TITLE: DSMC Data Submission Compliance	
SOP #: QA-724	**Page:** 1 of 2

Applicable Regulations & Guidelines:

Other References:

Responsible Personnel: DF/HCC Principal Investigator (PI), Site PIs, Study coordinators, Quality Assurance Office for Clinical Trials (QACT) Data Analysts, QACT DSMC Coordinator, DF/HCC DSMC

Policy Statement: The Overall DF/HCC PI is responsible for data compliance of all participating sites both within and outside DF/HCC for PI-Initiated trials.

Procedure:

1. The DF/HCC Data and Safety Monitoring Committee (DSMC) reviews data submission compliance by reviewing a) overall protocol percentage of total and toxicity forms missing and 2) all participating site specific total percentage of forms missing as reported on the QACT standardized Missing Form Reports.

   The DSMC defines data submission compliance as less than or equal to 10% of forms missing for both overall protocol compliance, as well as site specific compliance.

   In the event the percentage of forms is greater than 10%, but the total of number of forms missing is small, the DSMC Chair has the discretion to deem the trial compliant.

2. When protocols are identified as non-compliant with data submission during the DSMC meeting the following procedures, dependent on the percentage of missing forms, will be followed.

   <u>> 10% but <20% of data forms missing for the protocol or at any one site</u>

   1. Notice of percentage of forms missing and a reminder of data submission compliance criteria will be incorporated into the DSMC response memos.

   2. Protocol will be given a 3-month review and:

      a. If data compliant, protocol will be given next review based on DSMC recommendation of safety review.

      b. If remaining non-compliant at the 3-month DSMC review, a memo will be sent to the Overall PI, Site PI if applicable, study team and applicable clinical trial office defining deadlines for data submission compliance with the recommendation of accrual suspension (of protocol if overall % out of compliance or participating site accrual suspension if site % is out of compliance) if deadline is not met. The deadline given will be 2 weeks for ≤ 10% of forms missing. The memo will be e-mailed within 24 hours of the DSMC meeting.

If accrual is already closed for the protocol, the DSMC recommendation to the IRB will be to suspend activity on any new protocol submission for the Overall PI and Site PI, if participating site is out of compliance.

If the data deadline is not met within the stated 2 weeks, the QACT DSMC coordinator will submit a Closure to Accrual form on behalf of the DSMC to the IRB. If accrual is already closed on the protocol, a memo to the Director of the OHRS will be sent recommending suspension of activity on any pending protocols of the Overall PI and Site PI, if participating site is out of compliance.

No data analysis, abstract or publication of the trial may take place while the trial is out of data compliance.

In the event of special circumstances, the DSMC Chair has the discretion to lengthen the timeframes listed above.

c. The protocol will be reviewed quarterly for data submission compliance for one year.

<u>≥20% of data forms missing for the protocol or at any one site</u>

1. A memo will be sent to the Overall PI, Site PI if applicable, study team, Disease Program Leader and applicable clinical trial office defining deadlines for data submission compliance with the recommendation of accrual suspension (of protocol if overall % out of compliance or participating site accrual suspension if site % is out of compliance) if deadline is not met. The deadline given will be 2 weeks to render the study in compliance, i.e. ≤ 10% of forms missing. The memo will be e-mailed within 24 hours of the DSMC meeting.

   If accrual is already closed for the protocol, the DSMC recommendation to the IRB will be to suspend activity on any new protocol submission of the Overall PI and Site PI, if participating site is out of compliance.

   If the data deadline is not met, the QACT DSMC coordinator will submit a Closure to Accrual form on behalf of the DSMC to the IRB. If accrual is already closed on the protocol, a memo to the Director of the OHRS will be sent recommending suspension of activity on any pending protocols of the Overall PI and Site PI, if participating site is out of compliance.

   No data analysis, abstract or publication of the trial may take place while the trial is out of data compliance.

   In the event of special circumstances, the DSMC Chair has the discretion to lengthen the timeframes listed above.

2. The protocol will be reviewed quarterly for data submission compliance for one year.