TITLE: Data and Safety Monitoring Committee (DSMC) Data Submission Compliance		
SOP #: DATA-104 *(formerly QA-724)*	**Page:** 1 of 4	**Effective Date:** 3/1/14

1. POLICY STATEMENT:

The Overall Principal Investigator (PI) is responsible for data compliance of all participating sites both within and outside DF/HCC for PI-Initiated research.

2. BACKGROUND:

None

3. RESPONSIBLE PERSONNEL:

3.1. Sponsor
3.2. Overall Principal Investigator (PI)
3.3. Site Responsible Investigator
3.4. Study Coordinator
3.5. Quality Assurance Office for Clinical Trials (QACT) Data Analyst
3.6. QACT Data and Safety Monitoring Committee (DSMC) Coordinator
3.7. DF/HCC DSMC Chair

4. DEFINITIONS:

None

5. PROCEDURE:

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

5.1.1. The DSMC defines data submission compliance as less than or equal to 10% of total forms missing for both overall protocol compliance and site specific compliance. Toxicity reporting as a sub-category of missing forms will also be held to the less than or equal to 10% threshold for site specific compliance.

5.1.2. In the event the percentage of total missing forms and site specific toxicity forms is greater than 10%, but the total of number of forms missing is small, the DSMC Chair has the discretion to deem the protocol compliant.

5.2. 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.

5.2.1. If a protocol has > 10% but ≤20% of total forms missing for the overall protocol or toxicity forms missing at any one site:

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

5.2.1.2. The protocol will be given a 3-month review and:

5.2.1.2.1. If the protocol data is compliant, the protocol will be assigned its next review date based on DSMC recommendation of the safety review.

5.2.1.2.2. If the protocol remains non-compliant at the subsequent 3-month DSMC review, an email memo will be sent no later than the next business day (Monday – Friday) to the Sponsor, Overall PI, Site Responsible Investigator (if applicable), designated research team member and applicable clinical trials office defining deadlines for data submission compliance and consequences for failure to comply. Data must be compliant (<10% of total forms missing and <10% of site specific toxicity forms missing) within 2 calendar weeks after the DSMC meeting.

5.2.1.2.3. If the data compliance deadline is not met within 2 calendar weeks the following actions will be applied:

5.2.1.2.3.1. For protocols open to accrual where the overall % of missing forms is out of compliance, accrual will be suspended at **ALL** sites. The QACT DSMC coordinator will submit a Closure to Accrual form on behalf of the DSMC to the Institutional Review Board (IRB).

5.2.1.2.3.2. For protocols open to accrual where a specific site(s) is out of compliance, accrual will be suspended at the specific site(s). The QACT DSMC coordinator will submit a Closure to Accrual form on behalf of the DSMC to the IRB.

5.2.1.2.3.3. For protocols already closed to accrual, the QACT DSMC coordinator will send a memo to the Director of the Office for Human Research Studies (OHRS) recommending suspension of activity on any pending protocols of the Sponsor, Overall PI and/or Site Responsible Investigator where applicable.

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

5.2.1.2.5. The DSMC Chair has the discretion to lengthen the timeframes listed above.

5.2.1.2.6. The protocol will be tracked for data submission compliance for one year.

5.2.2. If the protocol has >20% of total forms missing for the protocol or toxicity forms missing at any one site:

5.2.2.1. An email memo will be sent no later than the next business day (Monday – Friday) to the Sponsor, Overall PI, Site Responsible Investigator (if applicable), designated research team member, and applicable clinical trials office defining deadlines for data submission compliance and consequences for failure to comply. Data must be compliant (<10% of forms missing) within 2 calendar weeks after the DSMC meeting.

5.2.2.2. If the data compliance deadline is not met within 2 calendar weeks the following actions will be applied:

5.2.2.2.1. For protocols open to accrual where the overall % of missing forms is out of compliance, accrual will be suspended at **ALL** sites. The QACT DSMC coordinator will submit a Closure to Accrual form on behalf of the DSMC to the IRB.

5.2.2.2.2. For protocols open to accrual where a specific site(s) is out of compliance, accrual will be suspended at the specific site(s). The QACT DSMC coordinator will submit a Closure to Accrual form on behalf of the DSMC to the IRB.

5.2.2.2.3. For protocols already closed to accrual, the QACT DSMC coordinator will send a memo to the Director of the OHRS recommending suspension of activity on any pending protocols of the Sponsor, Overall PI and/or Site Responsible Investigator where applicable.

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

5.2.2.4. The DSMC Chair has the discretion to lengthen the timeframes listed above.

5.2.2.5. The protocol will be tracked for data submission compliance for one year.

6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Subjects
21 CFR 54 – Financial Disclosure by Clinical Investigators
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
21 CFR 812 - Investigational Device Exemptions
45 CFR 46 – Protection of Human Subjects
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811

7. RELATED REFERENCES:

International Conference on Harmonization – E6

8. RELATED FORMS & TOOLS:

None