**UNMC FRED & PAMELA BUFFETT CANCER CENTER**

***Data and Safety Monitoring Committee***

***Report for Pilot, Phase 2 and Phase 3 Studies***

**IRB#** Choose an item. **PI:** Choose an item.

**TITLE:** Choose an item.

**Report date:** Click or tap to enter a date. **Date of last DSMC Review:** Click or tap to enter a date.

**SECTION I: PROTOCOL STAFF**

**Study Coordinator:** Choose an item.

**Study Nurse:** Choose an item.

**Personnel responsible for report:** Choose an item.

**SECTION II: PROTOCOL STATUS**

[ ]  Open to Accrual

[ ]  On Hold

 On Hold Date: Click or tap to enter a date. Hold Reason: Click or tap here to enter text.

[ ]  Study Closed to Accrual (CTA) – subjects on study-related therapy

 CTA date: Click or tap to enter a date. CTA Reason: Click or tap here to enter text.

[ ]  Study CTA – all subjects off study-related treatment (*Final Scheduled Report*)

 Date last subject received study-related treatment: Click or tap to enter a date.

**SECTION III: SINGLE OR MULTI-SITE STUDY**

[ ]  Single Site Study (If single site study – do no complete the rest of Section III)

[ ]  Multi-Site Study (If Multi-Site Study, list all participating sites)

 Sites: Click or tap here to enter text.

**SECTION IV: ACCRUAL – SINCE LAST SCHEDULED REVIEW and OVERALL**

1. **Newly enrolled patients since last scheduled DSMC review:**
	1. Number of new subjects registered at UNMC since last scheduled DSMC review:

Click or tap here to enter text.

* 1. Number of new subjects enrolled at each participation site since last scheduled DSMC review:

Click or tap here to enter text.

* 1. Number of new subject enrolled at all sites including UNMC since last scheduled DSMC review:

Click or tap here to enter text.

1. **Total number of subjects enrolled since study activation:**
	1. Total number of subjects enrolled on study at UNMC since activation:Click or tap here to enter text.
	2. Total number of patients enrolled at each participating site since activation:Click or tap here to enter text.
	3. Total number of patients enrolled at all sites including UNMC since activation:Click or tap here to enter text.

**SECTION V: TOTAL ENROLLED, WITHDRAWN and INELIGIBLE SINCE ACTIVATION**

Provide the following information:

| **Site** | **Total enrolled & received treatment** | **Total withdrawn without receiving treatment** | **Total found to be a screen failure** |
| --- | --- | --- | --- |
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**SECTION VI:** INTERIM ANALYSIS (IA) and STOPPING RULES

1. Does the protocol include an interim analysis? *If yes, answer items 1 and 2 below*

[ ]  Yes [ ]  No

1. Provide IA as defined in the protocol: Click or tap here to enter text.
2. Provide the time-frame for completing the IA: Click or tap here to enter text.
3. Does the protocol contain a stopping rule for safety?

[ ]  Yes [ ]  No *If yes, answer item 1 below.*

1. Provide details as outline in the protocol: Click or tap here to enter text.
2. Does the protocol contain a stopping rule for efficacy?

[ ]  Yes [ ]  No *If yes, answer item 1 below.*

1. Provide details as outlined in the protocol: Click or tap here to enter text.

**SECTION VII: ADVERSE EVENT REPORTING WORKSHEET**

Complete and attach an Adverse Event Reporting Worksheet (template located on the PRMS website), listing all reportable adverse events. If this study is a Multi-Site protocol, include all reportable adverse events from *all sites*.

Worksheet must include:

1. The subjects Study ID (including site ID) and initials (if necessary). **DO NOT USE MRNs**
2. The Site where the subject enrolled.
3. The **CTCAE term** required to define the event.
4. New events, not found on previous report: Place an asterisk (\*) before the CTCAE term to mark new events.
5. The state Date of the AE/SAE.
6. The end Date of the AE/SAE.
7. The Attribution of the AE/SAE.

Please note: If an update has been made to a previously reviewed event, place a strike through (~~abc~~) on the event and type the update on the same line as the previous event. In the comment section, state why a change was made.

Click or tap here to enter text. Click or tap to enter a date.

Printed name of person completing report Date

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Signature of Principal Investigator Date