POLICIES & PROCEDURES

Category: N/A
Title: Multidisciplinary Disease Group (MDG) Committee Protocol Review Policy
Departments: Sidney Kimmel Cancer Center

1.0 Abbreviations

ACH	Advanced Care Hub
ASP	Asplundh Cancer Pavilion
CCR	Center for Clinical Research (Abington)
CRLC	Clinical Research Leadership Committee
CRO	Clinical Research Organization
CTAC	Clinical Trials Advisory Committee
CTO	Clinical Trials Office
EDDO	Early Drug Development Office
JHE	Jefferson Health Enterprise
JNE	Jefferson North East
JNJ	Jefferson New Jersey
MDG	Multidisciplinary Disease Group
NCI	National Cancer Institute
PI	Principal Investigator
PRMC	Protocol Review and Monitoring Committee
SKCC	Sidney Kimmel Cancer Center
SOP	Standard Operating Procedure
TJU	Thomas Jefferson University
TJU Advanced Care Hubs	Abington, JNJ (Washington Township) JNE and Methodist. (Future Sites: JNJ (Cherry Hill) and Einstein sites)

2.0 Introduction

2.1 Purpose

As an NCI-designated cancer center, Sidney Kimmel Cancer Center (SKCC) has a responsibility to ensure safe and efficient conduct of clinical trials. The purpose of the Multidisciplinary Disease Group (MDG) Committees is to set priorities and oversee

the operations and management of clinical research for their group. The committees determine disease-specific clinical trial priorities across the enterprise. The purpose of this document is to define the responsibilities and procedures for MDG Committee protocol review.

2.2 Policy

All cancer research conducted within Jefferson Health Enterprise (JHE), including advanced care hubs (ACH), must be reviewed by an MDG Committee with the following exceptions: retrospective chart reviews, anonymous surveys, correlative laboratory-based trials that will utilize banked blood and tissue, and other studies that do not require informed consent.

2.3 Scope

This document describes the process for:

- The review of all new or revised cancer related concepts and protocols
- Subsequent review of trials that have been previously disapproved
- Re-review of trials that have been previously approved by the MDG but have passed the 6 month timeframe to submit to the Protocol Review and Monitoring Committee (PRMC)

3.0 Responsible Personnel

3.1 Committee Membership

MDG committee membership includes disease site subspecialty clinicians and researchers. The committee typically includes medical, surgical, and radiation oncologists, as well as population science faculty, nurses and other appropriate support staff. The number of voting members differs by MDG, due to the unique qualities of each disease. A committee quorum is required to vote on issues and new protocols. Quorum is defined below in section 4.3.

3.2 MDG Committee Leaders

Each MDG is overseen by a MDG Committee Leader. An MDG may also have Co-Leader(s). If Co-Leaders are selected, one leader will be appointed to serve as the main contact for the MDG. Committee Leaders are responsible for leading the disease-based team in the development and implementation of a focused research program which meets the needs of the SKCC catchment area and addresses SKCC priorities.

3.2.1 The leaders are accountable for the oversight of the committee, which includes scientific review of new protocols, resource utilization and fiscal integrity of the MDG, including the required CRO and/or ACH staff (regulatory, clinical coordination,

monitoring, and data management) to conduct the MDG's portfolio of trials. The MDG must ensure that the inclusion of women and minorities as participants on cancer trials under their committee's auspices is consistent with the demographics of the catchment area. They are required to make certain that all processes, trial performance, data quality and safety are monitored in a real-time fashion.

3.2.2 MDG Committee Leaders are approved by CRLC. MDG Committee Leaders may be reapproved, and there is no term limit.

3.2.3 MDG Committee Leaders are responsible for preparing and reviewing the meeting agenda with the MDG Committee Coordinator and reviewing new trials/concepts which may be appropriate for the portfolio. Open trials are to be reviewed for local and national accrual progress. The MDG Committee will address issues of low accrual, and discuss barriers, potential solutions, or make recommendations on study closure. Additionally, all pending trials should be reviewed and any delays to study start up addressed.

3.2.4 MDG Committee Leaders are to serve as mentors to junior investigators and encourage all PIs to prioritize and focus research interests. The MDG Committee Leader(s) should orient new PIs to the MDG and encourage trial screening in tumor boards and conferences.

3.2.5 MDG Committee Leaders are to ensure all Investigators complete and maintain their required GCP and protocol specific trainings.

3.2.6 MDG Committee Leaders will assist with transitions from one PI to another as needed and add new investigators to MDG protocols as part of the onboarding process.

3.2.7 MDG Committee Leaders are a liaison to the CTO, advocating for CTO staffing needs with leadership, participating in interviews of CTO candidates as needed, and helping to navigate CTO processes.

3.2.8 MDG Committee Leaders must attend 75% of CTAC meetings and attend cooperative group meetings to share updates with their MDGs.

3.2.9 MDG Committee Leaders should review important MDG metrics, based on team and SKCC priorities, with CRO Leadership twice a year.

3.3 MDG Committee Coordinators

MDG Committee Coordinators are the MDG project/program manager or someone that is delegated the task by this manager. This person is responsible for administrative tasks associated with MDG Committee activities, including but not limited to coordinating and preparing materials for meetings, writing and distributing meeting minutes, and assisting

with preparation of annual reports. A guide for meeting discussion is provided as a supplement to this SOP.

The MDG Committee Coordinators are appointed by the Senior Directors of the CTO/EDDO in conjunction with the MDG Leaders. They are voting members of the MDG Committee.

3.4 MDG Committee Members

MDG Committee Members are clinical and/or research representatives from their respective disease specific field with sufficient expertise and knowledge from a clinical and/or operational perspective. Members may come from the physician, nursing, pharmacy, genetic, or scientific community. Only voting members will be appointed by the MDG Leader as described below.

3.4.1 Voting Members

Voting members are a subset of MDG Committee Members who are appointed by the MDG Committee Leader(s). Voting members are responsible for the timely review of all new protocols in the docket. They should have the expertise to review protocols under consideration, and a willingness to participate in a minimum of 75 percent of the official voting review meetings. Attendance will be reviewed annually by MDG Committee Leader(s) for compliance with attendance requirements.

There is no limit on the number of times that a voting member may be reappointed. A member may be dismissed by MDG Committee Leader(s) if their contribution is deemed to be inadequate.

3.5 MDG Committees

The MDG Committees are responsible for:

- Evaluating trial concepts, population fit, and alignment with SKCC objectives.
- Assessing availability of adequate resources (both financial and feasibility to conduct clinical trials).
- Reviewing enrollment potential, including number of subjects meeting trial inclusion/exclusion criteria and any pending and open competing trials across the enterprise.
- Addressing trial priority within the existing portfolio of active and pending studies.
- Review of accrual to open protocols and any requests to re-open suspended trials, in conjunction with the SKCC leadership.
- Monitor accrual of women and minorities to open trials.

- Review and timely response to SKCC committees and boards (PRMC, PFC, IRB and DSMB) for pending and open trials in the MDG portfolio.
- Recommending closure of clinical trials that are not accruing or are not in alignment with the mission or objectives of SKCC.

The SKCC CRLC will oversee compliance with this SOP. CRLC assumes the institutional responsibility to monitor the activities of the MDG Committees and MDG Committee Leaders.

3.6 ACH Site Lead Investigators

The ACH Site Lead Investigators are responsible for:

- Championing ACH participation in relevant trials with ACH site investigators and staff.
- Assessing the availability of adequate resources at their site.
- Determining participant availability and existence of pending and open competing trials at their site.
- Advocating for inclusion of trials in portfolio that leverage ACH resources and staff.

4.0 Procedures

4.1 Meeting Schedule

MDG Committee meetings will occur a minimum of once each month.

4.2 Meeting Preparation

Investigators must submit the concept/ protocol to the appropriate MDG Committee Coordinator at least five business days before the scheduled committee meeting.

The meeting agenda, concepts/protocols to be reviewed, and the accrual reports for all open trials will be distributed to the MDG Committee voting members by the MDG Committee Coordinators at least 2 business days prior to the committee meeting.

Individual Study training and important study notifications will be added to the agenda as needed to allow for continued PI oversight and will be reflected in the meeting minutes. This is also discussed in the PI oversight guidance document.

4.3 Quorum

The members of the meeting must include the MDG Committee Leader, or MDG Co-Leader/s, MDG Committee Coordinator, and at least one Committee Member from each modality (such as surgery, radiation oncology, medical oncology, and population

science). Requisite modalities are to be determined by the MDG Committee Leader(s). Quorum is defined as no less than 50% of the total specific MDG voting membership list. If quorum is not met, no voting will occur. Members may still meet to discuss the status of protocols, accruals, PI study oversight, and patient specific items. Review items that require a vote will be re-presented at the next convened committee meeting.

Attendance will be documented in the minutes and will reflect voting members and any other attendees.

If a voting member cannot be present at the meeting, they may send their vote to the MDG Committee Coordinator prior to the meeting, and the vote will count towards the quorum. Their vote will be reflected in the minutes as an absentee vote.

4.4 Review of Concepts and Protocols

4.4.1 Concepts

Protocol concepts may be discussed at the meeting, however, a full, clean version of the completed protocol is needed for formal MDG review and approval

Unfunded or potentially funded concepts need to be discussed at the MDG for interest and prioritization. After initial discussion and recommendation to move forward by the MDG Committee Leader, a budget request from JCRI may be initiated by the MDG Committee Coordinator. JCRI budget request is initiated via email correspondence, by attaching all study related documents in one email (protocol concept, budget grid and any other documents needed for budget development). Once received, JCRI will initiate a meeting between the PI, JCRI administration, and the PM.

4.4.2 Protocols

Review of each new protocol shall include discussion of:

- Scientific merit of the protocol
- Fit into the committee's disease map
- Required and available clinical coordination and data management staff
- Availability of subjects
- Competitive trials for the patient population
- Inclusion of women and minorities on the trial
- Alignment to catchment area priorities
- Recruitment plans for the trial
- Feasibility to conduct the trial (including resources and infrastructure)
- Preliminary budget considerations
- Program assignment

The PI or designated co-investigator should be available to answer questions or comments from prior reviews, if applicable.

As a general rule, CRO will not activate sponsored trials that have already accrued more than 50% of their national accrual goal. However, if the trial is of special interest or of a rare disease for which JHE has particular expertise, it may be considered on an individual basis by the strategic operations committee

4.5 Finance

On a bi-annual basis, the leader(s) will meet with the Senior Director of the CTO/EDDO; Medical Director of the CRO and SKCC Administrator to review the revenue and expenses (to include CRO staff FTE and other expenditures) for trials conducted during the period.

4.6 MDG Priority Form

Each study must be assigned a priority within each MDG based on characteristics of the study. The MDG Priority Form consists of questions about the nature of the trial and assigns importance to each categorical response. Completing the form yields each trial's priority within the MDG's pipeline. The form must be completed by the MDG Committee Coordinator with the assistance of the PI or MDG leader(s) prior to submission to the PRMC.

4.7 Disease Map

New studies approved by the MDG must be entered into the committee's disease map.

The MDGs must maintain a list of disease-specific clinical trials segmented by disease specific criteria. The disease map must be reviewed and updated on a real time basis by the MDG Committee Coordinator. The current disease map must also be included in the initial submission to PRMC. The template used must be approved by the CRO and Associate Director of Clinical Research.

4.8 Accrual Monitoring

The MDG Committees are responsible for 1) selecting trials that will accrue patients, 2) ensuring adequate accrual based on PRMC criteria and 3) closing trials with poor accrual to ensure appropriate utilization of resources. Accrual monitoring will be discussed at least monthly at MDG meetings and documented in the minutes.

The PRMC will send the PI, and include the study site contact, program manager and regulatory coordinator listed in JeffTrial a low accrual notification via email. This warns the PI the status of the trial and requires the PI to write a corrective action plan, including potential reasons for low accrual and suggest efforts to increase enrollment. The meeting minutes reflect accrual review by MDG Committee and includes discussion of overall accrual of women and minorities.

4.9 Voting

After appropriate discussion, the MDG Committee Leader will call for a vote to approve or disapprove the trial. Once approved, the committee will assign or confirm the PI for the trial and assign the study program.

4.9.1 Absentee Votes

A committee member who has been excused from a meeting may vote by submitting their response within +/- 5 business days of the meeting via e-mail to the MDG Committee Coordinator stating their decision.

4.10 Outcomes

4.10.1 Approval

4.10.1.1 Concepts

Concepts cannot be voted on by the MDG Committee. A concept can only be given allowance to move forward for budget and protocol development. If a concept or protocol synopsis is not approved to move forward the reason for disapproval needs to be captured in the minutes.

4.10.1.2 Protocols

Formal notification of trial approval will be sent to the PI, ACH Director of Clinical Research, Study Site Lead Investigators, JCRI administration, CTO/EDDO Senior Directors and PSU regulatory manager, by a standardized e-mail originating from the MDG Committee Coordinator. The e-mail will include the MDG Committee's decision, the JeffTrial number, and that the protocol may now be submitted to Protocol Facilitation Committee for review.

Trials must be submitted to PRMC within six months of MDG Committee approval. Trials not submitted to PRMC within six months must be re-submitted to the appropriate MDG Committee for review and approval prior to PRMC submission.

4.10.2 Disapproval

The MDG Committee Coordinator will email the PI and the Senior Directors of the CTO/EDDO with a formal notification that the study was not approved to move forward. The Committee Coordinator will also document the study disapproval in the database tracking disapproved studies. Metrics will be kept on study disapprovals and be reviewed annually by senior leadership.

4.10.3 Contingent Approval and Protocol Deferral

The MDG Committee Coordinator will document in the minutes any protocol or concept discussion that was deferred or given contingent approval.

4.11 Minutes

Each committee is required to maintain written records of all meetings using standardized forms, including attendance and decisions concerning accrual, priorities, new concepts, absentee voting and protocol review. It is important to ensure that the protocols that are declined by the MDG are clearly documented in the minutes and reported. All meeting minutes and attendance records will be maintained in a centralized location, and available for review. Minutes will be completed by the MDG Committee Coordinator and reviewed and approved by the MDG Committee Leader. MDG Committee Leader may sign the minutes either with wet ink or via electronic signature. Minutes will be kept on standardized forms.

4.12 JeffTrial

All trials approved by the MDG Committee must be registered in JeffTrial by the MDG Committee Coordinator within 2 business days after the MDG meeting. This will generate the JeffTrial number used in the standardized email mentioned above (refer to section 4. 9.1.2).

4.13 Accrual Across the LifeSpan and Multi-Disease Clinical Trials

Accrual across the lifespan will be monitored by disease-specific MDG Committees. All other trials that are not disease specific and non-therapeutic; the main PI will be from the MDG Committee with the most projected subject accrual. If needed, senior leadership can assist with the discussion on PI assignment to multi-disease studies when accrual is not as evident.

4.14 Population Science Trials

The Population Science PI will decide the disease area anticipated to recruit the most subjects, and then approach the MDG Committee Lead of that disease area to discuss appropriateness for MDG committee review. The PI of the Protocol shall also consider the inclusion of a MDG committee member as a Co-I on the study.

The PI or designated study team member must present the study to any MDG Committees that will be enrolling subjects to the study prior to enrolling subjects from that MDG population.

4.14 EDDO/Phase I Trials

All Phase I trials enrolling multiple disease sites will be reviewed and approved by the EDDO MDG committee. Phase I trials enrolling to a single disease site will be reviewed by the disease specific MDG.

All single site Phase I first-in-human trials will be brought to the EDDO MDG for review to ensure that the disease specific MDG has resources in place to carry out trial activities.

If the disease specific MDG does not have sufficient resources to conduct a Phase I trial, EDDO leadership will review requests to have EDDO MDG staff manage trial activities. Approval or disapproval of requests will be documented in the EDDO MDG meeting minutes.

5.0 References

5.1 Priority Score Form
5.2 Semi-Annual Report Template
5.3 Meeting Minutes Template
5.4 New Study Approval E-mail Template

6.0 Document History

Version	Effective Date	Description of Change
1.0	9/26/2012	N/A
1.1	10/10/2012	
1.2	11/12/2012	
1.3	11/16/12	
1.4	6/12/2013	
1.5	1/6/2014	
1.6	1/29/2014	
1.7	12/10/2014	
1.8	2/25/2015	
1.9	9/16/2015	
2.0	4/27/2016	Update to new format
3.0	6/12/17	Updated Accrual Monitoring section to change new reporting method; removed specifications about leadership term; removed semi-annual report section; revised finance section to include quarterly meetings
4.0	12/4/17	Controlled Affiliate Integration
5.0	4/12/18	Addition of JCRI/MDG communication related to concept IITs; addition of population science membership and protocols

6.0	12/16/2022	Update for changes associated with new enterprise wide transitions; changed controlled affiliates to ACH; added JNE and JNJ and future ACH's; added EDDO MDG, accrual across the lifespan and Multi-disease clinical trials, clarifies Population Science MDG assignment

7.0 Approvals

Author's Signature	Cynthia Gifford-Hollingsworth, DrNP CRO Sr. Director CTO	**Date of Signature** 1/23/2023
CRO Executive Director Approval	Kristin Herman, MBA	**Date of Signature** 1/24/2023

Does this document require review and approval from the SKCC Associate Director of Clinical Research?

☒ **Yes** ☐ **No** **Initials** KLH

SKCC Associate Director of Clinical Research Approval	Wm. Kevin Kelly, DO	**Date of Signature** 2/3/2023

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

☐ **Yes** ☒ **No** **Initials**

SKCC Director Approval	Andrew Chapman, DO	**Date of Signature**