Office of Sponsor and Regulatory Oversight (OSRO)
Data and Safety Monitoring Boards (DSMBs) and CCR Principal Investigators (PIs)

OSRO DSMBs are convened by the authority of OSRO and are advisory to the CCR. The Protocol will include a section that briefly describes the DSMB and its activities. The DSMB Charter describes the standard operating procedure for the DSMB.

OSRO is supported by the Sponsor and Regulatory Oversight Support (SROS) contract. The Safety Oversight Support (SOS), part of the SROS contract, serves as the Executive Secretary to facilitate all communications and activities related to the DSMB. SOS is the meeting moderator for all DSMB Meetings, which are held virtually.

PI Responsibilities related to DSMB Meetings and Recommendations:

General:
- ➢ Attend scheduled DSMB Meetings. Designate an alternate, if unable to attend.
- ➢ Respond to SOS regarding preparation for Meetings and provide requested information.
- ➢ Access the secure SOS Committee Management System (CMS) to review DSMB Meeting materials. SOS will notify the PI once access is granted and will assist with any access issues.
- ➢ Communicate through SOS who serves as the DSMB Executive Secretary. Do not communicate directly with the DSMB Members outside of the DSMB Meetings, to avoid causing a potential conflict of interest and maintain the independence of the DSMB.

Initial DSMB Meeting for Protocol:
- ➢ Review the DSMB Charter prior to the Meeting.
- ➢ Provide and present a 10-minute Protocol Presentation to the DSMB. SOS will provide draft PowerPoint slides for the PI to modify and finalize.
- ➢ Respond to queries from the DSMB Members during the Meeting.

Periodic DSMB Safety Review Meeting:
- ➢ Review and provide critical comments on the draft Protocol Safety Summary Report prepared by the SROS Data Analytics Group.
- ➢ Immediately update the clinical database, as needed, to support generation of the Final Protocol Safety Summary Report.
- ➢ Do not attend the DSMB Safety Review Meeting regularly, however, must be available by phone during the Meeting to address study-related questions from the Members.

Post Meeting:
- ➢ Review and implement the DSMB Recommendations.
- ➢ If there is a recommendation that cannot be implemented, the PI will discuss with the OSRO Director and then provide to SOS, a written response to the DSMB with the rationale for not implementing the recommendation.
- ➢ Submit the DSMB Recommendations to the IRB.

If you have any questions, please contact SOS at SROS-SOS@tech-res.com or 202-830-2549 or Joni Love, OSRO Safety Oversight Coordinator, at joni.love@nih.gov or 240-281-3355.

Link to access the OSRO DSMB Wiki page at:
https://ccrod.cancer.gov/confluence/x/sICnE
Link to access the DSMB Meeting Calendar at:
https://ccrod.cancer.gov/confluence/x/2wW9Dw