

The Penn State Hershey Cancer Institute Data & Safety Monitoring Board Information Requirements

- 1) De Identified Enrollment List
- 2) List of Adverse Events, including grade, expected vs unexpected and related vs Unrelated for each participant from enrollment to present (form attached)
- 3) Documentation of Protocol Violations and Deviations
 -Submit Corrective Action Plan if Violations occurred
- 4) Statement as to whether there have been any breaches of confidentiality
- 5) Copy of Current IRB approved Protocol
- 6) Copy of Current IRB approved Consent Form
- 7) IRB Correspondence regarding the #5 and #6
- 8) Most recently submitted IRB Continuing Review form, including event log.

In addition to reviewing the above information, the DSMB will review interim analyses, if applicable, evaluate end point/stop point rules, review any updated IND information, and evaluate the aggregate analysis of adverse events, as applicable.

In order to accomplish a comprehensive review, the Board requires transcripts of any interim safety monitoring meetings held by the PI and co investigators. Please refer to your protocol and submitted DSMP for information regarding interim reviews.

Please be aware that the Board <u>may</u> request copies of clinical records of the study subjects if further information is required to complete the review.

All of the above information should be provided electronically to facilitate distribution and timely review and analysis.