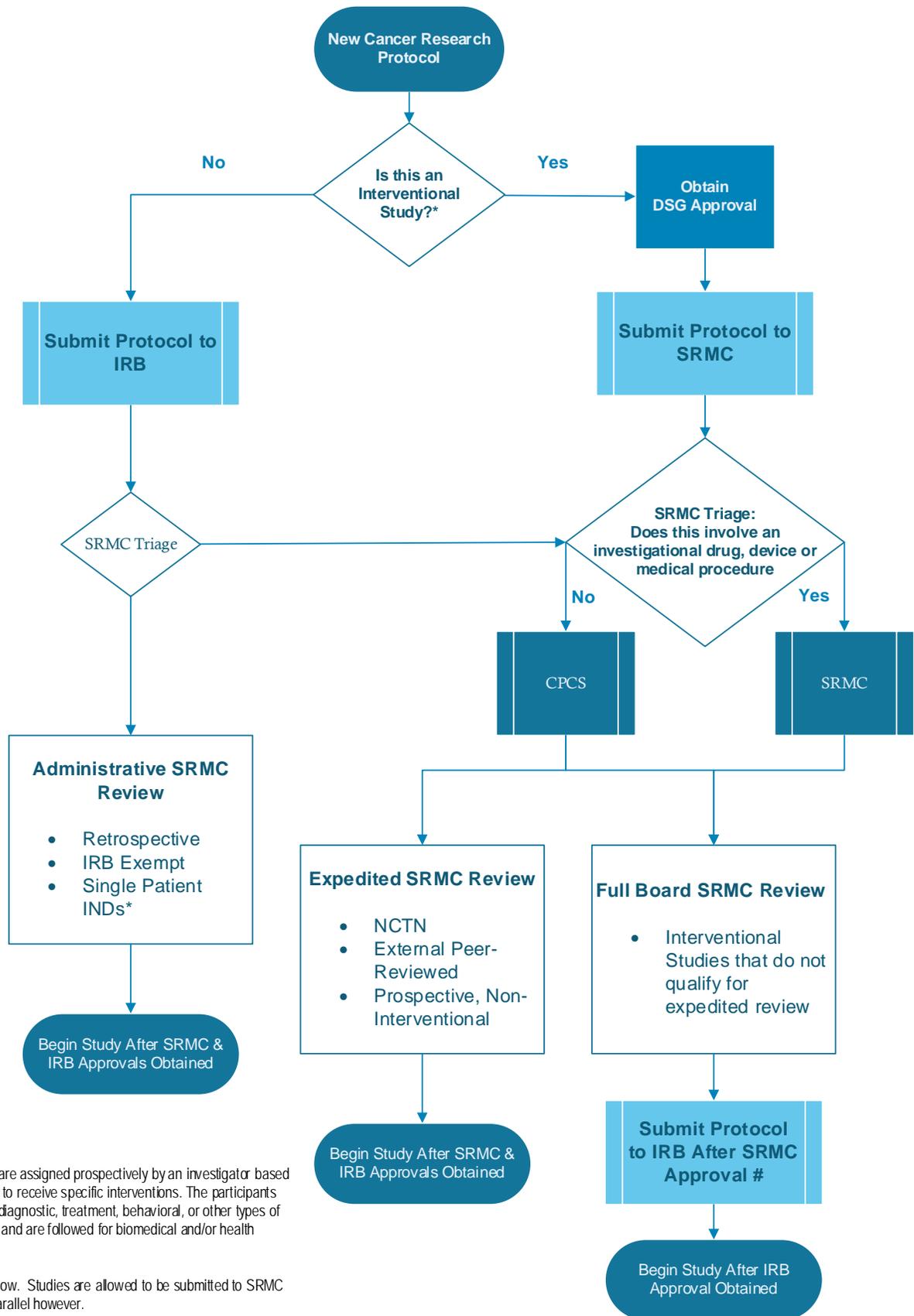
Appendix B: Disease Site Group & Research Program List

| Disease Site Groups & Research Programs | 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 & Research – Nam Dang, MD, PhD |
| Pediatrics | Clinical – William Slayton, MD Research – Sridharan Gururangan, FRCP |
| Experimental Therapeutics Group | Thomas George, MD |
| Cancer Therapeutics & Immuno-Oncology (CTHR) | Duane Mitchell, MD, PhD Christian Jobin, PhD |
| Mechanisms of Oncogenesis (MoO) | Robert Hromas, MD |
| Cancer Population Sciences (CPS) | Diana Wilkie, PhD, RN, FAAN Janice Krieger, PhD |

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 Submission Flowchart



Appendix E: DSG/RP Submission Form

**UF Health Cancer Center (UFHCC)
Disease Site Group (DSG) or Research Program Protocol Approval Form**

Instructions: Before a protocol may be submitted to the Scientific Review and Monitoring Committee (SRMC) the appropriate Disease Site Group or Research Program must thoroughly review and approve the protocol. Please submit the completed form to the appropriate UFHCC Clinical Trials Group Leader.

| | | | |
|------------------------------|-----------------------------------|-------------------------------------|---|
| DSG/Program: | Choose an item | Principal Investigator: | _____ |
| Protocol Number: | _____ | Sponsor: | _____ |
| Protocol Title: | _____ | | |
| <input type="checkbox"/> IIT | <input type="checkbox"/> Industry | <input type="checkbox"/> NCTN (NCI) | <input type="checkbox"/> Other External |

Has this study received prior peer-review by an NCI approved organization?
<https://cancercenters.cancer.gov/documents/PeerReviewFundingOrganizations508C.pdf>
(If yes, please attach supporting documentation for non-NCTN trials)
 NO YES

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)? _____

How many subjects have previously been enrolled into similar studies? _____

What is the UFHCC priority score for this trial? Choose an item.

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

Are there any competing protocols for this patient population? NO YES

If yes, name the competing protocol(s) and outline the algorithm to determine which protocol has priority: -

For IITs utilizing UFHCC CTO resources, will the study be conducted at any sub-sites?
(If yes, enter all sub-sites into CTMS) YES NO

For IITs utilizing UFHCC CTO resources, has the budget been approved by CTO leadership?
 PENDING YES NO

Additional Comments: _____

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

Signature of Associate Director for Clinical Investigation
Required for IITs only

Date

Appendix F: SRMC Submission Form:

SRMC Submission Form will be pulled from CTMS.

Appendix G: SRMC Full Protocol Reviewer Form:

Full-Board 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 Clinical Trials 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 research protocols, excluding low risk behavioral, nutritional, psychosocial and other nontherapeutic research protocols, must include a data and safety monitoring plan.

Does the study have a DSMB?:

- N/A
- Yes
- No. Local investigator-initiated research protocol and other protocols without an established data and safety monitoring plan can undergo monitoring by the UFHCC Data Integrity and Safety Committee (DISC). The Principal Investigator or SRMC can request monitoring by the UFSCC DISC. Once requested, SRMC is responsible for assigning the level of risk to the patient based on the complexity of the trial.**

Will the study require monitoring by the UFHCC's DISC?:

- No
- Yes, risk level assigned:**
 - Level 0** – Nutritional, behavioral, psychosocial, and other non-interventional studies without significant health or safety risks.
 - Level 1** – Low risk non-therapeutic interventional trials.
 - Level 2** – Moderate risk Investigator Initiated or externally sponsored therapeutic (such as drug, biologic or device) trials using FDA approved or commercially available compounds or interventions.
 - Level 3** – High risk Investigator Initiated or externally sponsored therapeutic 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).
 - 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 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

Reviewer Recommendation:

Scientific Merit:

- Approved
- Approved with stipulations
- Tabled
- Disapproved

Overall Assessment :

Reviewer Signature

Date

Appendix H: SRMC Biostatistician Protocol Reviewer Form

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

Biostatistician Protocol Reviewer Form

Protocol Number: [Click here to enter text.](#)

Protocol Title: [Click here to enter text.](#)

Principal Investigator: [Click here to enter text.](#)

New Application

Revised

Re-review

Reviewer: _____

Review Date: _____

Statistical Section:

Does this section properly identify and create a plan for addressing the following objectives: patient accrual; estimated duration of study; stopping rules; and provision for interim analyses

Add Comments/Concerns:

[Click here to enter text.](#)

16. Reviewer Recommendation:

Statistical Merit:

- Approved
- Approved with stipulations
- Tabled
- Disapproved

Overall Assessment Statistical Section:

[Click or tap here to enter text.](#)

Reviewer 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> | |
|--------------------------------|--|---------------------------------------|--|

Protocol Title:

New Application Revised Re-review

Reviewer:

SRMC Meeting Date:

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

Revised

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:

[Click here to enter text.](#)

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

Reviewer Decision:

- Approved
- Approved with stipulations
- Tabled
- Disapproved

Add Comments/Concerns

[Click here to enter text.](#)

Reviewer Signature

Date

Appendix K: 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:
 - o Studies of mechanisms of human disease
 - o Studies of therapies or interventions for disease
 - o Clinical trials, and
 - o 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

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 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.