University of Florida Health Cancer Center

Feasibility Group Charter

Version 2.0
Dated November 8, 2018

University of Florida Health Cancer Center
Clinical Research Office

Introduction:

The UF Health Cancer Center (UFHCC) Clinical Research Office (CRO) is committed to managing and conducting clinical trials that are feasible, scientifically meritorious and ethically sound. Much of a protocol's success is contingent upon performance of a thorough feasibility assessment during the early stages of development or activation. Protocols that do not fit our catchment area and patient population may suffer from a lack of accrual. In addition, protocols that require additional resources (personnel, financial, material) beyond what is customary may also encounter operational barriers.

The goal of the Feasibility Group (FG) is to provide investigator and research team decision support to ensure adequate assessments of institutional and clinical resources take place as part of protocol development. Such stakeholders include, but are not limited to, the Principal Investigators (PIs), Disease Site Group (DSG), and Research Program (RP) leaders. These reviews will be performed in the context of the requirements of good clinical practice (GCP), local Standard Operating Procedures (SOPs), UF Health Policies and Procedures and alignment with the applicable regulations. Recommendations of the FG will be communicated to the DSG research leader, PI and recorded in OnCore for all CRO-managed interventional clinical trials. The FG may also be consulted for any cancer-relevant interventional clinical trial regardless of management group, including those trials that are not meeting the minimum annual accrual targets as determined by the Scientific Review and Monitoring Committee (SRMC).

Any CRO-managed interventional clinical trial being put forth for scientific review to the UFHCC SRMC will require FG review prior to being scheduled on the SRMC agenda. In this way, studies that are not capable of meeting minimal feasibility requirements or accounting for additional resource needs will be identified and disclosed to the respective DSG and PI prior to scientific review. This document describes the steps for fulfilling the regulatory, staffing and financial requirements for assessing the feasibility of implementing a protocol or approving protocol amendments.

Scope:

This document applies to the activities involved in assessing protocols and amendments for interventional clinical trials conducted through the UFHCC CRO, otherwise using UFHCC CRO resources, not meeting accrual targets, or upon PI request.

Responsibility:

It is the responsibility of the research Directors and Managers within the CRO to adhere to the feasibility review process guidelines set forth in this document. Staff who are directly responsible for protocol development and activation processes are also directly responsible for upholding these processes.

Membership:

The FG includes diverse representatives from UFHCC administration, clinical research divisions within the CRO, and key experts from ancillary departments within UF and Shands. All group members play a critical role in providing expertise in key clinical, research and administrative areas. Their collective input is vital to ensuring that the resources needed to conduct the proposed trials are adequately anticipated.

Voting members are responsible for making recommendations on the final feasibility of the proposed trials after input and discussion from FG membership.

Voting Feasibility Group Members

- Administrative Director, CRO
- Assistant Director, Study Coordination and Data Management, CRO
- Assistant Director, Clinical Research Administration and Compliance, CRO
- Assistant Director, Project Management and Regulatory Affairs, CRO

Additional Non-Voting Feasibility Group Members

- Associate Director of Clinical Investigation, UFHCC
- Associate Director for Medical Affairs, UFHCC
- Associate Director for Administration, UFHCC
- Assistant Director, Pediatric Clinical Research
- CRO Unit Managers
- Protocol Activation Coordinators
- UF Health Tumor Registrar
- Investigational Drug Service (ad hoc)
- Other representatives from UFHCC research divisions (ad hoc)
- Ambulatory Clinic or Hospital Unit or other area Managers (ad hoc)
- Stem Cell Lab (ad hoc)
- Radiology (ad hoc)
- Pathology (ad hoc)

Meetings:

The FG meets twice per month for routine study reviews and on an ad hoc basis as necessary. Meetings are generally set for the first and third Tuesdays of the month. Either recommendation or an abstained stance by all voting members is required for a study recommendation to be provided to the PI and sponsoring DSG. If voting members are unable to be present at a convened meeting, they may complete their portion of the review virtually prior to or immediately following the meeting. When quorum is not met, the ADCI, or if there is a conflict of interest, the UFHCC Director, may act as group delegates. Quorum is defined by a majority of the voting members (50% + 1 = 3). Protocol feasibility assessment recommendations (as detailed below) will be prepared prior to and reviewed at the meeting. Minutes of attendance, discussion, recommendations and actions will be recorded.

Trials Qualifying for Feasibility Group:

In accordance with the definition adopted by the National Cancer Institute (NCI), a clinical trial is "a prospective study involving human subjects designed to answer specific questions about the effects or impact of a particular biomedical or behavioral interventions; these may include drugs, treatments, devices, or behavioral or nutritional strategies." Trial participants may include cancer patients or persons without cancer. Studies that include nutritional, behavioral, and psychosocial interventions are considered to be clinical trials. Studies evaluating diagnostics (imaging, etc.) in which findings alter the patient's clinical care are also considered to be clinical trials. Observational studies, epidemiologic

studies, studies of diagnostics that do not affect patient care, and studies that do not test interventions are not considered to be clinical trials and are not subject to feasibility review.

For clinical trials, "interventional" trials are of particular need of feasibility assessment. The NCI defines an "interventional" clinical trial as one in which "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."

Thus, any trial meeting the above NCI definition of an interventional clinical trial and is utilizing UFHCC CRO-management (or any other study upon consultative request) is subject to feasibility review prior to proceeding to SRMC and IRB review.

Submission Process:

Prior to protocol submission to the FG, the PI must determine the target accrual metrics, prioritization score, and the need for CRO resources. In addition, all protocols must be entered into OnCore. Once complete, the Protocol Activation Coordinator (PAC) will add the study to the agenda for the following meeting. The submission deadline is at noon one week prior to the next scheduled meeting.

Initial Submission

The PI or designee provides all necessary study documents to the PAC via email. The documents must include:

- Complete study protocol with all appendices or investigational plan
- SRMC Pre-Review approval confirmation (CRO-managed interventional investigator-initiated trials (IITs) only)
- Draft study budget
- Any other relevant study documentation

Submission of Amendments/Revisions

At the request of SRMC, the FG may provide a feasibility review of protocol amendments or revisions that are felt to impact budget, enrollment or institutional resource utilization.

Submission of Low Enrolling Studies

The FG will be notified of low enrolling studies by the SRMC administrator or designee. Unless SRMC specifically requests a full board review, the FG review will be completed as an expedited review and documented on the SRMC's Low Accrual Corrective Action Plan (CAP) form. These FG expedited reviews are to be completed by a FG voting member or a CRO Protocol Activation Coordinator. No additional actions are required on the part of the PI or designee. Any FG recommendations will be communicated to the SRMC for decision support by that committee or for use by the PI as a resource to incorporate into the CAP.

- If the assigned clinical research coordinator has a workload assessment score of greater than 200, there must be at least one other CRO clinical research coordinator with a score less than 125 identified to provide support on the trial.

A recommendation of “Acceptable” or “Unacceptable” with any relevant comments is recorded for this parameter.

Review of Anticipated Accrual (responsible party PAC and/or Unit Manager): The PI will provide the FG with their anticipated local annual and total target accruals. The PAC will work with the tumor registrar, i2b2 and other electronic records and registries to assess if these accrual goals align with our patient population. Should there be significant discordance, the review team will provide the PI with available data regarding the target population so the local accrual goals can be reformulated or interest in the study reconsidered. Past patient volumes, not projected new referrals, will be used to complete the accrual review. Recent historical enrollment to similar trials may also be considered in review of this parameter. To ensure the proposed protocols are feasible, the trial must be projected to meet the following accrual parameters:

- For non-rare disease and industry, trials must be projected to recruit a minimum of five subjects annually.
- For non-rare disease and non-industry, the reports generated by tumor registrar, i2b2, or other electronic records and registries must project five times the proposed annual accrual goal per year.
- For rare disease trials, the reports generated by tumor registrar, i2b2, or other electronic records and registries must project three times the proposed annual accrual goal over a two-year period.
- For prior similar trials, accrual performance will be taken into consideration.
- In general, competing trials for the same patient population will not be favorably recommended. If a compelling reason is made for having a competing trial, accrual to the currently open trial must demonstrate 50% or greater of the annual accrual target.

A recommendation of “Acceptable” or “Unacceptable” with any relevant comments is recorded for this parameter.

Review of Protocol Requirements (responsible party PAC and/or Unit Manager): To ensure the proposed protocols are clinically feasible, the review team will work with clinical staff to determine:

- Need for nursing unit or ambulatory unit support
- Requirements for specialized equipment or processes
- Need for the involvement of specialty physicians or services (i.e., pathology or radiology)
- Extended or after-hours support
- Special pharmacy or other ancillary department support (i.e., stem cell lab)

A recommendation of “Acceptable” or “Unacceptable” with any relevant comments is recorded for this parameter.

Review of Budget Requirements (responsible party Administrative Director): The review team will review the proposed clinical trial budget to determine if there is adequate coverage of non-Standard-Of-Care (SOC) items and services, required equipment and materials, and personnel. To ensure the proposed protocols are financially feasible, the trial must meet the following parameters:

- Industry trials budgets must cover operational costs including but not limited to staff effort, clinical costs, and ancillary service costs. Cancer Center funding may not be used to support industry-sponsored trials without written approval from the UFHCC Director.
- Non-industry trials (IITs and External Foundation or Academic) budgets should cover operational costs; however, CRO funding may be used to support selected trial costs with the approval of the CRO Administrative Director.
- NCTN and ETCTN trial budgets are expected to cover some clinical and ancillary service costs. There is no expectation of staff effort support and CRO funding may be used to support trial costs with the approval of the CRO Administrative Director.

A recommendation of "Acceptable" or "Unacceptable" with any relevant comments is recorded for this parameter.

Review of Regulatory Requirements (responsible party CRO Regulatory Manager): Protocols will be reviewed to determine the appropriate IRB to be utilized, identify any additional ancillary reviews, and assess IRB coordinator support. To ensure the proposed protocols are feasible, the trial must meet the following staffing parameters:

- The assigned CRO IRB coordinator must currently maintain sixty or less interventional trials (total assignment of 100 trials or less).

A recommendation of "Acceptable" or "Unacceptable" with any relevant comments is recorded for this parameter.

Compliance or QA Considerations (responsible party CRO Compliance Manager): Protocols will be reviewed to determine if there is need for unique training requirements, source document creation, special compliance or QA review. A recommendation of "Acceptable" or "Unacceptable" with any relevant comments is recorded for this parameter.

Review of Available Alternate High-Priority Trials (responsible party PAC or Unit Manager): The review team will provide feedback on whether any NCTN or other NCI-sponsored studies for a similar patient population (not currently available at our center) could be considered as a potential competing (and should be considered as an alternate) trial. This informational service will be provided to SRMC and the PI without a formal recommendation.

Full Board Re-Review of Low Enrolling Studies (responsible party FG Voting members or designates): As noted above, the FG will review studies that are identified as low enrolling at a scheduled FG meeting if requested by the SRMC. This re-review is intended to identify any enrollment barriers that might be affecting accrual as well as potential recruitment strategies that can be utilized to increase study participation. Voting members formally submit recommendation and signature on the FG questionnaire.

Any feedback or recommendations are non-binding and will be provided directly to the PI, DSG research leader and SRMC administrator.

Voting:

For each protocol, each parameter will be discussed and a motion of “acceptable” or “unacceptable” is put forward to a vote by the quorum of voting members. A study achieving uniform “acceptable” reviews for each parameter will be recommended as “feasible” to the PI and sponsoring DSG. If the study has a parameter that is “unacceptable” and cannot achieve such a designation through required internal CRO changes (i.e., budget modification), the study will be recommended as “non-feasible” to the PI and sponsoring DSG.

Decision Reporting:

The Protocol Activation Coordinator, or designee, will be responsible for recording and compiling FG meeting minutes and communicating recommendations via a memorandum to the PI and DSG. A recommendation letter will be generated each time a study is reviewed by the FG and will be uploaded into OnCore. The FG recommendation letter will be available to assist DSG decision making while determining if the protocol is supportable or insupportable and will be included in the submission packet to SRMC.

Appendices:

A. Feasibility Group Questionnaire
B. OPAL & Case Workload Scoring Tool
C. Ontario Protocol Assessment Level – Journal of Oncology Practice