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## Weill Cornell Medicine Data and Safety Monitoring Committee (WCM DSMC) Standard Operating Procedures

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## 1. Purpose

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This standard operating procedure (SOP) applies to the administration and operation of the WCM DSMC, which consists of the Meyer Cancer Center Data and Safety Monitoring Committee (MCC DSMC) and the General Weill Cornell Medicine Data and Safety Monitoring Committee (General DSMC). It outlines procedures for the oversight and monitoring of all WCM DSMC-monitored protocols and are intended to safeguard the well-being of study participants and to ensure study data integrity.

## 2. Abbreviations

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AE	Adverse Event
COI	Conflict of Interest
PRRF	Periodic Report Review Form
DSMC	Data and Safety Monitoring Committee
DSMP	Data and Safety Monitoring Plan
FDA	Food and Drug Administration
IB	Investigator’s Brochure
ICF	Informed Consent Form
IIT	Investigator Initiated Trials
IR	Immediate Report
IRB	Institutional Review Board
IMM	Independent Medical Monitor
JCTO	Joint Clinical Trials Office
MDL	Meeting Decision Log
NPRF	New Protocol Review Form
PI	Principal Investigator
PRF	Periodic Review Form
PRMC	Protocol Review and Monitoring Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
WCM	Weill Cornell Medicine



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### **3. Organization**

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#### **3.1. Membership Solicitation**

The need for new members may be identified by HRC staff, the WCM DSMC, or senior research leadership. New voting members may be identified through discussion with the full Committee, and Chairs are expected to initiate and lead this discussion.

#### **3.2. Member Appointment**

Once a new voting member has been identified and has agreed to join the WCM DSMC, the Associate Dean of Human Research Compliance must approve the appointment. Upon receipt of the official appointment letter, each new voting member will:

1. Receive a *“Welcome Packet,”* which includes:
  - a. An orientation letter
  - b. A copy of the roster
2. Sign a *“Member Acknowledgment”* to in acceptance of his or her responsibilities to maintain confidentiality and declare conflicts of interest in regard to their DSMC activities.
3. Undergo a new member training provided by the National Institutes of Health, which can be accessed via the following link:  
<https://dsmblearningcenter.niaid.nih.gov/Pages/default.aspx>.

#### **3.3. Ad Hoc Reviewers**

In the event that a WCM DSMC administrator, Chair, or reviewer deems that the review of a study would benefit from the expertise of an external reviewer, such a reviewer must sign an *“Ad Hoc Reviewer Acknowledgment”* to signify his or her understanding of the rules of confidentiality and conflict of interest governing the WCM DSMC’s activities prior to reviewing any trial documentation.

Ad hoc reviewers are not voting members and are not required to attend meetings. However, if any ad hoc reviewers are unable to attend meetings at which their assigned studies will be discussed, they must provide their review in writing.

### **4. Conflict of Interest (COI)**

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It is crucial that DSMC members remain objective and conduct unbiased assessments of the studies under their review to maintain subject safety and preserve the integrity of the WCM DSMC review process.

A voting member or ad hoc reviewer is considered to have a COI when any of the following apply:



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- The individual is an investigator on the trial
- The individual has a direct interest in knowing or influencing trial outcome or has a financial or intellectual interest in the outcome of any studies under review.
- The individual serves as a DSMC member on another DSMC evaluating the same, related or competing product

WCM DSMC voting members and ad-hoc reviewers must disclose all pharmaceutical companies, biotechnology companies, and CROs in which they hold financial interest. The WCM DSMC administrator must maintain current (i.e. within 1 year) conflicts information from all WCM DSMC voting members and ad hoc reviewers, which can be obtained from the following:

	Source of COI Information
WCM DSMC Voting Members and Ad Hoc Reviewers Employed by Weill Cornell Medicine	Conflict of Interest Office
Ad Hoc Consultant not employed by Weill Cornell Medicine	"Ad Hoc Acknowledgement Form," filed directly with the WCM DSMC

To facilitate member declaration of conflicts of interest at WCM DSMC meetings, the WCM DSMC administrative staff will indicate known conflicts of interest information for WCM DSMC members on the meeting agenda, including DSMC members who are known to be co-investigators or biostatisticians for studies under DSMC oversight. Members shall:

- Declare any COIs as defined in this document and in accordance with the Member Acknowledgment, and WCM Conflict of Interest Policy prior to agreeing to act as reviewer for a given protocol and during DSMC meetings, as needed; and
- Immediately notify WCM DSMC administrative staff when any new COIs arise.

Voting members who have study related COIs shall not participate during the WCM DSMC's deliberations of the aforementioned study, except to provide information requested by the WCM DSMC. In other words, such members must recuse themselves from deliberations, quorum counts, and votes on the relevant protocol. However, certain exceptions may be made for biostatisticians, as outlined in [Section 4.1](#).

In case of any question of COI, standards used by NIH in determining conflict of interest for advisory committee members and investigators shall apply.

#### 4.1. Special Considerations for Biostatisticians

Recusal exceptions due to conflicts of interest may be made for biostatistician members. If a biostatistician member is involved in the initial design of the study only and will not analyze



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study data, then these individuals may participate in a closed discussion of a study and their participation may count towards quorum. However, they cannot vote on the motions related to the study.

## 5. Meetings

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### 5.1. Quorum

Formal deliberations by the WCM DSMC may not begin until quorum is established. Quorum constitutes of three voting members, which must include :

- One Chair
- One clinician
- One biostatistician

Members can only fill one role towards quorum and cannot be counted multiple times (i.e. a member cannot count as both a Chair and clinician).

### 5.2. Frequency

The MCC DSMC and the General DSMC may regularly meet in-person and/or by teleconference every other month on an alternating schedule. Meetings may be cancelled if there are no decision items to discuss that require voting by the full board. Ad hoc meetings may be requested by a WCM DSMC Chair or administrative staff as needed.

### 5.3. Format

#### 5.3.1. Open Session

An open session may occur upon the request of the PI or by the WCM DSMC. This type of session involves the WCM DSMC voting members, WCM DSMC administrators, PIs and/or their designees (if applicable), and WCM DSMC ad-hoc expert representatives (if applicable). During an open session, the PI provides any information that would be useful to the WCM DSMC, or provides updates on a protocol in progress. Open sessions provide the WCM DSMC with the opportunity to engage in a dialogue with the PI and answer questions in real time. However, if the study under discussion is a blinded trial, unblinded data will not be discussed.

#### 5.3.2. Closed Session

The closed session follows the open session and is attended by WCM designated statisticians, WCM DSMC staff and administrators, and WCM DSMC members. Members of the study team, including WCM DSMC members that are Co-I's on the study, are not permitted to attend this session. During the closed session, the WCM DSMC voting members review trial data, including possibly unmasked data. In addition to the review of clinical trial data (i.e., interim analysis, Periodic Report, Adverse Event Report), the



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closed session may include discussion on toxicities, adverse events, study conduct, and subject risks. All materials, discussions, and proceedings of the DSMC in closed sessions are completely confidential, and all individuals present are expected to maintain confidentiality.

### Voting

Each WCM DSMC voting member in attendance that does not have any study-related conflicts (see [Section 4](#)) is entitled to one vote for motions made by the WCM DSMC. Examples of motions that may be made by the DSMC are provided in [Section 6](#).

### Expedited Reviews

If the WCM DSMC determines that a response from the PI does not necessitate discussion by a full board, the WCM DSMC can vote to have the response reviewed via expedited review procedures. This review will be conducted by a WCM DSMC Chair and/or designee.

Responses from the PI (also known as RTQs) to recommendations or actions requested by the WCM DSMC that may be eligible for expedited review include, but are not limited to:

- Adding or removing specific language as directed by the WCM DSMC.
- Minor clarifications that do not affect the DSMP or study design, as determined by the WCM DSMC (e.g. typo corrections or confirmation of enrollment numbers). If the DSMP or study design is affected, changes may still qualify for expedited review if adding or removing specific language as directed by the WCM DSMC.
- The WCM DSMC recommends the study continues without modifications, but requests additional information.

### Guest Attendees

Any individual who will attend a closed session and is not a WCM DSMC voting or ad hoc reviewer, or member of WCM DSMC administration is considered a Guest Attendee and must sign a *“Guest Acknowledgment”* confirming expectations and requirements regarding confidentiality.



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## 5.4. Meeting Records

### 5.4.1. WCM DSMC Meeting Agenda

When possible, WCM DSMC administrators will order the meeting agenda with respect to which members have conflicts of interest for which protocols. In this way, previously disclosed conflicts of interest will be effectively tracked, voting members will be prompted to recuse themselves, and alternate members will be prompted to transition their roles to voting member during a meeting.

### 5.4.2. Meeting Decision Log

Meetings are documented in writing by means of a Meeting Decision Log (MDL), which includes the following information:

- A list of attendees (e.g. voting members, ad hoc members, administrative staff, leadership, and guests)
- Main points of discussion, any recommendations from the DSMC, and a list of action items for each corresponding recommendation
- A record of whether quorum was achieved for discussion items requiring a formal vote by the WCM DSMC

The MDL is reviewed at WCM DSMC meetings for approval. If the Committee has comments to the MDL, the WCM DSMC coordinator will revise the MDL per the Committee's suggestions.

## 6. DSMC Submissions

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This section outlines the types of submissions that the WCM DSMC may review.

### 6.1 New Study

Studies for which the DSMP was not previously reviewed by the WCM DSMC, or active studies undergoing significant changes that require re-evaluation by the PRMC will be processed as new studies.

#### 6.1.1. Studies that have not yet been initiated

The PI may submit a request to the WCM DSMC via one of two following pathways:

- A direct email submitted to [DSMC@med.cornell.edu](mailto:DSMC@med.cornell.edu).
- Automatically through the IRB Study Submissions process via an automated email from WRG.





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The following documents are required for WCM DSMC review and can either be provided by the PI or extracted from WRG by the WCM DSMC administrator:

1. Protocol Draft
2. DSMP (if separated from the protocol)
3. ICF Draft
4. Current IRB application

#### *6.1.2. Studies that have been initiated*

The WCM DSMC may receive direct requests from a PI or the IRB to act as the monitoring entity for studies that have already been initiated. In such cases, the PI needs to provide the following to the WCM DSMC administrator:

1. The current protocol
2. The current DSMP (if separate from the protocol)
3. Current ICF
4. Current IRB Application
5. The reason why DSMC oversight is needed
6. Any available interim reports or accrued safety and enrollment data, for studies that have already enrolled subjects

#### *6.1.3. Administrative pre-review*

Upon receipt of a WCM DSMC oversight request, the WCM DSMC administrator will conduct a pre-review. Pre-review involves:

1. Verification that the following elements are adequately described in the DSMP:
  - The monitoring entity
  - Plan for safety review
    - List of expected AEs
    - AE grading and attribution
    - Procedures for reporting AEs
  - Assessment of protocol compliance (e.g. plans for reporting unanticipated problems such as protocol deviations)
  - Plans to ensure compliance with privacy related regulations



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- Assurance of compliance with IC principles.
2. An assessment of whether the WCM DSMC is the appropriate monitoring entity. WCM studies that require WCM DSMC oversight include, but are not limited to:
    - Studies for which the WCM IRB requires safety and monitoring oversight by the WCM DSMC
    - WCM investigator-initiated trials phase II or higher
    - Large, multi-site, randomized, blinded, and Phase III trials
    - Phase I and II studies for which risk to the subjects appears unusually high
    - Phase I studies for which the principal investigator is the IND/IDE sponsor or manufacturer and independent monitoring is required to maintain the integrity of the trial
    - Gene transfer studies
    - Studies with vulnerable populations or risky interventions/procedures or any other factors that might indicate high morbidity/mortality end-points
    - Multi-center clinical trials in which WCM is the coordinating center or the PI of the study is a WCM faculty member
  3. The WCM DSMC administrator will determine if the request is ready to be assigned to a WCM DSMC reviewer following the processes outlined in [Section 6.1.4](#). If the proposed DSMP does not include enough information that would allow the WCM DSMC to provide meaningful feedback, the following steps will be taken:
    - i. A list of the deficiencies will be communicated to the PI with a deadline to respond no later than 10 business days prior to the next scheduled DSMC meeting.
    - ii. The WCM DSMC administrator will review the responses and re-evaluate the DSMP.
    - iii. If the DSMP includes enough information to allow the DSMC to provide meaningful feedback, a WCM DSMC reviewer will be assigned.

#### *6.1.4.WCM DSMC Review*

1. The DSMC administrator will schedule the study for review at the next convened WCM DSMC meeting. A WCM DSMC member will be selected to act as the primary reviewer. A biostatistician will also be assigned to review the study's statistical plan,



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sample size, and stopping rules to ensure adequacy for data collection and subject safety. Reviewers will be selected based on:

- The DSMC member's area of clinical expertise, whenever possible.
  - Conflicts of interest. Assigned reviewers must not have any conflicts of interest, as defined in [Section 4](#) of this SOP.
2. Reviewers will be assigned studies at least 5 business days before the next scheduled DSMC meeting, unless the WCM DSMC receives an urgent request to review a study.
  3. If, at any time, a reviewer is unable to perform his or her review, or is no longer able to act as reviewer for the study, the WCM DSMC may re-assign the study to a new member or ad hoc reviewer with equivalent expertise.
  4. During the closed session, the WCM DSMC will vote on one of the following motions:
    - The DSMP is appropriate and WCM DSMC will serve as the monitoring entity.
    - Modifications to the DSMP are recommended.
    - WCM DSMC oversight is not required, or is not the appropriate entity for the study.
    - Deferred: The WCM DSMC is unable to provide any recommendations based on the information currently available and requests additional information.
  5. The outcome of the WCM DSMC's review and its recommendations will be provided in the form of an outcome letter within 5 business days of the WCM DSMC meeting date. The outcome letter will indicate whether the PI is required to respond. Procedures for processing such responses is outlined in [Section 6.2](#) of this SOP.

## 6.2. New Study Response to Questions

1. If the WCM DSMC requires a response from the PI (i.e. in cases which additional information is needed or modifications to the DSMP are recommended), the PI must respond 10 business days prior to the next scheduled WCM DSMC meeting.
2. If the PI does not agree with the WCM DSMC's recommendation(s), a formal response letter outlining the rationale and justification must be provided.
3. Submitted responses will undergo administrative pre-review by the WCM DSMC administrator to verify that the issues or recommendations noted by the WCM



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DSMC have been addressed. If the response contains significant issues (e.g. inconsistencies between the protocol document and response, incomplete explanations, etc.), the WCM DSMC administrator will notify the PI of the issues within 5 business days of receiving the response. Additional correspondences between the PI and the administrator may follow if any issues persist.

4. Once all issues are addressed, the response will be routed to the assigned reviewer(s) along with the New Study RTQ Review Form.
5. During the closed session, the WCM DSMC will vote on one of the following motions:
  - The PI's response was accepted, therefore the study's DSMP is approved and WCM DSMC will act as the monitoring entity.
  - WCM DSMC oversight is not required, or is not the appropriate entity for the study.
  - Modifications to the DSMP are recommended.
  - Deferred: The WCM DSMC is unable to provide any recommendations based on the information currently available and requests additional information.
6. The outcome of the WCM DSMC's review and any recommendations will be provided in the form of an outcome letter within 5 business days of the WCM DSMC meeting date.
7. If the WCM DSMC requires additional correspondences from the PI, this process may be repeated until the WCM DSMC no longer requires a response from the PI.

### 6.3. Periodic Reports

The Principal Investigator is responsible for submitting Periodic Reports to the WCM DSMC. The approved DSMP outlines the data that must be included in the report as well as schedule by which WCM DSMC will review cumulative study data. Although the actual documents included in these reports varies depending on the study, the report must include:

- Completed Periodic Report Form
- Current Consent Form
- Current Version of the Protocol
- A copy of the current DSMP
- Additional documentation, as specified in the approved DSMP



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The process by which Periodic Reports are processed are as follows:

1. The WCM DSMC administrator will send out a courtesy reminder to the PI prior to the deadline of the next scheduled WCM DSMC meeting. While WCM DSMC administrators send courtesy reminders to the PIs when a review period is forthcoming, it is the responsibility of the PI to notify the WCM DSMC of when reporting thresholds are met and after each interim analysis is performed, if applicable.
2. The PI must submit the report at least 15 business days prior to the scheduled WCM DSMC meeting.
  - i. If a PI fails to submit in a consistently timely manner, the WCM DSMC will notify HRC leadership.
3. Once the periodic report is submitted, the WCM DSMC administrator will conduct an administrative pre-review for completeness. The administrator will determine if issues identified in the periodic report are either minor or major and communicate these issues to the PI.
  - i. *Minor Issues:* Issues that would not affect the WCM DSMC's ability to carry out its responsibility to evaluate the data and make recommendations. Such issues include, but are not limited to minor typos or discrepancies in report documents. Minor issues will not preclude the DSMC administrator from routing the report to the DSMC.
  - ii. *Major Issues:* Issues that would affect the DSMC's ability to carry out its responsibility to evaluate the data and make recommendations. These would include, but are not limited to: reports missing significant data or inclusion of expired consent documents for actively recruiting studies. Such issues must be resolved to the satisfaction of the administrator at least 10 business days prior to the scheduled meeting date. Failure to resolve these issues to the satisfaction of the administrator will preclude the report from being routed to the DSMC.
4. Once the administrative pre-review is completed, the submitted report and relevant documents will be forwarded to the assigned reviewer(s), who will be given at least 5 business days to complete the review.



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5. Once the review comments have been received by the WCM DSMC administrators, the administrator will distribute them to the rest of the board before the convened meeting. If the reviewer(s) notes any concerns, the administrator may attempt to solicit a response from the PI as long as there is sufficient time available to so.
6. During the closed session, the WCM DSMC will discuss the data, vote to provide the PI one of the following recommendations:
  - Continue without modifications
  - Continue without modifications, but additional information is requested
  - Continue with modifications
  - Deferred: The DSMC is unable to provide recommendations based on the information that is currently available and is requesting additional information before any recommendations can be made.
  - Discontinue one or more study arms
  - Suspend study enrollment
  - Termination of study
7. The findings and recommendations of the WCM DSMC are provided to the study's PI within 5 business days of the WCM DSMC meeting date.
8. If the WCM DSMC requests a response, the PI must respond within 10 business days of receiving formal correspondence.

#### 6.4. Reportable Events

If an event qualifies as a Reportable Event according to the Human Research Protections Program Immediate Reporting Policy, the PI must adhere to the submission timelines as prescribed in the Immediate Reporting Policy. Upon the submission of the Immediate Report to the WCM IRB, the PI is also responsible for submitting the event report to the WCM DSMC.

Upon receipt, the WCM DSMC administrator will conduct a pre-review. If additional information is needed, the administrator will communicate this to the PI. Pre-review is not considered complete unless all questions have been addressed.



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The DSMC administrator will then route the submission according to the type of event that is being reported.

#### *6.4.1. Privacy Incidents*

Reportable Events that are Privacy Incidents will be saved in the DSMC's records and acknowledged. The DSMC will defer to the Privacy office and the IRB regarding the review and decisions for Privacy Incidents.

#### *6.4.2. Serious Adverse Events*

1. Once the administrative review is completed, administrator will route the following to the primary WCM DSMC reviewer and/or Chair:
  - A copy of the report
  - A current copy of the protocol
  - The most recent copy of the ICF approved by the IRB.
2. The reviewer(s) must review the report within 5 business days, and should note the following:
  - a. Whether the SAE increases subject risk.
  - b. Whether the SAE requires discussion at a convened meeting.
  - c. Any additional safety concerns.
3. The reviewers or the full WCM DSMC (if scheduled for review at a convened meeting) will make a recommendation to the PI. One of the following determination letters will be sent to the PI within 5 business days after a recommendation has been determined:
  - **Acknowledgement:** Such a letter will be issued if the reviewer(s) do not note any additional concerns and determine that the SAE does not increase subject risk. The PI is not required to respond to this letter.
  - **Further information needed:** The reviewer(s) or the WCM DSMC requires additional information before recommendations can be given. The PI is required to respond to all questions in a formal memo within 5 business days of receiving the letter.
  - **Continue with Modifications:** This letter may be issued if the full WCM DSMC determines that a SAE warrants modification to the protocol (e.g., dose reduction, early study termination of a study arm, ICF modification). The PI is



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required to respond to all recommendations within 5 business days after receiving the protocol.

- i. If the PI agrees with the WCM DSMC's recommendations, the PI must submit any changes in an amendment to the WCM IRB for approval. Additional reporting to other entities may be required in accordance with the study's approved DSMP (.g. non-WCM study sponsor, FDA via MedWatch Form, etc.) The PI is responsible for notifying the DSMC administrator of the amendment approval by the IRB.
  - Discontinue one or more study arms
  - Suspension (e.g. treatment, enrollment, etc.)
  - Termination of study

This process may repeat as needed if any questions are left unresolved by the PI, or if the WCM DSMC raises any additional concerns.

#### *6.4.3. Protocol Deviations*

1. Once the pre-review is completed, the WCM DSMC administrator will route the following to the primary WCM DSMC reviewer and Chair for review:
  - A copy of the report
  - A current copy of the protocol
  - The most recent copy of the ICF approved by the IRB.
2. Reviewer(s) must review the deviation within 5 business days, and should note the following:
  - Whether the deviation increases subject risk
  - Whether the integrity of the study data is impacted
  - Whether discussion at a convened WCM DSMC meeting is required.
  - Any additional concerns
3. The WCM DSMC may vote on a recommendation resulting in one of the following determination letters:
  - Acknowledgement: Such a letter will be issued if the reviewer(s) do not note any additional concerns and determine that the protocol deviation does not increase





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subject risk or impact the integrity of the study data. The PI is not required to respond to this letter

- Further information needed: The reviewer(s) or the convened WCM DSMC requires additional information before recommendations can be made. The PI is required to respond to all questions in a formal memo within 5 business days of receiving the letter.
- Continue with Modifications: This letter may be issued if the convened DSMC indicate that a Protocol Deviation warrants modification to the protocol (e.g., dose reduction, early study termination of a study arm, ICF modification). The PI is required to respond to all recommendations within 5 business days after receiving the protocol.
  - ii. If the PI agrees with the DSMC's recommendations, the PI must submit them in an amendment to the WCM IRB for approval. Additional reporting to other entities may be required in accordance with the study's approved DSMP (e.g. non-WCM study sponsor, FDA, etc.) The PI is responsible for notifying the DSMC administrator of the amendment approval by the IRB.

This process may repeat as needed if any questions are left unresolved by the PI, or if the DSMC (individual reviewers or convened meeting) raises any additional concerns.

### **6.5. Disagreement with DSMC Recommendations**

All WCM DSMC decisions will be deemed advisory to the PI, IRB, the PRMC and other reporting entities. If the PI disagrees with the WCM DSMC's recommendations:

1. A formal response letter outlining the rationale and justification for the disagreement must be provided to the WCM DSMC within 10 business days.
2. The PI may request an open session to present their rationale for rejecting the WCM DSMC's recommendations. This request must be made at least 5 business days in advance of the next scheduled meeting.
3. The PI's response will be discussed at the next available convened WCM DSMC meeting.
4. If the WCM DSMC accepts the response, a new letter will be issued to the PI indicating as such. Should the WCM DSMC choose not to accept the PI's response, the recommendation is considered final and cannot be overturned by another entity.



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## ***7. STUDY CLOSURES***

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The PI is required to promptly submit notice of study closure to the WCM DSMC. The notice should contain the following information:

- The date and reason for study closure
- A final report including the following information, if available:
  - Safety
  - Enrollment
  - Interim Analyses
  - External site data

The WCM DSMC will then acknowledge the closure at a convened meeting and send the PI an acknowledgment letter. The sending of the acknowledgment letter signifies that the WCM DSMC will no longer act as a data and safety monitoring entity for the trial.

## ***8. RECORD RETENTION***

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WCM DSMC administrators shall keep records of the following on a secure server:

- Member Appointment Letters
- Member, Ad Hoc, and Guest Acknowledgments
- Current DSMC Roster
- New protocol documentation, associated REDCap New Protocol Review Form, and DSMC outcome letters, including PI responses
- PRF, associated PRRFs, and DSMC disposition letters, including PI responses
- MDLs
- Protocol closure letters and associated DSMC acknowledgment letters
- DSMC Database or other protocol tracking mechanism
- Current DSMC Charter
- Current DSMC SOP

## ***9. MCC DSMC-Specific Procedures***

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Operations that are unique to processes that govern the MCC DSMC will be outlined in the MCC DSMP, which applies to all investigator-initiated interventional cancer studies conducted at WCM.



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## ***10. General DSMC-Specific Procedures***

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Operations that are unique to processes that govern the Non-Cancer DSMC will be outlined here. Study specific procedures will be outlined in the study DSMP.

## ***11. Related Documents, Forms, and Templates***

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1. Cancer DSMC Charter
2. Non-Cancer DSMC Charter
3. Data and Safety Monitoring Plan Template
4. Periodic Report Form Template
5. Ad Hoc Reviewer Acknowledgment
6. Welcome Packet Template
7. DSMC Administrator Guide
8. Immediate Reporting Form
9. WCM DSMC Member Acknowledgement Form
10. Guest Acknowledgment

## ***12. References***

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1. IRB Immediate Reporting Policy



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### **13. Definitions**

Term	Definition
<b>Clinical Trial</b>	A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Clinical trials may be described as therapeutic or non-therapeutic interventions (e.g. diagnostic) and can include drugs, treatments, devices, as well as behavioral or nutritional strategies.
<b>Monitoring</b>	The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
<b>Medical Monitor</b>	A physician or other medically qualified individual with relevant expertise independent of the study) who is responsible for providing independent safety monitoring for a clinical study. The medical monitor is independent of the study and does not have any conflict of interest related to the study (i.e. financial, scientific or other) and is not responsible for patient care at any of the participating sites