

## **Data Safety Monitoring Committee (DSMC) Initial Submission**

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The purpose of this information is to assist Weill Cornell Medicine (WCM) faculty and staff who are planning to conduct human subjects research that requires WCM Data Safety Monitoring Committee (DSMC) oversight. You are urged to read this information carefully to avoid unnecessary delay in obtaining WCM DSMC oversight approval.

Your study may require use of the WCM DSMC based on the criteria outlined in the [WCM DSMC SOP document](#). There may also be requirement for DSMC oversight stipulated in your grant award, FDA monitoring plan, or by your IRB of Record. It is your responsibility to request WCM DSMC oversight and provide an Initial Submission for review as outlined below.

Initial Submissions will be received by the DSMC on a rolling basis, and complete submissions will be placed on the next available scheduled DSMC meeting. Please review our scheduled meetings and submission deadlines on the DSMC website.

A complete submission is one that has been vetted by our DSMC administrators and deemed ready to be assigned to a DSMC member for review. All other submissions will NOT be assigned to a meeting until complete.

**It is your responsibility to provide a complete Initial Submission to the DSMC to obtain approval to initiate the study.**

If your study requires DSMC approval prior to a regularly scheduled meeting, you may request an Expedited Review, as outlined below. Expedited Review does not guarantee approval will be granted, and your study will still require review at a scheduled meeting before a determination letter will be provided. Please ensure to provide your complete Initial Submission as soon as possible to avoid delays in study start up.

If you have a question that is not answered below, visit the [DSMC website](#) or contact our administrative team at [DSMC@med.cornell.edu](mailto:DSMC@med.cornell.edu).

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### **Before you submit:**

- ☐ 1. Check whether your study requires WCM DSMC oversight based on the current SOP, available on the DSMC website.

If your study does not meet the requirements for oversight, your request for Initial Submission will be denied, and you will be asked to amend your protocol to remove mention of the WCM DSMC. **Please note that requirements differ between General and Cancer DSMC.**

- ☐ 2. Ensure that your protocol document clearly states WCM DSMC oversight will be used, and the proposed review frequency for periodic report submission.

Confirm the review frequency of your study is based on risk level as outlined in the monitoring plan or as approved by the Cancer PRMC.

- ☐ 3. Ensure that the WCM DSMC satisfies the requirements of your grant submission or FDA-approved monitoring plan, if applicable.

The WCM DSMC is an institutional committee and may not meet the requirements of membership or review frequency specified in your grant award or FDA monitoring plan. In such cases, it is the responsibility of the investigator to create a study specific DSMB to meet these data and safety monitoring needs. Ad hoc reviewers may be requested to supplement areas of expertise not present on

the DSMC. For more information on our membership and procedures, please see the DSMC SOP available on our website.

- ☐ 4. Prepare your charter document using our required template, available on the [DSMC website](#).

Ensure that you complete all required fields highlighted in **yellow background** before submission. Please submit an unsigned, word document version for review. In cases where highlighted sections are not applicable, please indicate NA below the section header.

- ☐ 5. *For all oncology studies:* Prepare your monitoring plan document using our required template, available on the [DSMC website](#).

Ensure that you complete all required fields highlighted in **yellow background** before submission. Please submit an unsigned, word document version for review. Monitoring frequency must be based on PRMC-approved risk level. Discrepancies will require correction before the DSMC will provide approval.

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### How do I request DSMC Oversight?

- ☐ 1. WCM DSMC oversight can be requested automatically in WRG-HS when completing the Protocol Initiation (Intake) Form. When prompted, select the WCM DSMC as the monitoring entity. This will trigger a basic email alert to the WCM DSMC listserv, including PI, IRB #, and Protocol Title. This will also trigger a requirement in the Study Activation Status Page (SASP) to submit to the WCM DSMC. For more information on SASP, see the What About SASP section below.
- ☐ 2. If you do not select DSMC oversight on your HS Protocol Initiation (Intake) Form, you will have to request DSMC oversight via a direct email request submitted to [DSMC@med.cornell.edu](mailto:DSMC@med.cornell.edu).
- ☐ 3. Requests for DSMC oversight will trigger a review process. If your study is applicable for DSMC oversight, you will receive confirmation via email by the DSMC administrators using the listserv [DSMC@med.cornell.edu](mailto:DSMC@med.cornell.edu).

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### How do I make an Initial Submission to the DSMC?

- ☐ 1. Once your request for DSMC Oversight has been approved, PIs and Study Teams must email the DSMC listserv directly with their Initial Submission documents for DSMC review.
- ☐ 2. The following documents are **required** for WCM DSMC review:
- Protocol document  
*Most current version, amendments may cause delays.*
  - ICF document
  - WCM Charter  
*Template document is available on the DSMC website.*
  - WCM Data and Safety Monitoring Plan (DSMP)  
*Required for Oncology studies using the Cancer DSMC only. If applicable, the template document available on the DSMC website must be used.*
- ☐ 3. **PRMC Approval is required ahead of initiation of DSMC review of the Initial Submission.** If your PRMC approval has not been obtained, the DSMC administrator will not begin review of your submission documents until approval can be confirmed.

- ☐ 4. If there is a reason the protocol requires an Expedited DSMC review, you must request via email, detailing the reason and timeline accordingly.
- The DSMC may provide approval to begin accrual prior to review of the study at a regularly scheduled DSMC meeting, depending on the submission quality and study risk level. Expedited approval is for accrual only and does not indicate study approval or departmental approval to initiate the study.
- ☐ 5. After submission of all required documents, the Initial Submission will go through a review process. When your submission is considered complete and has been assigned to a scheduled DSMC meeting, you will receive confirmation via email by the DSMC administrators using the listserv [DSMC@med.cornell.edu](mailto:DSMC@med.cornell.edu).

### **What about the Study Activation Status Page (SASP)?**

The Study Activation Status Page (SASP) is a dashboard where you can monitor a set of tasks and required activities which need to be completed for each of your study protocols. Depending on the specifics of the research, some requirements are not necessary, while others are always required:

- [Overview of The Study Activation Status Page \(SASP\)](#)

### **Questions/Concerns?**

For DSMC questions/concerns, please reach out to the DSMC Administrators at the listserv [DSMC@med.cornell.edu](mailto:DSMC@med.cornell.edu). Please ensure to include relevant information in your email subject line and body, including:

- ☐ WRG number (if available)
- ☐ PI Name
- ☐ Brief statement of issues
- ☐ Relevant deadlines