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| **RG#:       Principal Investigator:** |
| **Protocol Title:       Date Form Completed:** |

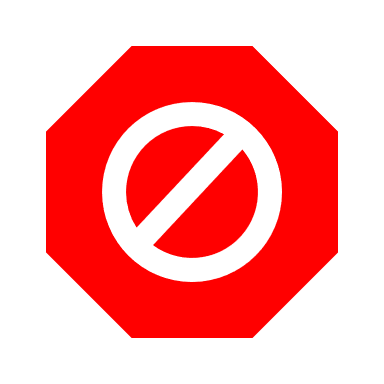
**The information provided in this form should be in accordance with the**

**Data and Safety Monitoring Plan written in the protocol.**

**Submit completed form and attachments to Clinical Research Support at** [**DSM@fredhutch.org**](mailto:DSM@fredhutch.org)**.**

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| **A. Summary of progress since the last DSMC review:** |
| **Summary:**  **Total Subjects Enrolled to Date:** |

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| **B. Data and Safety Monitoring Board (DSMB)** |
| **Does this study have an independent data monitoring committee (DMC) or DSMB that has met in the last year?**  **Yes** – Submit a copy of any available DSMB Result Letters, along with applicable meeting minutes and DSMB reports since the last DSMC review.  **No** – Complete sections C – J  **How often does the DSMB meet?**  Monthly  Quarterly  Biannually  Annually  Other (please elaborate):  **Next DSMB review will occur:**  **Additional Notes:** |



Only complete the following sections if the study does not have a DSMB

OR

the study has a DSMB that did not meet in the last year

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| **C. Adverse Events (AEs)** |
| Provide all AEs that have occurred since the study opened. |
| None – Subjects were followed, as described in the protocol, and no AEs were reported. |
| AEs were reported and a cumulative table organized by type and grade, as described in the protocol, is provided below.   * + - * Report must include the category; toxicity; grade and number of events.       * For multicenter studies where the Cancer Consortium is not the coordinating center, report only local events.       * For multicenter studies where the Cancer Consortium is the coordinating center, report study wide events.       * Include Grade 5 events for reporting number of deaths on study. |
| Number of subjects represented in the AE table below: |

*Example Table 1: Adverse Events*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| *Category (CTCAE)* | *Adverse Event/Toxicity* | *Grade and Number (N) of events* | | | | |
| *1* | *2* | *3* | *4* | *5* |
| *Gastrointestinal Disorders* | *Nausea* |  | *1* | *2* |  |  |
| *Gastrointestinal Disorders* | *Pancreatitis* |  |  |  | *1* |  |
| *Vascular disorders* | *Hypertension* |  | *3* |  |  |  |

*Example Table 2: Adverse Events*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Category* | ***CTC Term*** | ***Grade*** | ***Number of Events*** | ***Maximum Attribution*** |
| *Gastrointestinal Disorders* | *Nausea* | *3* | *8* | *Unlikely* |
| *Gastrointestinal Disorders* | *Pancreatitis* | *4* | *1* | *Possibly* |
| *Vascular Disorders* | *Hypertension* | *2* | *4* | *Unrelated* |

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| **D. Serious Adverse Events (SAEs)** | | | | | |
| Provide the SAEs with expedited reporting to the IRB since the study opened. | | | | | |
| **None** | | | | | |
| **Subject ID#** | **Serious Adverse Event** | **IRB Report Date** | **Agent** | **Subject Initial Outcome** | **Description** |
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| **E. Primary Endpoint** |
| The primary endpoint is |

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| --- | --- | --- |
| **F. Dose Escalation  Not Applicable** | | |
| **Dose Escalation (or multi-dose level) definition:**  For each subject enrolled to date, provide cohort and dose assignment.  Add rows as needed so that each subject enrolled to date is represented in their own row.  If a dose modification as per protocol was used, indicate the dose level and modification. | | |
| **Subject ID#** | **Cohort** | **Study Drug Dose Level/Modification** |
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| **G. Dose Limiting Toxicities (DLT)  Not Applicable** | | | |
| **Provide the dose limiting toxicity (DLT) definition** |  | | |
| **The DLT definition can be found in the protocol on page(s):** |  | | |
| **Identify DLTs** (add more rows, if needed): | Dose Level | Total # of Subjects at dose level | Total # of Subjects Experienced DLT |
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| **H. Study Stopping Rules  Not Applicable** | | |
| **Provide protocol-defined stopping rules** |  | |
| **Study stopping rules can be found in the protocol on page(s):** |  | |
| **Have any study stopping rules been met?** | Yes  No | |
| **Identify events that count toward stopping rule** (add more rows, if needed)**:** | Stopping rule: | # of Subjects/Events met Stopping Rule |
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| **I. Deaths of Subjects** |
| **Have there been any deaths of study subjects (for any cause) since the study opened?**  **No**  **Yes**        total deaths        unrelated to treatment        related to treatment  If unknown cause of death, please explain: |

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| **J. Unanticipated Problems** | | |
| Provide the unanticipated problems reported to the IRB since the study opened. | | |
| **None** | | |
| **RNI#** | **IRB Report Date** | **Description** |
|  |  |  |
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