Human Research Protections Researcher Checklist

Version Date: 9/1/2023

Data Safety Monitoring Committee (DSMC) Initial Submission

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 <u>DSMC website</u> or contact our administrative team at <u>DSMC@med.cornell.edu</u>.

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

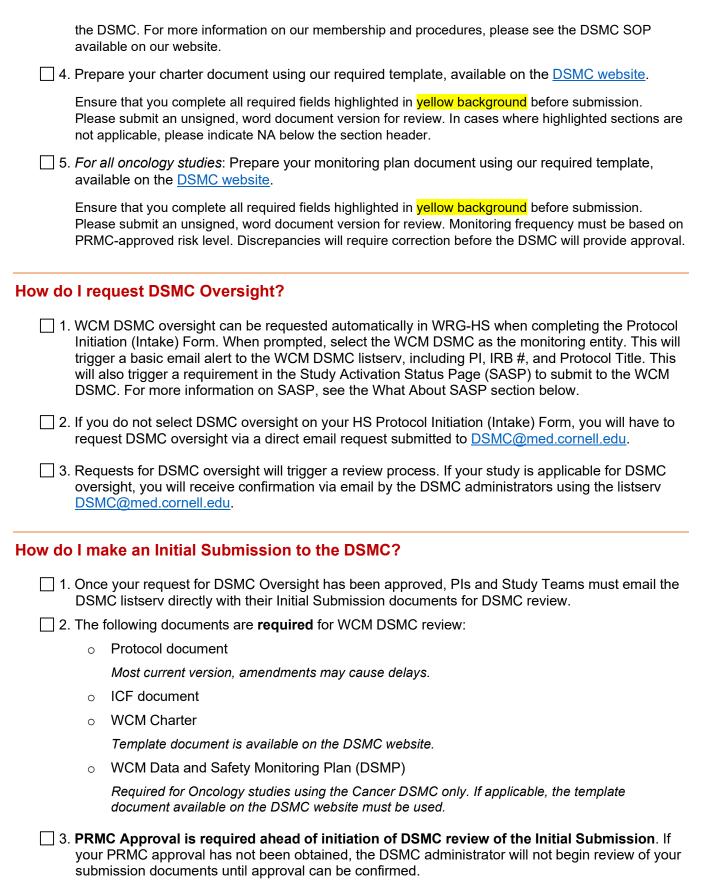
responsibility of the investigator to create a study specific DSMB to meet these data and safety

monitoring needs. Ad hoc reviewers may be requested to supplement areas of expertise not present on



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<u> </u>	. 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.	
<u> </u>	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 .	
at about the Study Activation Status Page (SASP)?		

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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:

o 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. 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