Yale CANCER CENTER
A Comprehensive Cancer Center Designated by the National Cancer Institute

Data & Safety Monitoring Review PI Narrative Form for Yale Investigator-Initiated Studies

Version 2
Revised: 2/14/2018

Instructions: Please complete the following form in its entirety. Note n/a whenever necessary.

Submission Requirement:

- PI Narrative Form
- Supporting safety data from Biostat Console in OnCore *(if applicable, see question #4a for instructions)*
- Supporting safety data from sponsor *(if applicable, see question #4a for instructions)*

Date: **HIC #:** **PI:**

Title:

1. Describe the objectives of the study.

2. Describe the study's design and treatment administration.

PHASES(S)/COHORT(S)

3a. If the study has multiple phases, which phase(s) are you participating in?

3b. If the study has cohorts, which cohort(s) are you participating in?

SAFETY DATA:

4a. Are the AEs for this protocol viewable in the DSMC Console in OnCore?

◯ Yes

◯ No

If no, please provide supporting safety data via the Biostat Console in OnCore.
Instructions: eCRFs/Calendars --> Biostat Console --> Data Export --> AE Form *click on export and export to excel and submit as a separate attachment with this form.*
If this information is not available through the Biostat Console, please provide a summary of the AEs from the sponsor.

4b. How many SAEs have been reported in each cohort?

4c. Have any of the SAEs been unexpected and related? *If yes, provide a detailed explanation of the event(s).*

4d. How many deaths have occurred on study? *Include the site and if deemed related for each death?*

4e. Are there updated or new toxicity concerns regarding the investigational products(s) not previously specified in the protocol? If yes, please provide a detailed explanation.

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5. Describe the Dose Limiting Toxicities (DLTs). (Phase I studies)
Describe in detail protocol specific DLTs and if any DLTs have been observed to date.
Definition: Describes side effects of a drug or other treatment that are serious enough to prevent an increase in dose or level of that treatment.

6. Summarize the Efficacy Results.
Summarize response data for Yale subjects. If the sponsor has provided any updates on efficacy data of the study/ recent publishing of data, please include this information.

STOPPING RULES:

7a. What are the study specific stopping rules?
Definition: in randomized controlled trials and other systematic experiments on human subjects, rules laid down in advance that specify conditions under which the experiment will be terminated, unequivocal demonstration that one regimen in a randomized controlled trial is clearly superior to the other, or that one is clearly harmful.

7b. Have the stopping rules been met?

- ◯ Yes
- ◯ No

7c. Provide a detailed explanation on how the stopping rules have been met or have not been met. Include the subjects' responses and/or toxicities with regards to the stopping rules.

7d. What is the current accrual? ☐

Per DSMC Charter: For investigator-initiated trials led by Yale that have a two-stage design with stopping rules, the Principal Investigator will submit a summary of progress to date outlining responses or other criteria used in the protocol to determine moving to the second stage of the trial.

☐ I acknowledge that **prior to beginning accrual to the second stage, I will submit summary of progress and data to the DSMC for review. During this time the study will be suspended in OnCore until DSMC approves the study to continue as planned.**

☐ I confirm that the protocol is not Yale investigator-initiated and/or does not have a two-stage design with stopping rules.

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8. Please state your conclusions to date and future plans for this study.

9. Have at least 90% of the eCRFs been completed?

- No more than 10% of the eCRF data should be outstanding at any given time while the trial is active.
- Calculation= (*To Do Forms + Started Forms) ÷ (Total # of Forms- Planned # of Forms)*

◯ Yes ◯ No

Additional comments:

10. Has OnCore been verified for accuracy and completeness?
OnCore DSMC Console Export Report should be used to verify that all information in OnCore is up-to-date for committee review

◯ Yes ◯ No

Additional comments:

11. Is the information provided in this form the most recent information? *i.e. the most recent information since the last report to the DSMC*

◯ Yes
◯ No

If no, please explain:

Enter digital signature here:
(or print & sign document)

As a reminder...
Per the DSMC Charter, Trials being monitored by the YCC DSMC will remain under the YCC DSMC purview until a DSMC review has occurred that includes the research activity of the last subject who completed the intervention, or until the DSMC feels there are no patient safety concerns that require further monitoring. The DSMC will determine the length of continued DSMC review on a study-by-study basis. Typically for studies without external monitoring, such as investigator-initiated trials, the protocol specific Data and Safety Monitoring Plan includes DSMC review every six months.