

DATA AND SAFETY MONITORING REVIEW REQUIREMENTS FOR EXTERNALLY MONITORED STUDIES

Effective April 2015, all new submissions to the PRC of studies that are externally monitored will not require annual DSMC review unless otherwise determined by the Protocol Review Committee (PRC) or DSMC. Deviations and SAEs for all YCC trials will continue to be reviewed on a monthly basis.

The Principal Investigator or research team designee will update OnCore on an on-going and timely basis with all deviations and SAEs per the FDA definition (<http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm>) from the time of each subject's first intervention thru 30 days after the last intervention, unless the protocol dictates SAE reporting after consent or a longer follow-up period for SAE reporting.

The Principal Investigator in conjunction with the research team designee in each Disease Aligned Research Team (DART) will review monitoring reports from external sponsors to ensure that all applicable deviations and SAEs identified are entered into OnCore in order to facilitate a complete monthly report of SAEs and deviations for the DSMC review.

If DSMC review is required, the following will be submitted upon request:

Requirements for Industry-Sponsored Studies

- Study Narrative

Requirements for NCTN/ NCI CIRB Studies

- Study Narrative
- Most recent DSMB report and/or Study Report from sponsor

Requirements for External Investigator-Initiated Studies

- Study Narrative
- Most recent DSMB report and/or summary

Study Narrative Criteria (to be written, signed, and dated by PI)

- Objectives of the study
- Design & treatment administration
- Safety data
Summarize toxicity data of Yale subjects. If the sponsor has provided any updates on safety data of the study/ recent publishing of data, please include this information.
- Efficacy results
Summarize response data for Yale subjects. If the sponsor has provided any updates on efficacy data of the study/ recent publishing of data, please include this information.
- Conclusion and plans
- Verification of accuracy and completeness of OnCore- *OnCore DSMC Console Export Report** should be used to verify that all information in OnCore is up-to-date for committee review