
Data Safety Monitoring Committee (DSMC) Periodic Report Submission

The purpose of this information is to assist Weill Cornell Medicine (WCM) faculty and staff who utilize the WCM Data Safety Monitoring Committee (DSMC) review for human subjects research. Studies using DSMC oversight have a requirement to submit periodic reports of study data and safety information. The review frequency of periodic reports ranges from every 2 months to annually, based on study risk level. The review frequency is captured in the study protocol and/or monitoring plan.

- Periodic reports will become due starting from the date of first subject enrollment.
- The frequency will be followed for the life of the study, until the end of DSMC oversight request has been acknowledged.
- The WCM DSMC recommends a periodic report be submitted for a meeting that falls *within* the review period to prevent a deviation from the protocol-approved frequency. For example, if your study review period ends on April 1st, submit your periodic report in time to make the February or March DSMC meeting at the latest.

A full list of scheduled DSMC meetings and submission deadlines are available on the [DSMC website](#) for the given calendar year.

- Meetings occur on the 3rd Wednesday of the month, alternating between General and Cancer DSMCs each month.
- Submission deadlines are 3 weeks prior to the scheduled meeting.
- DSMC administrators will provide reminders via email for studies that may have periodic reports coming due based on review frequency. These reminders will advise of upcoming submission deadlines 6 to 8 weeks prior to scheduled meetings and list the study number and PI.

It is ultimately your responsibility to track study review frequency and ensure timely submission to the DSMC.

It is recommended that you maintain a calendar of due dates for each of your studies and submit periodic reports well ahead of scheduled meetings (recommended 4 to 5 weeks prior) to allow for DSMC review and approval.

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. Failure to submit periodic reports to the DSMC review per the anticipated review frequency should be reported as a protocol deviation to the IRB.

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

Before you submit:

- ☐ 1. Confirm the review frequency of your study. Ensure to track your submission deadlines starting from the time of first subject enrollment.

How to find the review frequency of your study: Refer to your most recent IRB approved protocol, which will state the approved frequency for your study. The current approved protocol can be found in WRG-HS. *For Oncology studies only:* The monitoring plan will also outline the submission requirements of the study and anticipated frequency. The monitoring plan document should be saved in your Trial Master File (TMF).

- ☐ 2. Make sure that all subject accrual information (screening, enrolment, active, off-study) and safety information (adverse events, serious adverse events) have been entered in your Electronic Data

Capture (EDC) system. For multisite studies, work with your subsites to obtain information in a timely manner.

It is recommended that you lock your safety and accrual data **6 to 8 weeks prior** to the DSMC meeting you plan to submit for. This is to ensure that all summary information provided in your periodic report is complete and accurate.

- ☐ 3. Maintain cumulative, running logs for study deviations and adverse events (AEs)/serious adverse events (SAEs). Maintain descriptions of these events and their outcomes.

It is recommended that these logs, which will be requested as part of your periodic report, be maintained in real-time. For multisite studies, it is recommended that template logs be provided at the time of site activation, for local site study teams to maintain. All logs submitted to the DSMC are cumulative in nature and must contain all safety information and deviations from the start of the study to date of periodic report creation. The template forms can be found on the [Forms, Templates, & Guidance page of our website](#) under the Submission Templates & Checklists section. For AEs that are grade 3 – 5, maintain narratives per the guidance listed on the DSMC website. SAE cover sheets may be provided instead of narratives where applicable.

- ☐ 4. Be prepared with a summary of amendments to the protocol since the time of last periodic report. This must include any new and relevant information about your study, especially information associated with risk.

This summary can be found in the IRB application for the amendment in WRG-HS. Please specify if changes occurred due to new significant findings or risk to subjects. If yes, explain how subjects were informed and ICFs amended with these findings. Please be prepared to provide results or explain status of analysis. If accrual has not proceeded as expected, please be prepared to explain and provide strategies to improve accrual.

- ☐ 5. If you are requesting to amend your study review frequency, prepare draft versions of protocol and monitoring plan documents.

Please provide Word document versions of your protocol and monitoring plan with tracked changes of the proposed frequency for review. This does not include request to end DSMC oversight.

- ☐ 6. All documents submitted will be considered source documents and must comply with good clinical practice (GCP) requirements.

Ensure that your documents contain all relevant study information, including study number and PI name, and contain contemporaneous signature when attestation is required.

How do I submit my periodic report?

- ☐ 1. Make sure you have prepared all submission documents.

- Protocol Deviation Log
- Adverse Event & IND Safety Reporting Cumulative Table
- AE/SAE narratives
- Enrollment Summary Table or Multisite Enrollment Summary Table
Template enrollment documents are available on the [DSMC website](#)
- Current approved protocol document
- Current approved consent form(s)
- Current approved assent form(s)
- If applicable, Interim Analysis document(s)

- If applicable, Monitoring and Audit report(s)
- ☐ 2. Access the electronic periodic report form (ePRF) through RedCap using the following link:
https://redcap.ctsc.med.cornell.edu/redcap_protocols/surveys/?s=K38L4ARET7.
- ☐ 3. When you begin the form, you must enter the "Protocol Number" for the protocol under review prior to saving any information on the survey.
- ☐ 4. If you would like to save your completed work to return to later, you may select "Save & Return Later" at the bottom of the survey. Once you select "Save & Return Later", the survey will provide you with a Return Code. Write down, copy, or email the return code to yourself. You will need the code to continue where you left off.
 - NOTE: Failure to write down, copy, or email the return code to yourself can result in a delay of the submission. Contact dsmc@med.cornell.edu if you should need assistance with the Return Code.
- ☐ 5. Fill out and submit your ePRF. As you run through the form, note the following:
 - Questions are dynamic. Additional questions may populate based on how you answer.
 - Definitions for certain questions may appear within the field name or immediately below in **blue font**.
 - Required fields will be noted with *** must provide value** beneath the field name. Submission cannot occur until all such fields are completed.
 - Ensure that all attached documents meet GCP standards.
- ☐ 6. When prompted to provide Administrative Contact, please provide all personnel that are to receive DSMC correspondence related to the periodic report submission. This includes submission review queries as well as DSMC determination letter receipt.
- ☐ 7. Once you complete all required fields and have uploaded all attachments, you may select "Submit" to send the Periodic Report Form to the WCM DSMC.
 - You will not be able to return to the form once you submit it. Please review all data field entries for completeness and accuracy prior to submitting for review. When you've answered all questions, click the "Save + Complete" buttons at the top of the page.
- ☐ 8. Once you submit the report, you will be prompted to provide an email address for the confirmation email. If you do not receive a confirmation email, please contact dsmc@med.cornell.edu to confirm your submission was received. You also have the option of saving the completed form by clicking the download button below the return code. However, the downloading only saves the survey form and does not include the files attached to the form.
- ☐ 9. After submission, the periodic report 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.

Questions/Concerns?

For DSMC questions/concerns, please reach out to the DSMC Administrators at the listserv 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