Category:
Title: **Protocol Facilitation Committee Policies and Procedures**
Department(s):

1 Definitions

CRLC	Clinical Research Leadership Committee
DSMP	Data and Safety Monitoring Plan
FC	Protocol Facilitation Committee
IDS	Investigational Drug Service
MDG	Multidisciplinary Disease Group
PI	Principal Investigator
PRC	Protocol Review Committee
SKCC	Sidney Kimmel Cancer Center
TJU	Thomas Jefferson University
TJU Controlled Affiliates	Abington, Aria, Kennedy, and Methodist

2 Introduction

Protocol Facilitation Committee (FC) was created to assist in a consistent system for introducing new protocols to the TJU Research Community and help efficiently choose and execute appropriate protocols using good clinical practice

The Protocol Facilitation Committee evaluates all clinical trials involving patients with cancer or those at risk for cancer undertaken at the Sidney Kimmel Cancer Center (SKCC) and its controlled affiliates. The committee is responsible for:

- Assessing specific feasibility of the clinical trial within TJU Facilities and its controlled affiliates
- Assessing resources to execute the protocol appropriately
- Justification for accrual goals or prior accrual for similar population, and competing trials for each new clinical protocol
- Reviewing the priority scores submitted by the MDG for all new protocols

3 Responsible Personnel

The Clinical Research Leadership Committee (CRLC), FC Chairs (TJU and its controlled affiliates), FC Support Staff, and its members are responsible for the execution of these policies and procedures.

These policies and procedures are applicable to all SKCC Investigators conducting oncology-related research at the Sidney Kimmel Cancer Center and its controlled affiliates.

ROLE	RESPONSIBILITIES
Clinical Research Leadership Committee	Oversight of the committee receiving updates on a monthly basis at minimum, verification of PI response, review PI appeals and make final decisions, appoints the FC Chairs, approves roster

Chair: The Protocol Facilitation Committee Chair is responsible for the conduct of the Facilitation meeting and understands the resources that are need to conduct the study. The chair will be responsible for calling the decision outcome on all studies being reviewed at the meeting and providing their vote.

Vice-Chair: The Protocol Facilitation Committee Vice-Chair is responsible for providing back-up to the chair and their delegated duties. The Vice-Chair is a voting member at all meetings.

Committee Members: The committee members are to review all assigned studies and providing feasibility feedback of the studies as it pertains to their specific department/expertise in which the member represents. The committee members are also responsible for participating in the trial discussion and voting on the decision outcome. Additional information regarding membership is noted in Section 4.3.

MDG Coordinator: The MDG coordinator (or delegated study coordinator) is responsible for completing the Protocol Facilitation Committee Application, providing supporting document(s) and attending the committee meeting to speak on behalf of the trial.

Support Staff: The responsibilities of the Protocol Facilitation Committee's Support Staff (Facilitation Administrator and Facilitation Coordinator) are to provide administrative support to the committee including receiving submissions, distributing meeting agendas, taking meeting minutes, documenting committee decisions, maintaining committee rosters, tracking attendance, maintaining review forms, maintaining the committee webpage, filing documentation, among other things. Support staff is non-voting.

4 Procedures

4.1 New Studies

All MDG (Multidisciplinary Disease Groups) approved research studies involving patients with cancer or those at risk for cancer conducted at the SKCC or controlled affiliates must be submitted to Protocol Facilitation Committee. All new studies are received by the FC Administrative Coordinator and placed on the agenda the week before the meeting. All studies receive full committee review.

New Study Submissions

All new study submission documents must be e-mailed to facilitation-committee@jefferson.edu :

- Current Protocol Facilitation Committee Review Form (found in document library)
- MDG approved protocol

New Study Review Process

Full Review

Full FC review focuses on the utilization of the TJU facilities and its resources for proper trial execution. Review criteria have been developed to assist reviewers and Committee members in addressing all facilitation and resource aspects of a proposed study, including but not limited to:

- TJU has the facilities to execute the protocol as written
- The study team has the proper staffing resources
- The study has appropriate screening time to activate and enroll the required number of participants to the trial
- A data and safety monitoring plan is appropriately identified in the protocol

Each study receiving full committee review is reviewed by the entire membership roster. Reviews are documented on the FC review form at the time of the meeting. Each member is only expected to review and complete their section of the FC review form. If a member is unable to attend their feedback and vote is expected to be received electronically before the meeting. If review forms are not completed prior to the meeting, the protocol may be tabled until the next FC meeting, at the Chair's discretion.

New Study Review Outcomes

Once the new study review is completed, the FC Administrative Coordinator will prepare a review outcome notification that will be issued to the PI, relevant MDG Committee Coordinator (if applicable), Regulatory Coordinator/Manager and Submitter. Additional individuals may be copied on notifications, as specified below.

- Approved
  - The study is approved for eventual activation at TJU and its controlled affiliates as submitted and with no additional comments. The PI will receive an approval letter.
- Contingent Approval
  - The study review results in concerns that require a PI response. PI will receive a letter requesting a written response to the concerns within two weeks of receipt of the letter. Upon receipt of a successful response (as determined by the FC Administrative Coordinator, FC Chair, or the original reviewers affected, if necessary), the PI will receive a final approval letter.
  - If the PI does not respond to the concerns within 30 days, the study will be sent back to the MDG at the discretion of the FC Chair. The FC Chair will inform the CRLC.
- Deferred

  - Significant revisions to the study are necessary. PI will receive a letter requesting a written response to the concerns for re-submission and re-review at a full committee meeting.
  - If the PI does not respond to the concerns within 30 days, the study may be sent back to the MDG at the discretion of the FC Chair. The FC Chair will inform the CRLC
  - After three unsuccessful reviews a trial will be disapproved
- Disapproved
  - TJU or its controlled affiliates do not have the facilities or the resources to conduct the trial satisfactorily to the high quality expectations of the SKCC.
- Tabled
  - No representation from the clinical group coordinating the trial was present for the trial review
  - Departments directly involved with the trial did not provide their responses to the committee

If a trial is not submitted to the Protocol Review Committee within 3 months of the MDG approval date, the trial will need to be re-reviewed at Facilitation to confirm that resources are still appropriate.

4.2 Protocol Amendments

MDGs may choose to submit amendments to the FC for review. If the amendment affects the potential feasibility or resources of the trial the PI will submit to the FC a request for review from the department(s) affected. The review will only be completed by the specific department.

Submission of amendments maybe done simultaneously to the IRB and PRC.

Amendment Submissions

All amendment submission documents must be e-mailed to facilitation-committee@jefferson.edu.

Submission Requirements

Submission requirements for externally sponsored studies (industry-sponsored studies, NCTN studies, and multi-site institutional trials where TJU is a participating site):

- Tracked revised Protocol Facilitation Committee Form
- Summary of changes provided by the sponsor. If no summary of changes is provided by the sponsor, the Principal Investigator (or designee) must create one to be included in the submission.
- Clean, revised protocol *with an updated version on the protocol*

Submission requirements for investigator-initiated trials (IITs):

- Tracked revised Protocol Facilitation Committee Form
- Summary of changes including a reason or justification for each change
- Clean, revised protocol *with an updated version on the protocol*

Responding to Contingent Approval of an Amendment

The PI's response needs to include the following documents and should be e-mailed to FC (facilitation-committee@jefferson.edu):

- Summary of changes including a reason or justification for each change that addresses each of the FC's concerns, as detailed in the contingent approval notification. If a requested change is not made, there should be a rationale provided for not doing so.
- Clean copies of all documents revised in response to the Contingent Approval.

Amendment Review Outcomes

After review by the FC Administrative Coordinator and the affected department, the FC Administrative Coordinator will either prepare a review outcome notification, or prepare the submission for full committee review, depending on the outcome.

A review outcome notification for contingent approval will include an explanation of which revisions were not acceptable and why, and may contain suggestions on how the PI can make those revisions acceptable. Approval will not be granted until all of the concerns are addressed.

A review outcome notification for approval will be issued to the PI, Study Site Contact, Regulatory Coordinator and Submitter. If there are suggestions provided with the amendment approval notification, they are recommendations only.

4.3 Administrative Considerations

Meetings

The FC meets weekly at TJU and monthly at controlled affiliates. Meetings maybe cancelled if no agenda items and/or does not meet quorum.

FC Membership

FC membership will include broad representation across clinical/research departments involved in the conduct of cancer trials thus providing the highest quality study reviews. The members are expected to know the research operations of their department, have the ability to raise concerns, and place a vote.

The CRLC has oversight over this committee and appoints the chair of the FC.

Potential FC members are identified by the departments and presented to the CRLC to ensure proper breadth and depth of committee membership.

Members are expected to attend 75% of meetings annually or membership will be presented to the CRLC and the department for replacement.

Voting

After appropriate discussion, the FC Chair will call for a vote to provide an outcome to the trial.

Roster Members	Entitled
Department	one
FC chair	one
PM or Coordinator	one
JCRI	one
QUI	one
Regulatory	one

Absentee Votes- a committee member who has been excused from a meeting may vote by submitting an e-mail to the FC Administrative Coordinator stating their decision of the trials being reviewed.

Quorum

Meeting quorum is established once the following voting members are present:

- FC Chair (or designee, if Chair is absent)
- Coordinator or representative of the trial being reviewed

And 50% of the expected voters are in attendance and no less than 50% of the total specific FC site membership roster are present.

5 References

Applications:

- Protocol Facilitation Committee Review Form
- Protocol Facilitation Committee Support Staff Responsibilities

6 Document History

Version	Effective Date	Description of Change
1.0		Initial SOP
2.0		-Controlled Affiliate and Comprehensive Updates

7 Approval

Authors	Sylvia O'Neill, MD Executive Director, Clinical Research Organization	Date of Signature April 18, 2018
SKCC Associate Director of Clinical Research Approval	W. Kevin Kelly, DO	**Date of Signature** 4/19/2018

Does this document require review and approval from the SKCC Director or Deputy Director?

☒ **Yes** ☐ **No** **Initials**

SKCC Director/Deputy Director Approval	Karen Knudsen, PhD/Neal Flomenberg, MD	**Date of Signature** 4/19/18