**UNMC FRED & PAMELA BUFFETT CANCER CENTER**

***Data and Safety Monitoring Committee***

***Dose Level Change Report – For Phase 1 Protocols***

**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: INSTRUCTIONS**

1. Previous dose level being studied**:** Click or tap here to enter text.
2. Current dose level being studied: Click or tap here to enter text.
3. Date of change from previous dose to current dose: Click or tap to enter a date.
4. Reason for change: Click or tap here to enter text.
5. Provide the following information separately for each dose level studied:

Note: For studies sponsored by UNMC (*whether being conducted only at UNMC or at one or more additional participating institutions*) include information on **all subjects registered at all participating sites**.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Dose Level | Agent Name, Dose &Schedule | # Enrolled per Dose Level | Date of Dose Level Change | Reason for Dose Level Change (i.e. per protocol, MTD, DLT) |
|   |   |   |   |   |
|   |   |   |   |   |
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Signature of person completing report Date

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Signature of Principal Investigator Date