



Weill Cornell Medicine

New York-Presbyterian

Utilizing the WCM Data and Safety Monitoring Board

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JCTO.WEILL.CORNELL.EDU

General Information

1 DSMB, 2 Co-Chairs:

- General Clinical Trials: David Behrman, D.M.D
- Cancer Clinical Trials: Tomer M. Mark, M.D., M.Sc.

Membership:

- 12 Investigators across a variety of specialties (i.e. neurology, oncology, infectious disease, etc.)
- 3 Statisticians
- Institutional Official
- Director of Human Research Protections Program
- Director of Clinical Trials, Joint Clinical Trials Office
- 2 DSMB Coordinators
- Assistant Director of Quality Assurance Unit

Meeting Schedule:

- Regular monthly meetings, scheduled as posted on the DSMB website

Meeting Format:

- Open/closed sessions
- Review of new protocols, existing protocols and preliminary DSMP review

DSMB Webpage

<http://researchintegrity.weill.cornell.edu/DSMB.html>

THE OFFICE OF
**RESEARCH
INTEGRITY**

- ORI Staff
- Institutional Review Board (IRB) [MORE](#)
- WCMC-Qatar IRB
- Data Safety Monitoring Board (WCM DSMB)**
- Institutional Biosafety Committee (IBC) [MORE](#)
- Institutional Animal Care and Use Committee (IACUC)
- HIPAA In Research [MORE](#)
- Conflicts Management Office (CMO) [MORE](#)
- Educational Programs
- Human Embryonic Stem Cell Research
- Research Archive Storage
- Clinical Study Evaluation Committee (CSEC)

CONTACT US

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Office of Research Integrity > DSMB

Weill Cornell Medicine Data Safety Monitoring Board

The Weill Cornell Medicine (WCM) DSMB is available to aid WCM principal investigators and the Institutional Review Board (IRB) in providing an independent means of data and safety monitoring for clinical trials that involve significant risk to research subjects. The WCM DSMB reviews interim data on a schedule commensurate with the needs of a given protocol to evaluate research subject safety, rates of accrual, and efficacy of experimental intervention. After each evaluation, the Board provides the principal investigator with recommendations for protocol modification, continuation or termination.

Studies for which the WCM DSMB is appropriate as an independent method of monitoring include:

- 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 and II 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
- Studies with high risk of toxicity or other major medical risks

Downloads

WCM DSMB Periodic Report Form	Microsoft Word
WCM DSMB Roster	Adobe PDF
A Guide to Understanding Data Safety Monitoring Procedures	Adobe PDF



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Initial Submission

Initial Submission: *The Basics*

CSEC Review

- If you know that your study will be utilizing the WCM DSMB or if you are unsure whether your study needs a DSMB, contact the Quality Assurance Unit (JCTOQAU@med.cornell.edu) for assistance.
- Investigator-Initiated Trial Template:
<http://jcto.weill.cornell.edu/investigators/study-activation-and-conduct/researchers-toolbox>

When to Submit

- Prior to IRB review or concurrently **AND**
- At least 3 weeks prior to DSMB meeting date

What to Submit

- Protocol (with Data and Safety Monitoring Plan)
- Informed Consent Form
- Investigators Brochure (if available)
- Any IRB correspondence (if available)

How to Submit

- Email: DSMB@med.cornell.edu

Initial Submission: *Open Session*



PI's are invited and *highly* encouraged to attend the DSMB meeting to present their protocol and address any questions during the open session.

Initial Submission: *Closed Session*

DSMB Reviewer

- Assess overall appropriateness of DSMP, including:
 - Frequency of periodic reports
 - Review of any safety concerns
 - Interim analysis
 - Criteria for study discontinuation (stopping rules)

Outcomes

- DSMB votes to:
 - Approve the DSMP
 - OR
 - Modify the DSMP
 - OR
 - Request for additional information or clarification



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Periodic Reviews

Periodic Reviews: *The Basics*

When to Submit

- Periodic Reports are due based on the DSMB approved review schedule (i.e. annually, semiannually, quarterly, etc.)
- Reminders are sent 1 month prior to the DSMB meeting date
- Submissions are due 2 weeks prior to DSMB meeting date
- If your protocol requires a certain threshold be met prior to a review, it is the **PI's responsibility** to ensure the report is submitted on time

What to Submit

- Periodic Report Form
 - **AE and IND Safety Reporting Cumulative Table for Subjects on Study**
 - **AE Narratives**
 - **Enrollment Tables (by Arm and by Site)**
- Interim data as planned in the DSMP
- Protocol (with DSMP)
- Informed Consent Form
- Investigators Brochure (if available)
- Any relevant IRB correspondence (if available)

How to Submit

- Email: DSMB@med.cornell.edu

Periodic Reviews: *Open/Closed Session*

Open Session

- At the request of the DSMB, the PI or designee may be invited to attend the open session and present any relevant data/outcomes

Closed Session

- General conduct of the trial
- Accrual
- Review outcomes/results, including SAEs and toxicities

Outcomes

- DSMB votes to:
 - Continue without modifications

OR

 - Modify the DSMP
- OR**
- Request for additional information or clarification

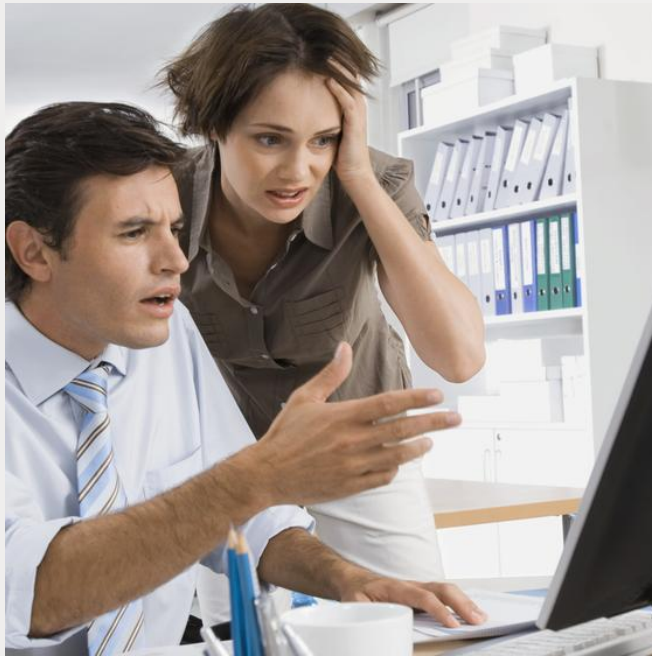


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Immediate Reports and Amendments

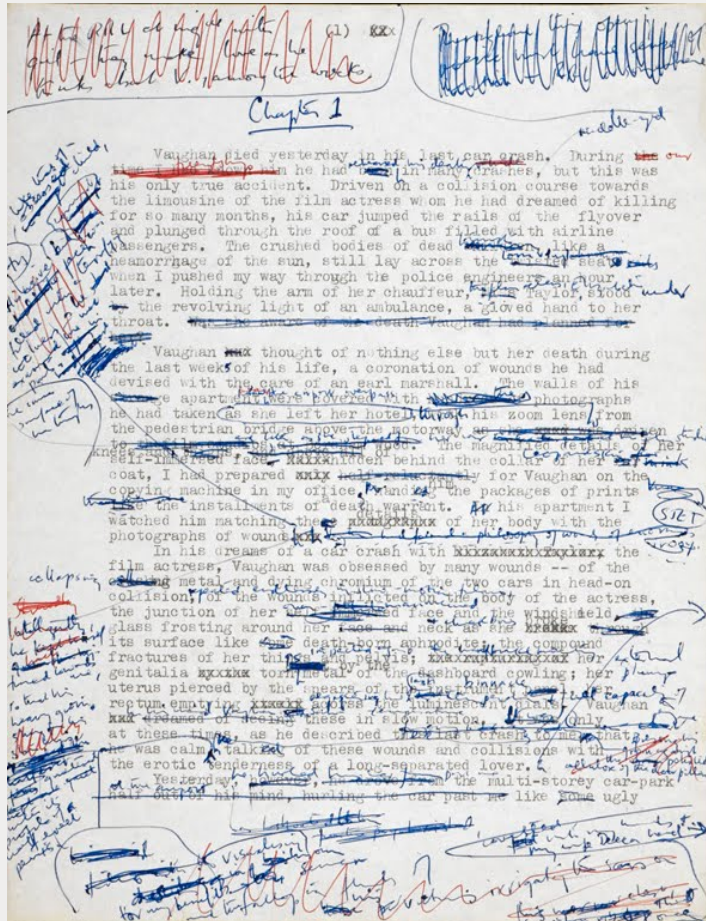
Immediate Reports



Institutional Policy

- If you are using the WCM DSMB you must also CC your Immediate Report to DSMB@med.cornell.edu
- The WCM DSMB will review the immediate report via email and provide an acknowledgment letter or request for additional information

Amendments



- Notify the WCM DSMB as soon as you are aware of any potential amendments to your protocol
- The WCM DSMB can provide guidance and make recommendations for any changes prior to IRB review



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Common Mistakes

Common Mistakes

- Protocol and eIRB application do not match
- Interim analysis is not submitted according to DSMP
- Protocol is submitted before/after threshold is met
- Enrollment tables do not include accrual from all sites participating in the study
- PIs signature is missing on AE/IND Cumulative Table and/or Periodic Report Form
- Missing attachments



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Questions?

Please direct any questions to DSMB@med.cornell.edu for a prompt response!