University of Florida Health Cancer Center

Scientific Review and Monitoring Committee (SRMC)

Policies and Procedures

Version: 9.0

Date: April 10, 2023

Table of Contents

Manual Updates

Version 9.0 replaces Version 8.0 dated 08/01/2022
• Updated the listing of acronyms to add EAP (page 5) • Updated the UFHCC SRMC's definition of cancer-relevancy (page 8) • Updated the Review Team requirements for review types including Industry trials (page 11) • Added EAP reviews to Review Team Chart and Expedited Reviews section (page 11 and 12) • Updated to include Cellular Therapy and Apheresis review process (page 24) • Updated Appendix A: Committee Membership List (page 26) • Added Appendix N: Cellular Therapy and Apheresis Review Form (page 60)

Abbreviations

ARC	Affiliate Research Consortium
BMSP	Biomedical Sciences Panel
BMT CTN	Blood and Marrow Transplant Clinical Trials Network
CAP	Corrective Action Plan
CCSG	Cancer Center Support Grant
CCPSP	Cancer Control and Population Science Panel
CR	Continuing Reviews
CRA	Clinical Research Associate
CRO	Clinical Research Office
CTEP	Cancer Therapy Evaluation Program
CTMS	Clinical Trials Management System
COE	Community Outreach and Engagement
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
EAP	Expanded Access Protocol
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
I2T3	Investigator Initiated Trial Think Tank
IIT	Investigator Initiated Trial
IND	Investigational New Drug
IRB	Institutional Review Board

JIT	Just-in-Time
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 Monitoring 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;
- Adequate processes for determining the potential for accruing minority and underrepresented patients from the catchment area;
- 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.

The University of Florida Health Cancer Center (UFHCC) incorporates the use of a two-stage review process to fulfill NCI requirements. Interventional studies are initially evaluated (first-stage) for feasibility in terms of accrual and available resources within their home Disease Site Group (DSG) and subsequently submitted (second-stage) to the Scientific Review and Monitoring Committee (SRMC) for review. When a new, interventional study is reviewed by a DSG, the group will identify if there are any currently active studies that could compete, identify resources needed (or lack thereof), and review for scientific soundness prior to SRMC submission.

The SRMC 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; 4) evaluating the potential and actual accrual of minority and underrepresented patients relative to the catchment area. 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. 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 otherwise has a significant impact on cancer-related outcomes; 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 4.3.

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. The UFHCC's CTMS is OnCore.

The SRMC does not require review of cancer relevant studies that are considered non-human or are student led projects initiated to fulfill degree requirements. However, student projects that involve any level of UFHCC support, including Clinical Research Office resources, financial or other in kind support, are subject to SRMC oversight.

3.0 First Stage Review Process

The first stage of review within the UFHCC's PRMS takes place within the Disease Site Groups (DSGs). DSG members come from and represent various academic and clinical departments that are engaged in cancer research. To ensure a multidisciplinary perspective, the DSG composition includes a broad range of specialties, including but not limited to basic science, medical oncology and hematology, pathology, radiation oncology, radiology, interventional radiology, laboratory research, surgery, and population-based science.

The first-stage review process does not require DSGs to review cancer-relevant clinical trials that are considered non-human or are student led projects initiated to fulfill degree requirements. However, cancer-relevant, interventional studies must receive DSG approval from the appropriate DSG before these studies can be submitted to the SRMC. An overview of the review processes are below.

3.1 Concept Enrichment Process

The UFHCC has a concept 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 Think Tank (I2T3), is mandatory for any IIT planning to utilize UFHCC resources, such as Clinical Research Office (CRO) study coordinator, data entry or Project Management Office (PMO) support. I2T3 review is also required for trials receiving UFHCC financial or other in-kind support. Concepts not meeting these specifications are exempt from this review, but are encouraged to take advantage of the concept review process. The aims of this multifaceted concept review are to provide feedback to the study team and establish if the concept has preliminary scientific merit and fulfills the current needs for the DSG research portfolio and the UFHCC area prior to development into a full

protocol. Protocols not having undergone prior concept review and approval often suffer significant setbacks during the development and implementation phases of the study. This concept review process enables institutional concepts, prior to development into a full protocol, to be reviewed for scientific merit and allows constructive feedback prior to significant investment of time and resources via the I2T3 mechanism. Concepts approved during this review, which have secured adequate support, are then sent forward for full protocol development. Approval during the concept review process does not guarantee ultimate approval by the SRMC.

Further details regarding the Concept Enrichment process can be found within the "UFHCC Project Management Office I2T3 Concept Review Form" document.

3.2 DSG New Trial Review

Upon availability of the full protocol, all interventional trials must be reviewed and approved by the primary DSG (see Appendix B) of record prior to SRMC submission. The PI and/or study team should submit necessary submission materials to DSG Support Staff at DSG-Support@cancer.ufl.edu. Upon intake of a new study, DSG Support Staff will confirm if the new study is disease specific or disease agnostic. The study will be forwarded to the appropriate DSG Research Leader for interest. If interest is confirmed, the DSG Research Leader for each group will determine if the study should be reviewed through an ad hoc review process or at the next scheduled DSG meeting. For studies reviewed through an ad hoc review process, the DSG Research Leader will identify key stakeholders from the DSG for the DSG administrator to contact for their vote. DSG meetings are administratively supported by the CRO and conducted either in person or via teleconference to review new studies and overview of trials within the DSGs portfolio. These meetings occur no less frequently than quarterly. Ad hoc meetings may be called at the discretion of the DSG leaders to ensure protocol development or review is not impeded. During review of a new study or trial, attendance will be noted via meeting sign-in sheet or teleconference attendance. Prior to conducting the DSG (or ad hoc) meeting, a meeting agenda and meeting materials will be sent to the DSG members by CRO administrative staff. DSG portfolio reviews include ongoing trials, accrual status relative to stated targets, upcoming SRMC continuation reviews and address study specific items relevant to recruitment efforts and/or proposed changes to the study portfolio.

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 "DSG Submission 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. The SRMC may consider competing studies when the proposed trials include 1) early phase studies, 2) there is an adequate patient population to meet both study enrollment expectations and/or any current competing studies are anticipated to complete accrual before the new trial is opened, or 3) studies that do not have completely overlapping eligibility criteria. In general, studies competing for the same patient population will be rejected by default in the absence of such justification provided by the DSG.

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

- **Endorsement:** The study is scientifically sound and fulfills a need in the current DSG research portfolio as well as in the UFHCC catchment area. After the study is endorsed, the DSG submission form will need to be completed and signed by the DSG Research Leader.
    - If the study has a primary DSG that is disease agnostic, such as the ETG or CCPS, and the study targets a patient population of another DSG, the other DSG will need to acknowledge this study via review by the acknowledging DSG leader(s).

    - All comments will be provided to the DSG research leader who can summarize or include them in their endorsement to SRMC and/or provide feedback to the study leadership team.
- **Tabled:** The PI and study team will need to make changes to address the concerns of the group. These concerns could include scientific validity or fulfillment of the DSG research portfolio and the UFHCC catchment area. Once revisions are completed, the DSG leader(s) will make the final decision. The minutes will be updated to reflect the final decision.
- **Declination:** The study is not scientifically sound and/or does not fulfill a need in the current DSG research portfolio as well as in the UFHCC catchment area. Once the study is declined, the study will not move past the DSG.
    - If the study team chooses to re-work the concept, or the protocol is substantially modified a new review by the DSG will be needed in order to move forward.

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

4.0 Second Stage Review: SRMC Review Process

4.1 Protocol Prioritization

The SRMC will ensure the prioritization submitted by the DSG during the first stage review 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.

4.2 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 recruitment 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 (completion of first-stage review), the protocol is then submitted to the SRMC.

As noted in Section 3.2, 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 CRO. All submissions to the SRMC must be made via the ePRMS Console within the CTMS. Study staff may request SRMC submission assistance via the SharePoint SRMC Intake Form.

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 submission 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 (qualifying IITs only; see section 3.1)
- Celllular Therapy/Apherisis form (qualifying interventional studies only) (Appendix N)
- 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. Note that submission of amendments/revisions is only required for studies initially approved (or that would have qualified) at SRMC as a 'Full Review." Amendments/revisions are only required to be submitted from the time of the initial SRMC approval until the study is permanently closed to accrual. The submission 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

4.2.1 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:

Panel	Type of Study	Reviewer Quantity & Type
BMSP	UF Interventional IIT	Minimum of 6 including two primary reviewers (one who is a physician), one biostatistician, one feasibility, one COE, and one Citizen Scientist
CCPSP	UF Interventional IIT	Minimum of 6 including two primary reviewers, one biostatistician, one feasibility, one COE, and one Citizen Scientist
BMSP	Industry or Other Externally Sponsored Interventional Trial	Minimum of 3 including one primary reviewer, one COE, and one feasibility
CCPSP	Externally Sponsored Interventional Trial	Minimum of 3 including one primary reviewer, one COE, and one feasibility
BMSP/ CCPSP	NCTN, ETCTN or EPR Interventional and Non-Interventional Studies	Minimum of 3 including one primary reviewer, one COE, and one feasibility
BMSP/ CCPSP	Prospective, Non-Interventional Studies	One primary reviewer
BMSP/ CCPSP	Amendments/Revisions to Full Review Studies	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

Panel	Type of Study	Reviewer Quantity & Type
		any changes that affect the statistical section of an interventional IIT protocol.
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* DSG, ADCR and Administrative Director endorsement required.
Admin	Banks/Registries	Administrative review only
All interventional studies undergo feasibility and COE review at the time of initial submission.		

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

4.3 Review Types

Full reviews require a brief summary presentation by the Principal 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). For initial reviews, a feasibility review and a COE review will be provided to the SRMC committee. 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 - M).

Full reviews are conducted for the following protocol types:

- All UF sponsored Interventional Investigator Initiated Trials (IITs) that have not previously undergone external peer review by one of the NCI approved groups (see Section 2.0) or via a NCI-approved external PRMS.
- 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 2.0) or via a NCI-approved external PRMS.
- 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 P for the SRMC intake policy for IRB approved studies.

Expedited reviews of new studies 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. Amendments/revisions to applicable ongoing studies (see Section 4.2) that qualify for expedited review will be evaluated to ensure continued scientific merit.

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 2.0) 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.
- Legacy studies that would have initially met the criteria for a full review as described above. (If a study would have met the full review criteria when initially submitted, then subsequent amendments that meet the criteria above will need to be reviewed by the SRMC)

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:

- Continuation reviews for studies that have been suspended for ≥ 3 months during the review period
- Chart review studies (Retrospective and/or Prospective)
- Retrospective, Non-Interventional studies
- Tissue and/or data banks/registries
- Most studies that meet criteria for IRB exempt status
- Expanded access studies. DSG, ADCR and Admin Director endorsement is required for these studies.
- Single patient INDs
- Studies meant to fulfill the degree seeking purposes of a student (that do not utilize CRO support)

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.

**Study accrument expectations were adjusted during the COVID-19 pandemic. See Appendix Q for additional details.*

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 review 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.

4.4 Possible Decisions

4.4.1 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.

4.4.2 Expedited Review Decisions

Any review that is considered expedited as described in Section 4.3, 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 outlined in Section 4.2 then apply.

4.4.3 Administrative Review Decisions

Any review that is considered administrative as described in Section 4.3 shall be reviewed to ensure the study meets the criteria for administrative review. Reviewer(s) 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.
- Deferred: This decision type may only be used when a study has been suspended for a significant portion of time and no committee decision can be made until further information is available (i.e., the study is open to accrual long enough for a continuation review decision to be made).

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 timeframe are subject to re-review by the SRMC. Unapproved studies that have unresolved SRMC queries for greater than 6 months may be subject to subsequent review; these items may be forwarded to the SRMC Chair or delegate for further SRMC action determination inclusive of possible application disapproval.

4.5 Continuation Reviews

CRs 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 collaboration with the UFHCC CRO (as an investigator team resource) to help support recruitment.
- 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 collaboration with the UFHCC CRO (as an investigator team resource) to help support recruitment. 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. This CAP must be generated by the study team in collaboration with the UFHCC CRO (as an investigator team resource) to help support recruitment. 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. A feasibility assessment will not be required for studies at this time.
- If a study does not Open to Accrual within 12 months of an SRMC approval the SRMC will administratively disapprove the study (At this time the PI can request an extension on the SRMC 12-month deadline (i.e. pending funding, FDA response, etc.)).
- If the study team is unable to resolve SRMC queries within 3 months of the queries being sent the study will be administratively disapproved.
- If there is no response from the study team within 1 month of SRMC queries being sent to the study team the study will be administratively disapproved.

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 will be taken into consideration in scheduling CR reviews. 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.

In addition to assessing the overall number of enrollments relative to target expectations, the demographics of the subjects enrolled (e.g., age, gender, race, ethnicity) will be reviewed at all interventional study continuing reviews.

4.5.1 Special Considerations

A modification to the above accrual and activation requirements will be made for studies that meet certain special considerations. These special considerations are discussed in more detail below.

Special consideration of accrual requirements will be given to rare disease studies, Phase 1 portion of trials where enrollment opportunities are limited and/or only intermittently available, national protocols where UF faculty serve in a leadership capacity as documented on the protocol cover sheet, IITs involving translation of UF science, and IITs accruing at affiliate sites where UF is the coordinating center. These special considerations of accrual requirements will allow a study to be open to accrual for up to 24 months. If the study still has not accrued any study participants, the SRMC will terminate the study.

In addition, the SRMC will give special consideration of activation requirements to studies that use the Just-in-Time activation method.

The SRMC, inclusive of COE and CRO, will make recommendations to enhance the absolute number and diversity of subject recruitment whenever possible.

Rare Disease Designation

An accrual modification will be made for studies involving rare cancers as defined per the UFHCC's rare disease definition. The UFHCC defines a rare cancer as one with an incidence of ≤ 3 newly diagnosed persons out of a population of 100,000 persons per year (≤ 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 ≤3/100,000 patients per year (<9,600 total patients per year in the U.S.). Incidence of mutation will be evaluated within individual tumor sites for disease agnostic studies. 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.*

Phase 1 Trials

Trials that are designated as Early Phase, Phase I, or Phase I/II may be granted an accrual modification. To be considered, these trials must be enrolling to the Phase 1 portion of the study. Such study phases typically have limited enrollment opportunities, yet are high priority for the UFHCC and catchment area.
Trials designated as 1) rare disease or 2) Phase I at the time of initial SRMC review will be subsequently reviewed every 12 months after open to accrual. Rare disease or Phase I 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. A Phase I study accrual modification expires at the time of a SRMC continuing review when the study is no longer enrolling with limited slot availability (e.g., competitive cohort expansion phase).

If a study moves forward from a Phase I study to the Phase II portion of a study, the study is no longer considered a special consideration. Once the study re-opens to accrual during the beginning of Phase II, the study will proceed using the standard continuation review and zero tolerance requirements.

National Leadership Roles for Investigators

Trials where a Principal or Sub-Investigator is listed on the Protocol cover sheet as a study Chair or National Study Champion will be considered a special consideration. In addition, this will count for studies where a Principal Investigator (or sub-Investigator) is documented as being involved in the creation of a multi-site national study. These trials will be identified within OnCore under staff listing as well as requested confirmation on the SRMC submission documentation.

UF IITS

Trials that are UF IITs and are identified as involving UF translational science may be granted an accrual modification. In addition, UF IITs that are accruing at affiliate sites where UF is the coordinating center may also be granted an accrual modification.

Just-in-Time Trials

Trials that are approved by senior leadership to use the Just-in-Time (JIT) activation method will remain in an on-hold status within OnCore until a subject has been identified, at which time they will be activated. Only treatment studies in rare diseases may be eligible for JIT activation. These trials will complete all activation activities, including SRMC and IRB review, but may remain on-hold for an extended amount of time before they are moved to an open to accrual status. These trials are exempt otherwise from timeline policies that impose automatic termination by or re-application to SRMC.

4.5.2 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 a special consideration or sufficient documentation for suspended status is provided).

There is a caveat for special consideration qualifying studies (see Section 4.5.1). 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 closed at the time of continuation review unless one of the following items are met resulting in a waiver:

4.5.3 CR Review Decisions

- 12 Month Approval: The study continues to be scientifically sound and is meeting or 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 collaboration with the UFHCC CRO and COE (as an investigator team resource) to help support recruitment.
- Closure Required: Closure (or Closure to Accrual if patients remain on study or in follow-up) may be required for studies that are no longer scientifically sound or have inadequate accrual for continuation.

4.6 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 chronic low accrual
- Amendments or developments that render the study no longer scientifically sound
- Recommendations from the DISC
- Upon request from the PI

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 and ensure that the OnCore status is updated accordingly.

4.7 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.

4.8 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. SRMC determinations may be modified upon further review or protocol understanding to alter the review classifications previously assigned during SRMC review.

4.9 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**.

4.10 Consideration of Previously Closed Protocols

Protocols previously disapproved or terminated for poor accrual may be reconsidered by SRMC approval if appropriate protocol ammendments have been made that address previously identified scientify issues or barriers to accrual. The PI must provide clear documentation on how the protocol ammendents sufficiently address committee concerns. The opportunity for SRMC re-review is at the discretion of the ADCR. All studies authorized to move forward will be submitted as a new protocol.

5.0 SRMC 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 for Clinical Research, 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 population sciences, 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 Citizen Scientist. 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 including a COE representative, and Citizen Scientists. 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.

6.0 SRMC Meetings and Administrative Coordination

The SRMC is comprised of two different panels (Biomedical Science and Cancer Control and Population Science) with differing specialists, but both fulfill the same function and comply with the same policies. The appropriate NCI guidelines apply to both the BMSP and the CCPSP. Each panel meets twice monthly for initial and continuing study reviews. Approximately one week prior to each panel 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 4.2.1), 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 each panel meeting. 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, all Vice Chairs, SRMC Administrator, Associate Director for Clinical Research, Administrative Director of Clinical Research 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 and addresses any unique needs of the individual panels.

6.1 Biomedical Science Panel (BMSP)

The SRMC Biomedical Science Panel (BMSP) reviews treatment studies that involve investigational drugs, devices, or medical procedures. Members of the BMSP will either volunteer or be assigned for review based on need and availability from the relevant areas of expertise. These scientific themes are not exclusive, however, and decision as to review assignment will ultimately be decided by the SRMC BMSP Chair and Vice-Chairs. 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.

Meetings may be conducted virtually or in person and are led by the BMSP Chair. Meetings may only start once quorum is met, which is defined as at least 8 voting members (i.e., appointed core committee members in attendance) including a minimum of one Chair or Vice Chair and one biostatistician.

6.2 Cancer Control and Population Science Panel (CCPSP)

The Cancer Control and Population Science Panel (CCPSP) 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 CCPSP. This panel 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 CCPS Chair.

Meetings may be conducted virtually or in person and are led by the CCPSP Chair. Meetings may only start once quorum is met, which is defined as at least 5 voting members, (i.e., appointed core committee members in attendance) including a minimum of the CCPSP Chair (or a delegate approved by the SRMC and CCSP Chairs) and one biostatistician.

7.0 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.

7.1 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

8.0 Responsibilities

8.1 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
- Evaluate the accrual of minority and underrepresented patients relative to the catchment area
- 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.

8.2 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, all members (regardless of panel) must have an attendance level of at least 51%. 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.

8.2.1 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 & Merit: 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?
- Feasibility: Are there adequate institutional, financial, personnel and patient resources available?
- Community Outreach and Engagement: Is the study relevant to the catchment area? Does the study have the potential to accrue minorities and underrepresented populations relevant to the catchment area? Are there additional recruitment efforts that could be recommended?
- 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, feasibility and COE.

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.

Community Outreach and Engagement Review (COE): The COE component of the SRMC review process is performed at the initial review of each interventional study (see 7.2.1). COE review encompasses study elements relative to the catchment area including aspects of inclusivity, impact and involvement. COE partners with a wide variety of community members and clinicians throughout the catchment area; their focus is collaboration with the communities that are served to help provide innovative research and healthcare services to those within our area. Their review also detects possible barriers to enrollment and identifies potential resources for recruitment.

The COE reviewer or their delegate will provide a written review. This review will be taken into consideration during the SRMC review.

As part of the COE review, the following protocol elements are taken into consideration relative to the catchment area:

- *Inclusivity*: Eligibility of participants relative to age, race, gender, ethnicity, etc. with particular focus on disparate or underrepresented populations.
- *Impact*: Targeted disease(s) or outcomes of importance to catchment area needs.
- *Involvement*: Assessment of potential recruitment barriers and identification of potential resources that may assist with overall diversity of participant participation.

COE catchment area impact score will be generated for each interventional trial using a rubric based upon key UFHCC catchment area priorities.

COE also participates in SRMC executive committee meetings where enrollment metrics and participant demographics are reviewed, helping to identify trends in enrollment disparities both at a trial and institutional level.

Feasibility Review: Feasibility review for successful deployment of the study will be conducted as part of the initial SRMC review for all interventional studies and continuation reviews where accrual is significantly underperforming (see 7.2.1). Feasibility review will be conducted by CRO staff familiar with protocol and institutional resource utilization and will be documented throughof the Feasibility Assessment Form. This review will be taken into consideration during the SRMC Committee review. The proposed study must be determined feasible in order to receive initial SRMC approval.

The UFHCC CRO assists study teams with determining local enrollment potential through centralized access to institutional databases including the Integrated Data Repository (using NIH-funded i2b2 tool), tumor registry and other electronic datasets. Projected enrollment also takes into consideration historical enrollment to similar studies. As part of feasibility review, enrollment goals are better aligned based on patient population data.

Feasibility review for low enrolling studies at continuation review will be incorporated into the SRMC CAP. An ad hoc feasibility assessment may be conducted as part of a change review that impacts enrollment targets or institutional resource utilization. Any questions or comments related to any feasibility review will be provided to the study team.

Feasibility review assesses the following relative to successful protocol conduct:

- Accessible subject population and enrollment goal refinement

- Availability of adequate institutional and clinical resources (e.g., need for specialized equipment/processes, specialty providers or services, extended or after-hours support, special pharmacy or other ancillary department support, etc.)
- Compliance and regulatory requirement considerations
- Any additional resources that need to be considered prior to trial activation and/or continuation including community stakeholder involvement through COE

Cellular Therapy/Apheresis Review: An additional feasibility review done by the Cellular Therapy and Apheresis Group to ensure the availability of adequate Cellular Therapy and/or Apheresis resources and support to conduct the protocol.

9.0 Academic Research Consortium Program

At the request of a UFHCC Academic 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 Citizen Scientist Reviewer Form

J. SRMC Expedited Protocol Reviewer Form

K. SRMC Expedited Change Reviewer Form

L. COE Reviewer Form

M. Feasibility Assessment Form

N. Cellular Therapy and Apheresis Review Form

O. SRMC Scientific Scoring Guidance

P. SRMC Intake Policy for IRB Approved Studies

Q. Adjustments to SRMC Continuation Review Policy Due to COVID-19

R. NCI Study Primary Purpose/Phase/Type Classification

Appendix A: Committee Membership List

Biomedical Sciences Panel (BMSP)			
Ryan Thomas, MD	Chair	Surgical Oncology*	GI; Microbiome
Randal 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	
Karen Daily, DO	Core	Medical Oncology	Breast
David DeRemer, PharmD	Core	Pharmacy	ETI
Bently Doonan, MD	Core	Medical Oncology*	Cutaneous
Nosha Farhadfar, MD	Core	Medical Oncology	HM-BMT
Coy Heldermon, MD, PhD	Core	Medical Oncology*	Breast
John Hiemenz , MD	Core	Medical Oncology	HM-BMT
Joanne Lagmay, MD	Core	Medical Oncology	Peds; Sarcoma
Karen Miller, JD	Core	Citizen Scientist	
Jennifer Woodard, MPH, RN, CCRP	Core	COE	
Petr Starostik, MD	Core	Pathology	Molecular
Yan Gong, PhD	Core	Pharmacogenomics	
Ji-Hyun Lee, PhD	Core	Biostatistics	
Yi Guo, PhD	Core	Biomedical Informatics	
Zhanna Galochkina, MS	Core	Biostatistics	
Roy Arkaprava, PhD	Core	Biostatistics	
Muxuan Liang, PhD	Core	Biostatistics	
Cancer Control and Population Sciences Panel (CCPSP)			
Michael Weaver, RN, PhD	Chair	Nursing	
Carma Bylund, PhD	Core	Communications/Policy	
Georges Khalil, PhD	Core	Cancer Prevention	
Janice Krieger, PhD	Core	Communication	
Karen Miller, JD	Core	Citizen Scientist	
Deidre Pereira, PhD	Core	Clin Health Psychology	
Jennifer Woodard, MPH, RN, CCRP	Core	COE	
Lakeshia Cousin, Ph.D., APRN, AGPCNP-BC	Core	Cancer Survivorship	
Stephen Anton, PhD	Core	Psychology	Cancer Prevention
Yan Gong, PhD	Core	Pharmacogenomics	
Ji-Hyun Lee, PhD	Core	Biostatistics	
Yi Guo, PhD	Core	Biomedical Informatics	
Zhanna Galochkina, MS	Core	Biostatistics	
Roy Arkaprava, PhD	Core	Biostatistics	
Muxuan Liang, PhD	Core	Biostatistics	

* Translational scientist

Biostatisticians can perform duties for either BMSP or CCPSP committee as needed.

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

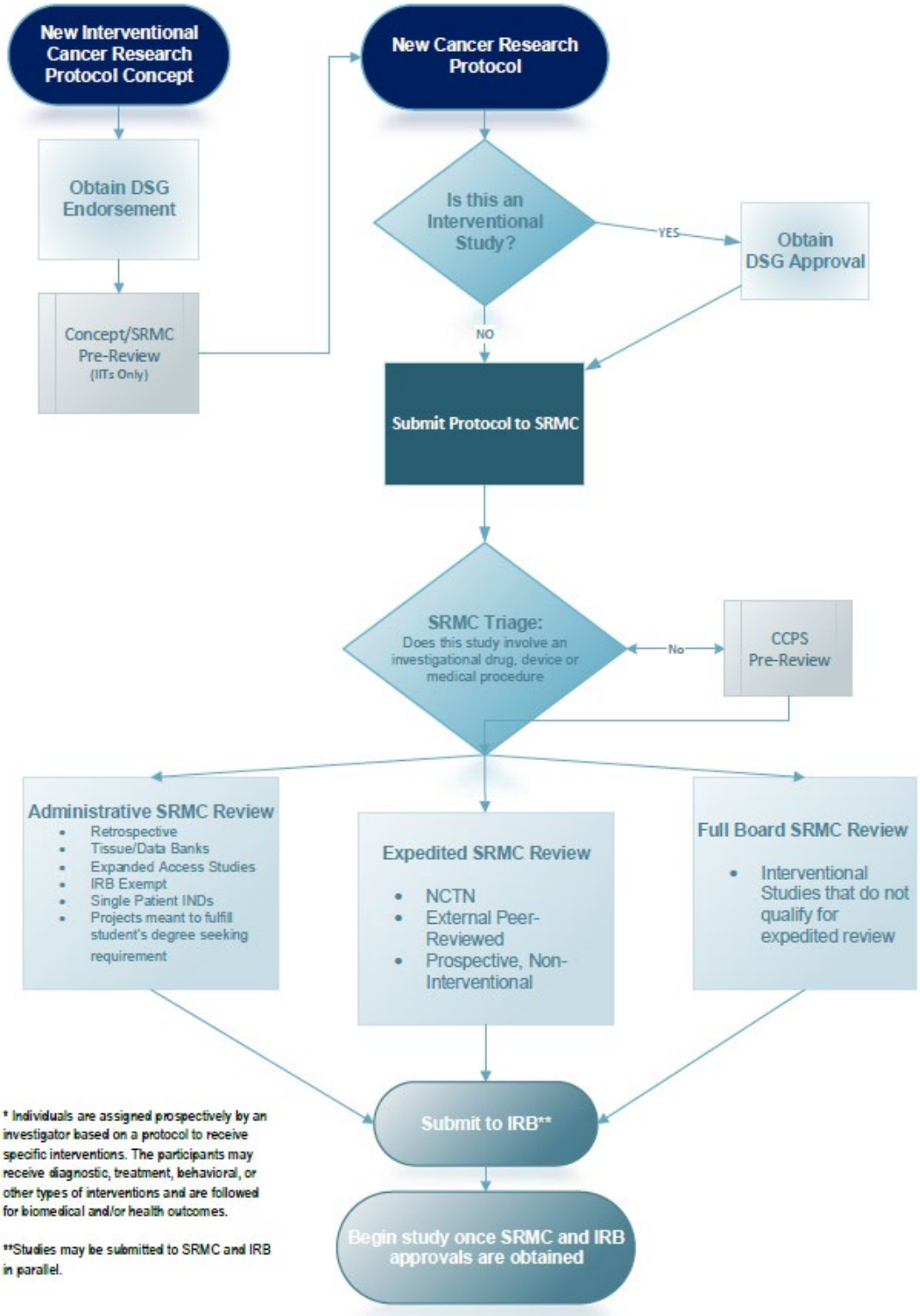
Appendix B: Disease Site Group List

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

Appendix 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) or Research Program Protocol Approval Form

Instructions: Before an interventional protocol may be submitted to the Scientific Review and Monitoring Committee (SRMC) the appropriate DSG must thoroughly review and approve the protocol. Please submit the completed form to the appropriate UFHCC Clinical Trials Unit Leader.

DSG/Program:	Select One	Principal Investigator:	
Protocol Number:		Sponsor:	
Protocol Title:			
Sponsor Type:		UFHCC Priority Score:	Select

1. Has this study received prior peer-review by an NCI approved organization?
   You can find a list of NCI-approved organizations at the following URL: click here (PDF).
   ◯ Yes* ◯ No *Note: If yes, please attach supporting documentation.

2. Is the trial scientifically sound?
   ◯ Yes ◯ No

3. Are all physical resources currently available to conduct the trial?
   ◯ Yes ◯ No

4. Is an adequate patient population currently available to support projected enrollment?
   ◯ Yes ◯ No

5. What is the projected number of subjects you plan to enroll at this site?
   Total: **Annual:**

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

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

8. Are there any protocol or eligibility requirements that may limit UF's ability to recruit patients? ◯ Yes ◯ No
   a. If yes, please comment. Be specific to potential issues that may affect enrollment (eligibility criterion, testing windows, overnight stays, etc.).

9. Does this study involve Cellular Therapy and/or apharesis? ◯ Yes ◯ No
   a. If yes, additional review is needed. Contact UFHCC-BMTCellularTherapy@ufl.edu

10. Will this study target a non-English speaking population? ◯ Yes ◯ No
    a. If yes, Which language: _____

11. If applicable, have all barriers to enrollment been adequately addressed by the DSG?
    ◯ Yes ◯ No

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

DSG Submission Form | Page 1

13. Is this trial serving a rare disease?
The UFHCC defines a rare case as one with an incidence of ≤ 3 newly diagnosed persons out of a population of 100,000 persons per year (<9,600 cases/year). Only cancer origin, histology and molecular profile are used to determine rare disease status.
◯ Yes* ◯ No *Note: If yes, please attach supporting documentation.

14. Will this trial be conducted using UFHCC Clinical Research Office (CRO) resources including Project Management Office (PMO) services, research coordinator or data entry support, regulatory management, financial, or other in-kind support?
◯ Yes ◯ No

15. Do the following individuals have more than 1+year of experience conducting trials?
Principal Investigator: ◯ Yes ◯ No
Primary Study Coordinator: ◯ Yes ◯ No ◯ N/A
Name of Study Coordinator:

16. Does this trial have the potential to accrue minorities or underrepresented patients?
◯ Yes ◯ No

17. Does this study exclude older adults (>65)?
◯ Yes ◯ No

18. Does this trial specifically target any of the following populations or those that self- identify as (Check all that apply):
☐ Black
☐ Hispanics
☐ LGBTQIA+
☐ Elderly ≥65
☐ Rural Residency (as defined by the RUCC codes)
☐ Socially Vulnerable Community Member (Per the CDC)
☐ Other (Please specify, " ")

19. Does this protocol target patients with advanced-stage or metastatic disease (cancer that is unlikely to be cured or controlled with treatment)?
◯ Yes ◯ No

20. Does this protocol target tobacco or a tobacco-related cancer?
◯ Yes ◯ No

21. Does this study address the following:
◯ Survivorship ◯ Palliative Care

22. How does this study fulfill a need in the current DSG research portfolio?

23. How does this study fulfill a need in the UFHCC catchment area?

24. Additional Comments:

For UF Investigator-Initiated Trials:
Please ensure you have a fully executed I2T3Concept Review Form for all IITs utilizing CRO resources and categorized as interventional, or otherwise involving investigational drugs, devices or medical procedures, prior to submitting to the SRMC committee. I2T3 Concept Review should be obtained prior to full development of the trial. More information can be found within the UFHCC IIT Policy document.

Note: Your signature below provides assurance to UFHCC Clinical Trials Group Leader and the Scientific Review and Monitoring Committee (SRMC) that the disciplines necessary to complete this protocol have read and agreed with the study.

_____ _____
Signature of the DSG or Research Program Leader Date

Appendix 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:

UFHealth CANCER CENTER

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 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. **Background/Scientific Rationale:** Is there adequate justification for conducting the study based on results of prior studies and/or pilot data? Does the protocol address relevant scientific and/or clinical questions?

◯ Acceptable ◯ Not Acceptable

2. **Research Objectives and Study Design:** Are the objectives and endpoints of the protocol clearly defined? Do the objectives measure the impact of the proposed intervention? Does the proposed protocol design align with the protocol's objectives and scientific rationale? Is the proposed intervention described in sufficient detail to allow the protocol to reach the endpoints proposed? Is the schema accurate and easy to follow? If a treatment intervention, does the protocol describe therapy including the treatment doses/schedules, dose adjustments, duration of therapy and clear schema.

◯ Acceptable ◯ Not Acceptable

3. **Eligibility and Study Requirements:** Are the proposed eligibility criteria reasonable in light of the study objectives and proposed intervention/investigation? Are there any criteria that place an unnecessary restriction on enrollment?

◯ Acceptable ◯ Not Acceptable

4. **Intervention and Toxicity Management Information:** If therapy involves a drug or medical procedure, is there adequate information regarding dosing, administration, frequency and duration as applicable? Does the study describe special precautions or instructions for staff or subject regarding *the* intervention, delivery and toxicity mitigation/management?

◯ Acceptable ◯ Not Acceptable ◯ Not Applicable

5. 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.

5.1. 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:

5.2. Does the study have an established independent Data and Safety Monitoring Board?:

- ◯ Yes - Go to Q6
- ◯ No – Local interventional IITs must be under the oversight of DISC or anequivalent DSMB. **For externally sponsored studies, DSMB oversight is *only* required for Phase III studies per the NIH.**

5.2.1 Specify the type of study

- ◯ UF sponsored IIT – Complete Section 5.3
- ◯ Non-UF sponsored Phase 0-II Study – Go to Q6
- ◯ Non-UF sponsored Phase III Study – Go to Q6. This study cannot be approved without an independent DSMB

5.3 Does the study have a Data and Safety Monitoring Plan that includes the following?:

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 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

6. **For interventional studies, has the DSG adequately evaluated the proposed impact on the catchment area? (e.g. women, minorities, disease burden, etc.)**

◯ Acceptable ◯ Not Acceptable ◯ Not Applicable

7. **Inclusion of Children, if applicable:**

◯ Acceptable ◯ Not Acceptable ◯ Not Applicable

If a primary Pediatric trial, what is the upper age of enrollment eligibility? _____

8. **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.

9. 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.
- ◯ **Device Feasibility (DEV)**: Protocol designed to evaluate one or more interventions for the feasibility of the product or to test a prototype device and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.
- ◯ **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.
- ◯ **Pragmatic Clinical Trial**: A clinical trial that is designed to study a health intervention in a real-world setting that is similar or identical to the one in which the intervention will be implemented.
- ◯ **Other (OTH)**: Not in other categories

10. Merit Score: Select one score below that represents the overall scientific impact of this trial (REQUIRED):

- ◯ 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

Required Scoring Assessment (Please summarize strengths and weaknesses to justify your scoring):

Reviewer Recommendation:

Scientific Merit:

- ◯ Approved
- ◯ Approved with stipulations
- ◯ Tabled
- ◯ Disapproved

Reviewer Signature

Date

Appendix H: SRMC Biostatistician Protocol Reviewer Form

UFHealth CANCER CENTER

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: Initial	

Trial Phase:	Randomization:	Blinding:
☐ Pilot / Feasibility ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Non-Therapeutic ☐ Other:	☐ Randomized ☐ Not Randomized	☐ Open Label ☐ Single-Blinded ☐ Double-Blinded ☐ N/A

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 Citizen Scientist Reviewer Form

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

Investigator-Initiated Trial Citizen Scientist Reviewer Form

Protocol Number: _____ **Principal Investigator:** _____

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.

1. Protocol & Eligibility

☐ Is the study addressing a question that is important to patients?
☐ Does the scientific rationale/background describe how the intervention might be better than what currently exists?
☐ Are quality of life and other patient experience factors being investigated?
☐ Does the proposed intervention seem reasonable/acceptable?
☐ Does the proposed intervention, study schedule or testing involve a significant burden to the patient/family?
☐ Do the criteria for inclusion and exclusion seem reasonable and necessary in light of the intervention?
☐ Is 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).
☐ Do the described risks of the intervention seem like they are balanced by potential benefit?
☐ Is there a Data and Safety Monitoring Plan included in the protocol?

Include an overall assessment of strengths and weaknesses of the protocol:

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):

_ A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

_ A description of any reasonably foreseeable risks or discomforts to the subject.

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

_ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

_ A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

_ For research involving more than minimal risk, 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.

_ An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

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

2.1. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

_ 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.

_ Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

_ Any additional costs to the subject that may result from participation in the research.

_	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
_	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.
_	The approximate number of subjects involved in the study.
_	When seeking informed consent for applicable clinical trials, as defined in 42 U.S.C. 282(j)(1)(A), the following statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify the clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank under paragraph (j) of section 402 of the Public Health Service Act. The statement is: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."
_	The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.
_	Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

Please assess whether or not the consent accurately reflects the protocol document.

OVERALL EVALUATION OF PROTOCOL - ACTION RECOMMENDED:

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

Comments:

Reviewer Signature **Date**

Appendix J: SRMC Expedited Protocol Reviewer Form

UFHealth CANCER CENTER

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

Expedited Protocol Reviewer Form

Protocol Number:	
Protocol Title:	
Principal Investigator:	
Sponsor:	
Phase:	

◯ New Application ◯ Revised ◯ Re-review Review

Reviewer: _____ Sent 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.
- ◯ **Device Feasibility (DEV):** Protocol designed to evaluate one or more interventions for the feasibility of the product or to test a prototype device and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.
- ◯ **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.
- ◯ **Pragmatic Clinical Trial**: A clinical trial that is designed to study a health intervention in a real-world setting that is similar or identical to the one in which the intervention will be implemented.
- ◯ **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**

Reviewer Decision:

◯ Approved
◯ Approved with stipulations
◯ Recommend for Full-Board
◯ Review Disapproved

Add Comments/Concerns

Reviewer Signature

Date

Appendix K: SRMC Expedited Change Reviewer Form

UFHealth CANCER CENTER

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

Change 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 Research Office.

Protocol Number:	
Protocol Title:	
Principal Investigator:	
Sponsor:	
Phase:	

Risk Level Assessment Assigned: N/A

Data Table 4 Study Type Assigned:

☐ **Change Review**

Reviewer: **Review Sent 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. Background/Scientific Rationale: Is there adequate justification for conducting the study based on results of prior studies and/or pilot data? Does the protocol address relevant scientific and/or clinical questions?

◯ **Acceptable** ◯ **Not Acceptable**

2. **Research Objectives and Study Design:** Are the objectives and endpoints of the protocol clearly defined? Do the objectives measure the impact of the proposed intervention? Does the proposed protocol design align with the protocol's objectives and scientific rationale? Is the proposed intervention described in sufficient detail to allow the protocol to reach the endpoints proposed? Is the schema accurate and easy to follow? If a treatment intervention, does the protocol describe therapy including the treatment doses/schedules, dose adjustments, duration of therapy and clear schema.

◯ Acceptable ◯ Not Acceptable

3. **Eligibility and Study Requirements:** Are the proposed eligibility criteria reasonable in light of the study objectives and proposed intervention/investigation? Are there any criteria that place an unnecessary restriction on enrollment?

◯ Acceptable ◯ Not Acceptable

4. **Intervention and Toxicity Management Information:** If therapy involves a drug or medical procedure, is there adequate information regarding dosing, administration, frequency and duration as applicable? Does the study describe special precautions or instructions for staff or subject regarding *the* intervention, delivery and toxicity mitigation/ management?

◯ Acceptable ◯ Not Acceptable ◯ Not Applicable

5. 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.

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

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

5.2. Does the study have an established independent Data and Safety Monitoring Board?:

- ◯ Yes - Go to Q6
- ◯ No – Local interventional IITs must be under the oversight of DISC or anequivalent DSMB. **For externally sponsored studies, DSMB oversight is *only* required for Phase III studies per the NIH.**

5.2.1 Specify the type of study

- ◯ UF sponsored IIT – Complete Section 5.3
- ◯ Non-UF sponsored Phase 0-II Study – Go to Q6
- ◯ Non-UF sponsored Phase III Study – Go to Q6. This study cannot be approved without an independent DSMB

5.3 Does the study have a Data and Safety Monitoring Plan that includes the following?:

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 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

6. **For interventional studies, has the DSG adequately evaluated the proposed impact on the catchment area? (e.g. women, minorities, disease burden, etc.)**

◯ Acceptable ◯ Not Acceptable ◯ Not Applicable

7. **Inclusion of Children, if applicable:**

◯ Acceptable ◯ Not Acceptable ◯ Not Applicable

If a primary Pediatric trial, what is the upper age of enrollment eligibility?

8. **If the changes in the protocol merit a change in the assigned study category please 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.

9. 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.
- ◯ **Device Feasibility (DEV):** Protocol designed to evaluate one or more interventions for the feasibility of the product or to test a prototype device and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.
- ◯ **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.
- ◯ **Pragmatic Clinical Trial:** A clinical trial that is designed to study a health intervention in a real-world setting that is similar or identical to the one in which the intervention will be implemented.
- ◯ **Other (OTH):** Not in other categories

10. Merit Score: Select one score below that represents the overall scientific impact of this trial (REQUIRED):

- ◯ 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

Required Scoring Assessment (Please summarize strengths and weaknesses to justify your scoring):

Reviewer Recommendation:

Scientific Merit:

- ◯ Approved
- ◯ Approved with Stipulations
- ◯ Disapproved
- ◯ Recommend Full-Committee Review

Reviewer Signature

Date

Appendix L: COE Reviewer Form

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

Community Outreach and Engagement Reviewer Form

Protocol Number:	
Protocol Title:	
Principal Investigator:	
Sponsor:	
Phase:	
COE Continuum:	Select

COE Reviewer: _____ **Review Sent Date:** _____

COE Rubric

- ☐ Does this trial have the potential to accrue minorities or underrepresented patients?
- ☐ Does this trial specifically target an underrepresented population?
- ☐ Does this protocol target patients with advanced-stage or metastatic disease?
- ☐ Does this protocol target tobacco or a tobacco-related cancer?
- ☐ Does this trial target a top 10 cancer?

Are there any potential recruitment barriers or COE resources that may assist with overall and diversity of subject participation? (See comments below)

Additional comments or concerns:

COE Reviewer Signature _____ **Date** _____

Appendix M: Feasibility Assessment Form

SRMC Feasibility Assessment Form

UF Health Cancer Center
P.O. Box 103633
Gainesville, FL 32610-6366
Protocol_Activation@cancer.ufl.edu

GENERAL INFORMATION: Review Type: Initial Review

OnCore #: | PI Name: | Sponsor: | Sponsor Protocol #:

Protocol Title:

Is this a UF IIT that involves FDA regulated drugs or devices? Yes ☐ No ☐

If yes, what is the FDA status? Please attach any supporting documentation.

If yes, does this study involve an IDE? Yes ☐ No ☐

If yes to the above, does this study require First Coast Medicare Coverage submission? Yes ☐ No ☐

Please confirm if Medicare Pre-Approval review is applicable/begun with UF Research Billing Office. ☐ Confirmed ☐ Not Started

https://ctsi-clinicalresearch-intranet-sop.sites.medinfo.ufl.edu/study-management/billing-plan/device-medicare-preapproval/ides/

PATIENT POPULATION:		COMMENTS
CY ☐ FY ☐	**How many patients with this diagnosis were seen at UF during the last CY or FY?** *Please attach a copy of the data source with this form.*	
Yes ☐ No ☐	**Will this study be opened at any additional sites?** *If yes:* • *Please list each site that this study may be activated at.* • *Also, Indicate if UF will be the coordinating site*	
ENROLLMENT:		**COMMENTS**
Yes ☐ No ☐	**Are target accrual goals reasonable compared to the number of patients with this diagnosis* seen at UF?** **note: this may refer to a variety of populations including healthy subjects if this is a population science study.*	
Yes ☐ No ☐	**Are there any anticipated barriers to enrollment?** (i.e. delayed enrollment due to eligibility requirements, progression, washout, prolonged screening, referrals or non-common ancillary services)	
Yes ☐ No ☐	**Are there any competing protocols that may affect feasibility?**	
Yes ☐ No ☐	**Are there any NCTN/ETCTN protocols that target the same patient population?** *If 'yes', please note the study number in the comments.*	

PROTOCOL DETAILS:	COMMENTS
Will this study include any of the following: ☐ None Applicable ☐ Is coordination with the CRC required? ☐ Is Clinical Safety Committee review applicable? ☐ Is coordination with UF Health inpatient units required? ☐ Does this study involve apheresis or cellular therapy? ☐ Does this study require the use of BioRepository staff or services? ☐ Does this study require the use of Blood Bank staff or services? ☐ Does the trial require biosafety review and approval (i.e., studies involving gene therapy, live vaccines, recombinant DNA, viruses, vectors, etc.)? ☐ Does this trial expose the patient to radiation (machine generated or otherwise) that they would not be exposed to if they were not participating in the research? Examples include but are not limited to: additional radiation from being exposed to this trial, research required MUGA, research required DEXA, research required X-Ray, or research required CT scan.	

COMPLIANCE/QUALITY ASSURANCE:		COMMENTS:
If this is an IIT study, please estimate the appropriate risk level below. *For more information, please reference the Risk Table found in the DSMP. Risk level to be confirmed by SRMC.* **Level 4 – Complex ☐ Level 3 – High Risk ☐ Level 2 – Moderate Risk ☐ Level 1 – Low Risk ☐ Multi-Center ☐ N/A ☐**		
Yes ☐ No ☐	Do study-specific policies or SOPs need to be created?	
Yes ☐ No ☐	Is this study being managed by a new PI or SC?	

Other general comments and/or concerns:

Recommendation:

☐ No Concerns

☐ Concerns

Signature

Date

Appendix N: Cellular Therapy and Apheresis Review Form

UFHealth CANCER CENTER

Cellular Therapy and Apheresis Review Form

Study ID # _____ OCR # _____

Principal Investigator _____

Study Title _____

1. Does this study require that patients have a known diagnosis (current or previous) or suspected diagnosis of cancer as part of the eligibility criteria?
   - ☐ Yes
   - ☐ No
   - ☐ Other; please specify _____

2. Type of immune effector cells product?
   - ☐ CAR T-cell
   - ☐ CAR NK cells
   - ☐ Dendritic cells
   - ☐ Therapeutic vaccine
   - ☐ Others; please specify _____

3. What is the projected number of subjects you plan to enroll at this site? _____

4. What is the projected enrollment period? In months _____

5. Source of immune effector cells?
   - ☐ Autologous
   - ☐ Allogeneic

Apheresis Unit and Stem Cell Laboratory

6. Will the trial be conducted using UF apheresis unit or stem cell laboratory resources?
   - ☐ Yes
   - ☐ No

7. Will the starting material (immune effector cells product) be collected at the UF clinical program's apheresis center/UF collection facilities?
   - ☐ Yes, go to question 8
   - ☐ No, a third-party provider will directly send the cellular therapy product. **Skip question 8 and 9**

8. Will mobilization (administration of Granulocyte colony-stimulating factor (G-CSF) or other agents) be required for collection of cellular products?
   - ☐ Yes, indicate the name of mobilizing agent _____
   - ☐ No

9. Is there a need for manipulations of the immune effector cell product in UF stem cell laboratory after collection?
   - ☐ Yes, please specify
   - ☐ No

10. Is there a need for thawing and other manipulations of the product by UF stem cell laboratory before administration to the recipient?
   - ☐ Yes, please specify
   - ☐ No

Clinical Unit Facility

11. Will this trial be conducted using Transplant and Cellular Therapy **inpatient resources** (administration of preparative regimen, administration of cellular therapy product, initial post administration care)?
   - ☐ Yes, please go to question 13
   - ☐ No

12. Please indicate the minimum required or expected number of hospitalization days?

13. Will this trial be conducted using Transplant and Cellular Therapy **outpatient resources** for **administration of preparative regimen** and/or cellular therapy product?
   - ☐ Yes
   - ☐ No

14. Will this trial be conducted using Transplant and Cellular Therapy **outpatient resources** for **follow up of subjects who received immune effector cells after discharge** from the hospital?
   - ☐ Yes
   - ☐ No

This portion to be completed by Cellular Therapy and Apheresis Group Representative.

Does the group have any comments or concerns?

Is this study feasible at our site?
- ☐ Yes
- ☐ No

Signature of Cellular Therapy and Apheresis Group Representative

Date

Cellular Therapy and Apheresis Form
OCR#

Appendix O: 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 P: 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
• UF Interventional Investigator Initiated Trial • Industry, External Academic or Foundation Interventional Trials (non-external peer-reviewed)	Full	Expedited
• National Clinical Trials Network Trials • External Peer-Reviewed Trials (NCI approved groups) • Prospective, Non-Interventional Studies	Expedited	Expedited
• 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 Q: Adjustments to SRMC Continuation Review Due to COVID-19

UF Health Cancer Center
Clinical Research Office
P.O. Box 103633
Gainesville, FL 32610-6366
trials@cancer.ufl.edu

MEMORANDUM

DATE: October 28, 2020

TO: Investigators and staff involved in cancer-relevant research

FROM: Alison M. Ivey, RN, MS, OCN, CCRP
Administrative Director
Clinical Research Office
UF Health Cancer Center
Digitally signed by Alison Ivey
Date: 2020.10.29 12:13:44 -04'00'

Thomas George, MD
Associate Director for Clinical Research
UF Health Cancer Center
Digitally signed by Thomas J. George, MD, FACP
Date: 2020.10.29 11:03:37 -04'00'

RE: Adjustments to Scientific Review and Monitoring Committee Continuation Review Due to COVID-19

The Scientific Review and Monitoring Committee (SRMC) approved of adjustments to SRMC continuation review due to the impact of COVID-19 on UFHCC trial enrollment.

These new adjustments are provided below and are effective March 1, 2020.

	Documents Required	Review Type	Possible Decisions
If annual accrual is **> 0** and **less than 33%** of the study's annual accrual goal	PAR Form CAP Form	Full	6-month probationary continuation 12-month continuation
If annual accrual is **greater than 33%** of the study's annual accrual goal	PAR Form	Expedited	12-month continuation

In addition, the SRMC's Zero Tolerance Policy will be modified to require mandatory study closure if there are zero enrollments in 12 months (previously this was 6 months) for all studies that have activated since January 1, 2020.

This policy will be re-reviewed on March 1, 2021.

UF Health Cancer Center
Clinical Research Office
P.O. Box 103633
Gainesville, FL 32610-6366
trials@cancer.ufl.edu

MEMORANDUM

DATE: February 11, 2021

FROM: Clinical Research Office, UF Health Cancer Center

RE: Adjustments to Scientific Review and Monitoring Committee (SRMC) Continuation Review Due to COVID-19 Pandemic

---

The Scientific Review and Monitoring Committee (SRMC) approved adjustments to the SRMC continuation review process for studies not reaching their 6-month accrual goals due to the impact of COVID-19 on UFHCC trial enrollment; this policy went into effect on 10/28/2020 as presented in the memo dated 10/28/2020.

This policy was re-reviewed at an ad hoc SRMC Executive Meeting on 02/11/2021. The committee determined that the SRMC COVID-19 adjustments will no longer be continued. As of 02/11/2021, the SRMC reverted back to their original continuation review policies as outlined within the SRMC manual.

Alison M. Ivey, RN, MS, OCN, CCRP
Administrative Director
Clinical Research Office
UF Health Cancer Center

Thomas George, MD
Associate Director for Clinical Research
UF Heath Cancer Center

Appendix R: 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.

Device Feasibility (DEV): Protocol designed to evaluate one or more interventions for the feasibility of the product or to test a prototype device and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.

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.

Pragmatic Clinical Trial: A clinical trial that is designed to study a health intervention in a real-world setting that is similar or identifical to the one in which the intervention will be implemented.

Other (OTH): Not in other categories