UFHCC Process for Investigator-Initiated Trial Review, Approval, Development and Activation

This document outlines the University of Florida Health Cancer Center's (UFHCC) policy for all investigator-initiated, cancer-relevant, clinical trials 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.

The University of Florida defines human subject "cancer relevant" research 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 or tobacco-associated studies, surveys, hepatitis or HPV vaccines, etc.), or
- The local PI plans to exclusively enroll current, former or potential cancer patients into the study.

Investigator-Initiated Trials (IITs) are institutional priorities and represent the combination of intellectual property and scientific output from our UFHCC translational science programs. These studies are proposed upon the initiative of clinical investigators and are without a company or industry partner assuming the role of the principal sponsor. They require rigorous scientific review, monitoring and resources to support their conduct. Those without funding suffer from limited resource allocation. Our intention is to support the successful completion of every IIT inclusive of peer-review for scientific rigor, a detailed budget with identification of appropriate funding sources and full compliance with the UFHCC oversight committees (i.e., SRMC and DISC). This will help the trial move efficiently through the activation pipeline and avoid failure due to inadequate study design or resources.

The aims of this comprehensive, 2-stage review are to 1) improve the feasibility, scientific merit and ultimate success in completing cancer-relevant IITs, 2) shorten the timeframe from concept approval to protocol activation and 3) maximize staff and investigator effort in protocol development. Importantly, UFHCC Project Management Office (PMO) resources will not be utilized to construct the full protocol or any study related regulatory submissions until the concept has received first stage review and approval and funding has been secured. **Protocols not having undergone first stage review and approval often suffer significant setbacks during the development and implementation phases of the study**. This 2-stage review process enables institutional concepts, without a full protocol, to be reviewed for scientific merit and allows constructive feedback prior to significant investment of time and resources. Concepts approved in this first stage, which have secured adequate support, are then sent forward for full protocol development.

This document outlines the process and party responsibilities associated with these important studies. **Figure 1** outlines the workflow for UFHCC IIT development.

Initial Concept Phase (First Stage Review & Approval)

All cancer-relevant IITs conducted at UF and categorized as "interventional treatment" (see **Appendix 1**) or otherwise involving investigational drugs, devices or medical procedures are eligible for review via IIT Concept Development Group (CDG). Additionally, all IITs that are going to utilize UFHCC CRO resources (PMO services, research coordinator or data entry support, regulatory management, financial, or other in-kind support) must receive concept approval through the CDG.

The above-mentioned CRO resources cannot be used for protocol development or project management until funding has been secured, with the exception of protocols where prior written approval has been submitted by UFHCC Leadership. Concepts not meeting these specifications are exempt from this otherwise mandatory pre-review.

The IIT CDG approval process involves documentation of provisional peer support through the respective Disease Site Group (DSG), valid statistical plan, scientific rigor, appropriate institutional budget development, and confirmation of appropriate staff resources for conduct. The UFHCC Associate Director for Clinical Investigation (ADCI) provides final approval for initial concept submission upon verification of the above pre-requisites. Qualifying concepts must receive approval from the CDG (and ultimately ADCI) prior to submission to external collaborators. With rare exception, UF IIT concepts are expected to be capable of conduct and completion within an 18-24 month period following study activation.

The UFHCC PMO serves as the clearing house for this initial phase of initial concept approval. It is recommended that the PI reach out to the PMO, via the 'CRO IIT Project Management Services Request' web form (accessible through the UFHCC website) at the initiation of a concept or letter of intent. PMO resources are assigned by the Director of the Clinical Research Office.

During this phase, the PI will be responsible for the following actions:

- Assurance that the concept has been preliminarily reviewed by the appropriate representatives from external collaborators
- Development of the initial concept/letter of intent, inclusive of the scientific justification and rationale
- Presentation of the concept to the appropriate peer group (DSG) to obtain feedback and ensure alignment with clinical algorithms and non-competing protocols
- Work with appropriate clinicians and clinical research staff to conduct a needs assessment (resources and personnel requirements) and confirm feasibility
- Determine study design and sample size in conjunction with a statistician (UFHCC statistical support will be provided for validation if not used for primary development)
- Determine co-investigators and key protocol personnel
- Work with PMO staff in developing initial concept draft budget and identification of all potential and/or actual funding sources for study completion

The UFHCC PMO can perform the following services:

- Facilitation of initial concept review by all applicable parties, including the DSG, Biostatisticians, Director of the CRO and the ADCI or their designee
- Soliciting and incorporating feedback from the study team and CDG into proposed concepts
- Development of study budgets
- Preparation of the concept and support documentation for submission to the potential collaborators
- Triaging and archiving of all communications with external collaborators

All concepts submitted in this manner will be vetted for completeness by PMO staff, who will provide feedback on next steps needed. During the concept development phase, PIs should be aware that adequate financial support is necessary to cover minimal pre-defined expenses related to the conduct of the proposed study. Investigators must develop a detailed budget with funding sources identified as

part of the letter of intent or initial concept development. The PMO will provide a draft budget template based on the initial concept design. Funding sources can include any combination of internal, external and industry support. PIs will identify all potential and/or actual funding sources when submitting new concepts to the PMO.

PIs should seek to manage trial costs by evaluating, for example:

- Have the use of standard of care testing and scheduling been optimized?
- Can fewer patients be accrued?
- Can fewer scans be scheduled?
- Can the spacing of testing be adjusted?
- Can correlatives be adjusted?
- Can PI costs be waived? (Requires departmental approval)
- Can the number of sites be minimized?
- Are there other costs that can be avoided, waived or re-negotiated?

PIs are responsible for addressing budget shortfalls and should actively seek support from one or more of the following sources:

- Industry (drug, funds, etc.);
- Federal or extramural (e.g., NIH/NCI R21, Florida Biomedical Research, FACCA);
- PI start-up or discretionary funds;
- College/Department/Division (e.g., academic enrichment);
- UFHCC Research Program(s), Pilot Program or other intramural RFA;
- Philanthropy/Development

NOTE: Support requested from any of the intramural UFHCC Research Programs and most extramural sources require written applications and peer-review. Please allow time for this process.

For all non-UFHCC managed studies, estimates for any requested services (PMO, coordination, etc.) will be provided by the Director of the CRO as part of draft budget development. Please note, PMO services rendered during the first stage of initial concept development are available free of charge to eligible Cancer Center Members.

IIT Concept Development Group (CDG) Membership

The group convenes in a virtual manner upon receipt of a concept by a PI with written endorsement by the sponsoring DSG. The membership represents signatories over the specific aspects of pre-review as listed below:

- Scientific review of preclinical data and study design (Carmen Allegra – Chair)
- Financial review of budget (Director of CRO)
- Biostatistical review (UFHCC Quantitative Science Core)
- Feasibility (PMO Manager)
- Final determination of approval (ADCI)
- Additional members/senior content experts at the discretion of the chair

All components of pre-review must be deemed acceptable in order to support final approval, unless otherwise determined by the ADCI. Upon final approval by the IIT CDG, the group will also provide a prioritization score to support UFHCC resource allocation, development and activation of a protocol undergoing this pre-review. Prioritization score takes into consideration translation of UF basic-scientific discoveries, impact of study on UFHCC catchment area, UFHCC membership collaboration and clinical

impact. The IIT CDG will have the authority to recommend provision of intramural resources, when available, to support the highest quality IIT concepts. The final approval document with prioritization score will be provided to the PI and associated DSG leader for submission to SRMC at the time of final protocol submission.

Protocol Development (Second Stage Review & Approval)

For qualifying concepts that have achieved first stage IIT CDG approval, PMO resources will be available to support protocol development and activation.

The UFHCC PMO can perform the following services:

- Protocol authoring, including revisions and protocol clarification memos (allow 15 business days from the original request for the initial working protocol draft)
- Informed Consent Form authoring (allow 5 business days from the release of the initial protocol draft for initial consent form draft)
- Triaging and archiving of all communications with external collaborators
- Initial and ongoing submission of IND/IDE documents to the FDA
- Assistance with study submission to the Feasibility Group, DSG, SRMC, and IRB
- Assistance with CRF design
- Protocol entry into ClinicalTrials.gov and other central trial clearinghouses
- Facilitation of study sub-site identification and assessment of qualification
- Budget finalization based upon protocol specifications
- Facilitation of agreement submissions and compliance documents
- Coordinating study drug shipment to site and sub-site(s)
- Conduction of site initiation visit (SIV)

During the second-stage review process, PIs must be personally engaged in the drafting of the protocol document. PIs will furnish the PMO with a full scientific background, basic eligibility parameters, description of the intervention, basic schedule of events and planned adjustments to the intervention if applicable. The PI must be responsive to all PMO requests for information with the expectation that all queries will be addressed within two business days. The PI's responsibilities during the full protocol development process also include:

- Meet with PMO as requested to review protocol details
- Evaluation of the draft protocol to confirm that it contains adequate descriptions of the research and content required by the UFHCC and applicable regulations
- Submission of the final draft protocol to the DSG for further evaluation of scientific merit, ensure alignment with group priorities and needs, and resource allocation
- Presentation of the study to SRMC to include key points addressing study rationale, design, selected endpoints, and potential scientific impact
- Attend calls or meeting with the FDA if requested
- Ensuring collaborating site selection is approved by the Feasibility Group, SRMC, DISC, and IRB prior to site initiation
- Be involved in the design, review and sign off for data collection forms
- Attend any IRB meetings where the study will be discussed

IIT protocols not requiring CDG review may proceed directly to SRMC after DSG endorsement (see SRMC Manual). For CDG approved concepts, the SRMC application must be accompanied by the CDG/ADCI approval. **SRMC review is significantly expedited by the first stage review**.

Final protocol refinement and ultimate consideration of approval, human subject protection and risk assignment for monitoring will be provided by the UFHCC SRMC and UF IRB. No clinical trial may proceed with activation at UF without both SRMC and IRB approvals.

Protocol Activation and Management

UFHCC PMO protocol activation and management resources are prioritized based upon the IIT CDG approval prioritization score for the highest priority IIT studies. For IITs conducted at UF (with or without additional affiliate sites), the study team including the PI must prepare and conduct training for team members, clinic staff and associated personnel. For studies that will use UFHCC resources, the PMO will conduct a site initiation visit that will serve as training for the PI, other study staff, clinic staff, and associated personnel. In addition, the PMO can continue to assist with all of the activities outlines in the "Protocol Development" section, along with maintenance and reporting for ClinicalTrials.gov and general data review and export. The PMO does not perform routine data verification (i.e. comparison of data against source documentation) however, the UFHCC does have clinical research monitoring resources available.

Following protocol activation, PI responsibilities include:

- Oversight of all aspects of study conduct, especially ensuring that study staff are appropriately trained to perform all responsibilities delegated to them
- Ensuring that the study is conducted according to all applicable regulations, that research follows the protocol, and that all rights and welfare of subjects are maintained
- Maintenance of data and CRFs in accordance with IRB guidelines and federal regulations
- Assurance that all investigational product records are maintained, including records of drug receipts, shipments, dispensing and destruction or return
- Timely reporting of serious adverse events to UF IRB, as well as the FDA and industry partners (if applicable), as specified by the protocol
- Review of the study to validate data and to maintain safety of enrolled subjects
- Adherence to the proscribed DISC monitoring plan

The investigator may delegate any of these responsibilities to appropriately trained study personnel. However, the investigator must retain knowledge of and overall authority for the conduct of all aspects of the study. The investigator will personally supervise study staff who are qualified by their education and training to accept these responsibilities for study-related activities.

Following protocol activation, the UFHCC PMO can perform the following services:

- Protocol amendments, including revisions and protocol clarification memos
- Informed consent form revisions
- Continued triaging and archiving of all communications with external collaborators
- Distribution of related external unexpected serious adverse reaction (SUSAR) reports
- Ongoing submission of IND/IDE documents to the FDA, including protocol amendments and annual reviews
- Maintain protocol records within ClinicalTrials.gov and other central trial clearinghouses
- Facilitation of study sub-site identification and assessment of qualification

Protocol Resulting and Completion

For IITs conducted at UF (with or without additional affiliate sites), the PI is responsible for approving the authorship of any presentations, publications or abstracts associated with the study. These presentations must adhere to the reporting requirements, if any, that were established with any collaborating industry or private/public partners including reporting timelines and submission for review and feedback prior to submission/presentation. The PI is responsible for assurance that all co-I or collaborating investigators have met requirements for authorship and that conflicts of interest have been accurately disclosed. In general, IITs should support authorship inclusion of all collaborating team members, particularly from intra or inter-programmatic UFHCC Programs. For all UF IITs, primary study outcomes must be reported within 12 months of study completion or as required per contractual obligations.

Additionally, for those IITs that undergo CDG pre-review, PI must adhere to the UFHCC Publication Policy (Appendix 3).

Specific Personnel Responsibilities

The following sections outline the responsibilities of each party involved in the IIT protocol development process (see **Figure 1**).

Principal Investigator (PI)

- Fully responsible for general trial conduct, including timely and accurate communications with all collaborating partners, regulatory agencies and study-associated staff. While the UFHCC will support PIs with the workload as outlined during the protocol lifecycle in the specific sections above, the PI is ultimately responsible for trial oversight and management, which cannot be delegated.
- Responsible for all subjects and data enrolled on trial (i.e., ultimate study oversight). To that end, PI must have demonstrated full compliance with responsibilities in PI role for non-IITs at UF prior to serving as an IIT PI at UF. In the absence of such demonstrated experience, co-PI responsibilities with a more experienced mentor may be required (as determined by the UFHCC ADCI).
  All UFHCC IITs incorporating any FDA regulated intervention must be reviewed to determine the need for an IND or IDE application, even if planning for exemption, as part of protocol development (see **Appendix 2**).
- The PI must complete all UFHCC PI training, including IIT-specific requirements established by the UFHCC
- Comply with all other requirements as outlined in this document and those related to the SRMC and DISC.
- Personally represent study when reviewed or discussed at SRMC, DISC and IRB. Delegation to a sub-I due to schedule conflicts should be minimized. Delegation to study staff is prohibited.

When PMO resources are in use, the PI must ensure:

- The PMO must be copied on, or initiate, all communications pertaining to study
- The PMO will retain version control of all essential study documents

- PIs must make available any pertinent documents which may aid in the development process; e.g., investigator's brochure, sponsor consent form templates, etc.
- PIs may not modify and/or distribute study documents without PMO review and approval
- PIs must respond to routine PMO queries in a timely fashion (within two business days)
- PIs must meet with the PMO quarterly to review study progress for trials that will be managed by the PMO throughout their life cycle

Disease Site Group (DSG) Review

The DSG Research Leader will ensure that IITs at a minimum:

- Are scientifically sound;
- Align with the clinical program and have adequate patient population to support the successful completion of the trial in the specified time;
- Has no competing studies within the DSG or UFHCC research portfolio without reasonable justification;
- Support UFHCC objectives, including prioritization of trial type, programmatic development, meeting needs of our community and national reputation building;
- Have a detailed budget with all funding sources identified to support feasibility.

Associate Director for Clinical Investigation

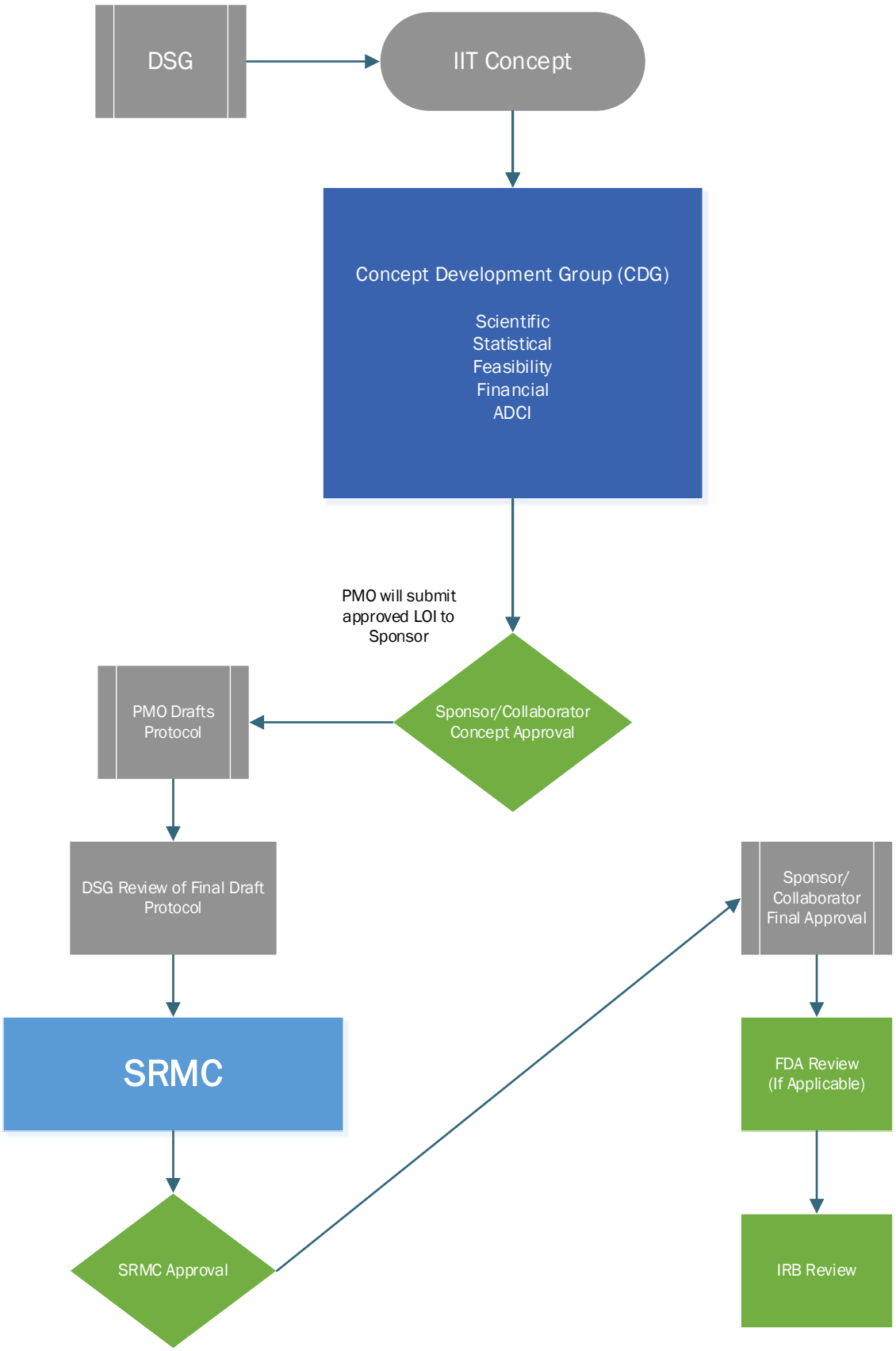
The ADCI will be involved in review of the study concept through the IIT CDG. The ADCI, in consultation with the CDG Chair, may involve other experienced investigators in the review process to ensure study design is optimal and successful. If there are any concerns, the ADCI will communicate with the PI, copying the appropriate DSG Leaders, the UFHCC Deputy Director, the CDG Chair, the UFHCC Associate Director for Administration, and the Director of the Clinical Research Office. Appropriate steps will be taken to resolve any issues that arise.

NOTE: Funding availability must be confirmed prior to SRMC review, and **must be received or contracts pertaining to funding must be fully executed prior to protocol activation**.

To successfully move IITs forward at UF, it is the responsibility of the DSG (Research) Leader and the ADCI to evaluate the trial based on the following:

- Scientific merit.
- Feasibility: Accrual potential (target goal reflective of target population).
- Does the trial fill a need/niche within the DSG's portfolio?
- Does the trial bring synergy with other ongoing clinical/translational research?
- What is the likelihood of generating subsequent extramural funding?
- Does it align with UFHCC's priorities/research strategic plan?
- What importance does it bring to the PIs career?
- Does it involve a compound or translate a laboratory finding developed at UF?
- What impact will it have on the UFHCC national reputation and media presence?

Figure 1. Workflow of UFHCC Investigator Initiated Trial Development



Appendix 1: Clinical Research Definitions

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

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

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

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

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

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

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

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

Other (OTH): Not in other categories

Appendix 2: IND/IDE Basic Determination

IND Basic Determination		
1. Is the drug/biologic product lawfully marketed in the US?	YES	**NO**
2. Is there any intent to report the findings of your investigation to the FDA as a well-controlled study in support of a new indication or any other significant change in the labeling of the drug?	**YES**	NO
3. Is the study intended to support a significant change in the advertising of the drug?	**YES**	NO
4. Will the investigation involve a change in any of the following factors:		
a. Dosage level (either raising or lowering dose, frequency or duration compared to approved label)	**YES**	NO
b. Patient population	**YES**	NO
c. Any other factor that significantly increases (or decreases the acceptability of the risk) risk associated with the use of the drug product (21 CFR 312.2(b) (1)(iii)).	**YES**	NO
5. Is the Investigation intended to promote or commercialize the drug product (21 CFR part 312.7)?	**YES**	NO
If you selected any bolded responses, an IND application will be required		

IDE Basic Determination		
1. Will the study investigate a device that is the subject of a cleared 510(k) (ref §812(c)(1))?	YES	**NO**
2. Will the device be used in the study in accordance with the FDA-cleared indications for the device (ref. §812(c)(1))?	YES	**NO**
3. Is the test device invasive (ref. §812.2(c)(3)(i))?	**YES**	NO
4. Does the test device require an invasive sampling procedure that presents a significant risk (ref. §812.2(c)(3)(ii)?	**YES**	NO
5. Does the test device, by design or intention, introduce energy into a subject (ref. §812.(c)(3)(iii)):	**YES**	NO
6. Will the study only investigate consumer preferences with respect to the device?	YES	**NO**
7. Will the study test a modification of an approved or cleared device?	YES	**NO**
8. Is the device an implant (a device placed into a surgically or naturally formed cavity of the human body, and intended to remain there for a period of 30 days or more) (ref. §812.3(d)) that presents a potential for serious risk to the health, safety, or welfare of the subject (ref. §812(m)(1))?	**YES**	NO
9. Is the device purported or represented to be for use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject (ref. §812.3(m)(2))?	**YES**	NO
10. Is the device for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject (ref. §812.3(m)(3))?	**YES**	NO
11. Does your device present a potential for serious risk to the health, safety, or welfare of a subject in a way other than those described in Questions 8-10 (ref 21 CFR 812.3(m)(4))?	**YES**	NO
If you selected any bolded responses, an IND application will be required		

Appendix 3: UFHCC Publication Policy

I. Publication Policy Overview

This document describes the policy that governs scientific dissemination of research findings that were supported by the UFHCC Project Management Office (PMO). These policies apply to any faculty serving as Principal Investigator (PI) of clinical research with regards to abstracts, publications or presentations. It is the responsibility of the PI who utilizes UFHCC PMO services to comply with these policies as they related to dissemination of the study's primary endpoint. Failure to comply constitutes a breach of the agreement set forth at the onset of PMO service use and may result in discontinuation of PMO services or denied access in the future to such services or similar resources.

II. Responsibilities of Study Team Members

The protocol PI is responsible for preparing presentations/publications disseminating the results of the primary endpoint analysis according to the Timelines in Section III. The PI is generally the first author of the primary endpoint publications.

A. First Author: The first author, who may also be the protocol PI, is responsible for:

1. Guaranteeing the integrity of the work
2. Adhering to the this UFHCC Publications Policy
3. Working with the protocol/project team, which may include the UFHCC Quantitative Science Core and PMO staff, to develop the initial draft of the abstract/manuscript
4. Insuring that all co-authors have had the opportunity to review and provide feedback for all publications and presentations
5. Submitting and completing abstracts and manuscripts in a timely manner
6. Complete required conflict of interest disclosures
7. Communicating the status of the submission to the PMO including providing final copies

B. Co-author(s): The co-authors must review and approve abstracts, presentations, and manuscripts in a timely manner and complete required conflict of interest disclosures in order to maintain co-authorship.

C. UFHCC Quantitative Science Core (QSC): The QSC will work collaboratively with the protocol PI and other investigators to provide data quality and data analyses of study endpoints and approved ancillary projects.

III. Timelines

The submission of all abstracts, manuscripts, and presentations that utilize UFHCC PMO-supported data or resources will follow these timelines. The PMO will work with the responsible PI and biostatistician to develop a publication timetable for each study/project analysis. The timetable will be conveyed in writing to the first author, DSG research leader, assigned biostatistician and ADCI at the time of final patient enrollment.

A. Primary Endpoint Reporting - It is expected that preliminary results of the primary endpoints of these studies will be presented at scientific meetings within six to nine months of completion of the study analysis (if not sooner, based on the relevance of the results) and that a full draft manuscript of the study results will be prepared in parallel and submitted for publication in the peer-reviewed literature (not as an abstract) within one year of the availability of the primary study results based on the completion date of the study recorded in the U.S. National Library of Medicine database, clinicaltrials.gov.

B. External & Corporate Collaborators Review: All abstracts, manuscripts and presentations reporting the results of trials that involve external partners must be submitted in compliance with contractual obligations. This includes, but is not limited to, NCI for agent(s) supplied under CTEP Collaborative Agreements (e.g., CRADA, CTA, or CSA) and industry partners for potential comments. The UFHCC PMO is responsible for submitting all study results to external collaborators, including:

1. *Abstracts* – The first author and responsible statistician must submit an abstract to the UFHCC PMO two (2) weeks before the society/conference submission deadline. The UFHCC PMO will submit the approved abstract to the NCI (if relevant) at least three days prior to the submission deadline. In addition to the NCI, pharmaceutical/biotechnology collaborator(s) will have courtesy review of any abstracts as soon as possible (preferably at least three days prior to submission), but in any case, prior to presentation or publication.
2. *Manuscripts* – In at least 30 days in advance of submission for publication. An additional 30 days may be requested in order to ensure that confidential and proprietary data, in addition to the intellectual property rights of the collaborator(s), are protected. Manuscripts will not be submitted to a journal without this review.
3. *Presentations* – The first author must submit their presentation to the UFHCC PMO at least two weeks prior to the presentation date. After check of authorship line and appropriate acknowledgements, the UFHCC PMO will submit presentations to NCI or other external collaborators at least one week prior to presentation or publication.

IV. Publications Guidelines

A. General Considerations

The UFHCC should be clearly cited within the manuscript and all federal grant numbers should be cited on the manuscript cover page, along with the Clinical Trials (https://clinicaltrials.gov/) registration number for the trial. Additionally, all abstracts, publications

and presentations resulting from work that originated with the support of the UFHCC PMO must acknowledge the following: **"This research was supported by the University of Florida Health Cancer Center."**

1. The UFHCC PMO will prepare a written timeline and submission checklist for each publication in consultation with the first author and the responsible biostatistician and will be updated by the PI as the publication develops.
2. The selection of the appropriate journal for submission will be determined by agreement of the first author, in consultation with the co-authors.
3. Co-authors will review and comment on the abstract, publication, and presentation prior to submission to a conference or to a journal for publication. Co-author reviews of manuscripts are due within two weeks of receipt.
4. The UFHCC PMO will be the clearing house for all UFHCC manuscripts submitted to a journal for publication, as well as all abstracts related to the primary endpoint of the study.

B. Author Line Determinations

UFHCC leadership believes strongly that inclusive authorship opportunities demonstrate collaboration inherent in team-based science. However, authorship on UFHCC PMO supported studies is restricted to investigators who significantly contribute to the scientific development of the study/project, the data analysis, and abstract/manuscript writing and review, as well as those who provide scientific data (patient accrual, clinical data, and biological material submission). All authors must contribute to the development, writing of the manuscript, and review of the publication.

The UFHCC PMO Manager, in conjunction with the Director of Quantitative Science, determines and approves the authorship line in close collaboration with the first author, statistician and in discussion with the co-authors based on the requirements below. Written appeals will be adjudicated by the UFHCC ADCI.

1. General Considerations

a) The total number of authors is subject to meeting/journal policies.
b) The UFHCC PMO-approved authorship line is final and must be used for submission.
c) Any authorship position, including the first author, can be reassigned by the ADCI if the original author does not complete his/her responsibilities according to the agreed upon timeline.
d) Authorship for an individual is granted only for the per-protocol endpoints or specific ancillary analysis in which they are involved. No author is granted authorship in perpetuity for work beyond that stated above.
e) The policy used to establish authorship listing for the study primary endpoint is intended to be used as a guideline for secondary endpoint publications and other ancillary analyses, recognizing that the key authorship positions will reflect the contributions of all study team members involved.
f) In general, staff that supported conduct of the trial, but who were not otherwise involved in concept scientific development or analyses, are not included as authors. Individual cases must be approved by the UFHCC PMO manager prior to inclusion in the authorship line.

2. Authorship Determination and Order

a) First Author
   - The protocol principal investigator/study chair (PI) is expected to be the first author on the initial reporting of the primary endpoint. The study PI may delegate this authorship to the identified Junior Faculty Co-I, as identified on the protocol face sheet. In such situation, the PI is expected to assume the senior author position.
   - It is recommended for secondary endpoints resulting publications, the first author will be the appropriate study sub-investigator responsible for that aspect of data analysis (i.e., translational co-I)

b) Second Author
   - *Biostatistician* - The primary study statistician will be listed as second author on protocol specified analyses, including the primary endpoint. When appropriate, additional statisticians may be included for authorship, particularly when involved in concept development, data monitoring and generation of analysis.

c) Third Author and Beyond
   - *Other Sub-Investigators* – Other faculty or staff who appropriately contributed to the publication may be listed as coauthors. The sequence of authorship for contributing sub-investigators is at the discretion of the PI, with final approval (as outlined in Section IV.B) by the UFHCC PMO. If a contributing author leaves the UFHCC, he/she maintains authorship rights provided that he/she continues to fulfill his/her study responsibilities. Inclusion of deceased authors will follow authorship guidelines for the particular journal to which an article is submitted.
   - *Accrual Authors* - An effort will be made to maximize the number of investigators offered authorship due to accrual contributions. Data related to identifying the faculty who contributed as accrual qualifying authors will be provided to the PI by the UFHCC Clinical Research Office. Authorship based on accrual will be granted to individuals which enrolled the largest number of patients to a study. All authors listed on the manuscript should have contributed significantly to the design or its implementation including data acquisition, accrual, or analysis and interpretation. All authors must have been involved in the writing/editing of the manuscript at draft stages, and have read and approved the final version.

d) Senior Author
e) The Disease Site Group (DSG) Research Leader at the time of study activation holds the right to senior authorship, subject to fulfilling his/her responsibility to have major scientific participation in the development, conduct, completion

and analysis of the study. If a study has a designated Junior-Co-I identified on the protocol face sheet and that individual is delegated by the PI to the lead author position, the DSG Research Leader will assume the Third Author position.

V. Publication Process

A. Abstracts

1. Any abstract related to the study's primary endpoint must conform to this policy document.
2. It is the responsibility of the first author/PI and the assigned statistician to notify the UFHCC PMO when abstract preparation begins so that resources can be appropriately allocated.
3. The UFHCC PMO will provide the first author/PI a check list of necessary elements required as part of abstract approval and submission.
4. The first author drafts the abstract and sends it to the statistician. The first author and statistician work together with any other key co-authors to finalize the abstract draft in preparation for co-author review.
5. It is the responsibility of the first author/PI to send the final draft to the UFHCC PMO for the review/approval of authorship order. Submission by the first author/PI to the UFHCC PMO must be in compliance with the timelines required in Section III.
6. The UFHCC PMO will distribute the final draft abstract to all co-authors and external collaborators, collecting any COI forms or confidentiality agreements required per the abstract sponsoring organization. Communication with external collaborators, based upon contractual obligations, is the responsibility of the UFHCC PMO.
7. The first author/ PI is responsible for collating and approving any edits or comments made by the co-authors into the final document version.
8. The first author/PI and PMO staff will work together to obtain signed COI author forms or other required elements of the submission process. Any co-authors failing to meet submission deadlines will be administratively removed from the abstract authorship list.
9. The UFHCC PMO will submit the final abstract and provide the first author/PI a copy of the submission. The first author/PI is responsible for notifying the co-authors, including providing final versions of submitted documents and providing abstract status updates.
10. The UFHCC PMO will notify the first author/PI of any abstract review decisions. Likewise, the first author/PI is responsible for notifying the PMO if they receive notice of an abstract decision.

B. Manuscripts

1. Any manuscript related to the study's primary endpoint must conform to this policy document.
2. It is the responsibility of the first author/PI and the assigned statistician to notify the UFHCC PMO when manuscript preparation begins and what target journal is proposed so that resources can be appropriately allocated.
3. The UFHCC PMO will provide the first author/PI a check list of necessary elements required as part of manuscript approval and submission.
4. The first author drafts the manuscript in conjunction with the statistician and other key co-authors to finalize the manuscript draft where it is complete enough to be reviewed by the co-authors for scientific accuracy.
5. It is the responsibility of the first author/PI to send the final manuscript draft to the UFHCC PMO for the review/approval of authorship order. Submission by the first author/PI to the UFHCC PMO must be in compliance with the timelines required in Section III.
6. The UFHCC PMO will distribute the final draft manuscript to all co-authors and external collaborators, collecting any COI forms or confidentiality agreements required per the abstract sponsoring organization. Communication with external collaborators, based upon contractual obligations, is the responsibility of the UFHCC PMO.
7. The first author/ PI is responsible for collating and approving any edits or comments made by the co-authors into the final document version.
8. All co-authors will have fourteen (14) days to return their comments, required documents or other needs. The first author/PI and PMO staff will work together to obtain signed COI author forms or other required elements of the submission process. Any co-authors failing to meet deadlines of submission will be administratively removed from the authorship list.
9. The near final manuscript will be returned by the first author/PI and biostatistician to the UFHCC PMO with a minimum of 2-week timeline for any final edits needed prior to submission to the target journal.
10. The UFHCC PMO will submit the final manuscript and provide the first author/PI a copy of the submission. The first author/PI is responsible for notifying the co-authors, including providing final versions of submitted documents and providing status updates. NOTE: UFHCC dose not support publication of manuscripts in what has been termed "predatory journals." Predatory journals are open-access journals that use exploitative practices including charging fees for publication and low or no quality control (peer-review). Acceptable target journals must be indexed by PubMed. https://www.ncbi.nlm.nih.gov/pubmed/advanced. If the target journal for publication is not listed in PubMed please contact UFHCC PMO for approval PRIOR to starting the submission process.
11. The UFHCC PMO will notify the first author/PI of any review decisions. Likewise, the first author/PI is responsible for notifying the PMO if they receive notice of a decision.
12. Addressing any journal reviewer comments are the responsibility of the first author/PI. Resubmission of a revised manuscript addressing reviewer comments or submission to a different journal must occur within thirty (30) days of receipt of first submission response. This process and timeline is to be repeated until the manuscript is ultimately accepted.

C. Presentations

1. Any formal presentation related to the study's primary endpoint must conform to this policy document.
2. It is the responsibility of the first author/PI and the assigned statistician to notify the UFHCC PMO when presentation preparation begins so that resources can be appropriately allocated.
3. The UFHCC PMO will provide the first author/PI a check list of necessary elements required as part of presentation approval.
4. The first author/PI and statistician work together with any other key co-authors to draft the presentation based upon prior abstract development.
5. It is the responsibility of the first author/PI to conform the presentation to the authorship order approved by the UFHCC PMO for the accompanying abstract.
6. Communication with external collaborators, based upon contractual obligations, is the responsibility of the UFHCC PMO related to presentations of abstract material.
7. Feedback on the presentation by abstract co-authors may occur via written, verbal or mock presentation formats.
8. The first author/ PI is responsible for collating and approving any edits or comments made by the co-authors into the final presentation version.
9. The presenting author is responsible for submitting the final presentation slides to the UFHCC PMO in accordance with the timelines required in Section III. The UFHCC PMO will ensure the presentation content conforms with the abstract data, authorship listing and grant acknowledgement.
10. The UFHCC PMO will distribute the presentation for review to appropriate external collaborators or entities providing study support, to comply with grant or contractual requirements.
11. The UFHCC PMO will provide the presenting author/PI with written approval to proceed with presentation submission.
12. The presenting author is responsible for submitting the final approved presentation slides to the appropriate sponsoring venue consistent with their requirements.