**UNMC FRED & PAMELA BUFFETT CANCER CENTER**

***Data and Safety Monitoring Committee***

***Report for Phase 1 Studies***

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

**TITLE:** Choose an item.

**Report date:** Click or tap to enter a date.

**Date last review Submitted:** 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 (*only for Multi-Site studies*): Click or tap here to enter text.
	2. Number of new subject enrolled at all sites including UNMC since last scheduled DSMC review (only for Multi-Site studies): 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 (*only for Multi-site studies*):Click or tap here to enter text.
	3. Total number of patients enrolled at all sites including UNMC since activation (*only for Multi-site studies*):Click or tap here to enter text.

**SECTION V: TOTAL ENROLLED, WITHDRAWN and INELIGIBLE SINCE ACTIVATION**

Provide the following information: (If this is Single-Site study, *do not complete the Multi-Site section*)

|  |  |  |  |
| --- | --- | --- | --- |
| **Site** | **Total # enrolled at UNMC** | **Total # withdrawn without receiving****treatment at UNMC** | **Total # ineligible at UNMC** |
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**SECTION VI: FOR *MULTI-PHASE* STUDIES ONLY – TOTAL ENROLLED, WITHDRAWN and INELIGIBLE**

Current enrollment to each phase of this protocol:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Phase** | **Date last subject was** **enrolled to this phase** | **Total # of subjects enrolled** **to this phase**  | **Total # of subjects enrolled** **to this phase** | **Total # of subjects** **enrolled to this phase** **at all sites** |
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**SECTION VII:** INTERIM ANALYSIS (IA) and STOPPING RULES

1. Does the protocol include an interim analysis?

[ ]  Yes [ ]  No *If yes, answer items 1 and 2 below..*

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: DOSE LEVEL(S) STUDIED AT EACH PARTICIPATING SITE**

Provide the following information separately for each dose level studied at each participating site:

Dose level(s) studied at UNMC:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Dose Level*** | ***Dose & Schedule of Agents*** | ***Total # of subjects enrolled at this dose/schedule*** | ***Total # of subjects withdrawn without receiving treatment*** | ***Total # ineligible***  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

***For Multi-Site Studies ONLY: (duplicate the table for each participating site)***

**Participating Site:** Click or tap here to enter text.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Dose Level*** | ***Dose & Schedule of Agents*** | ***Total # of subjects enrolled at this dose/schedule*** | ***Total # of subjects withdrawn without receiving treatment*** | ***Total # ineligible***  |
|  |  |  |  |  |
|  |  |  |  |  |
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**2nd Participating Site:** Click or tap here to enter text.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Dose Level*** | ***Dose & Schedule of Agents*** | ***Total # of subjects enrolled at this dose/schedule*** | ***Total # of subjects withdrawn without receiving treatment*** | ***Total # ineligible***  |
|  |  |  |  |  |
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**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 to enter a date.

Signature of person completing report Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Click or tap to enter a date.

Signature of Principal Investigator Date