External Data and Safety Monitoring Board (EDSMB) 
Standard Operating Procedures (SOP)

Obtaining Initial EDSMB Oversight

1. The Institutional Compliance Office sends a notification to the PI and study staff notifying them that the study is subject to an institutional conflict of interest management plan.
2. The EDSMB coordinator reviews the protocol in PDOL to see if an external DSMB has already been chosen and if monitoring milestones have been included. If necessary, the EDSMB coordinator reaches out to the PI and study staff to choose an external DSMB and incorporate monitoring milestones.
3. If the External MD Anderson DSMB is chosen as the monitor, the EDSMB sends an EDSMB Oversight Letter to the PI and study staff notifying them of their responsibilities while the protocol is being monitored.
4. PI responds via PDOL generic memo accepting EDSMB Oversight.

Review and Approval of Modifications

1. PI and study staff submit modification via PDOL.
2. EDSMB Coordinator administratively reviews modifications and if necessary sends to the EDSMB 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.

Annual Review

1. EDSMB annual review would begin approximately 1 year after an external IRB has taken on oversight.
2. Two months prior to the review meeting date, the EDSMB coordinator will notify the PI of their upcoming review.
3. The PI should provide the study statistician all pertinent cleaned data at least 30 days prior to the meeting.
4. The study statistician will complete an EDSMB report and a PI report, and submit the EDSMB report to the EDSMB coordinator.
5. EDSMB coordinator compiles all reports and pertinent information into the EDSMB Agenda.
6. 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 EDSMB report during the closed session.
7. The EDSMB holds executive session and make a formal motion.
8. The EDSMB 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 EDSMB Chair and the study statistician. If that is the PI’s prerogative, the PI should reach out to the EDSMB coordinator requesting the appeal meeting. The EDSMB 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, the external IRB, and keep a copy in their regulatory binder. This memo should also be included in the study’s continuing review.