Data and Safety Monitoring Board (DSMB) Standard Operating Procedures (SOP)

Obtaining Initial DSMB Oversight
1. DSMB Coordinator confirms that the protocol should be under MD Anderson DSMB Oversight and sends DSMB Oversight Letter to the PI and study staff notifying them of their responsibilities while the protocol is being monitored.
2. PI responds via PDOL generic memo accepting DSMB Oversight

Review and Approval of Modifications
1. PI and study staff submit modification via PDOL.
2. DSMB Coordinator administratively reviews modifications and if necessary sends to the DSMB Designee and Informed Consent Editor for review.
3. Once the review is completed, the modification can be either:
   a. Approved and handed over to the IRB
   b. Returned to the PI for more information or to make corrections. The PI would provide the information or make corrections and resubmit.

Activation and Annual Review
1. The PI submits an activation request, and the protocol is activated.
2. DSMB annual review would begin approximately 1 year after activation.
3. Two months prior to the review meeting date, the DSMB coordinator will notify the PI of their upcoming review.
4. The PI should provide the study statistician all pertinent cleaned data at least 30 days prior to the meeting.
5. The study statistician will complete a DSMB report and a PI report, and submit the DSMB report to the DSMB coordinator.
6. DSMB coordinator compiles all reports and pertinent information into the DSMB Agenda.
7. The PI and study statistician will present the study at the meeting. The PI will give a brief update on the progress of the study, accrual, adverse events, etc. during the open session. The study statistician will present the formal DSMB report during the closed session.

8. The DSMB holds executive session and make a formal motion.

9. The DSMB coordinator sends a memo with the formal motion via PDOL generic memo. If for some reason the PI is not in agreement with the motion, the PI has the option to request an appeal meeting with Dr. Buzdar, the IRB Chair, the DSMB Chair and the study statistician. If that is the PI’s prerogative, the PI should reach out to the DSMB coordinator requesting the appeal meeting. The DSMB coordinator will work to schedule the meeting as soon as possible with all necessary parties. The PI should forward this memo to the sponsor, if applicable, and keep in their regulatory binder. This memo should also be included in the study’s continuing review.

10. The DSMB coordinator sends a copy of the memo with the formal motion to the IRB of record.