**Instructions:** Review Section I: Accrual Monitoring Report and accompanying Closure Recommendation Notice for the study referenced below which is under consideration for closure by the Yale Cancer Center (YCC) Protocol Review Committee (PRC) due to low or no accrual. Complete Section II: Principal Investigator Assessment and Justification then submit form to PRC via ePRMS in OnCore by the deadline noted in the Closure Recommendation Notice.

**Section I: Accrual Monitoring Report**

Date of Accrual Monitoring Report:

HIC # Principal Investigator:

Study Title:

Yale Open to Enrollment Date:

Actual Months Open to Accrual: :

Percentage of Target Accrual Rate:

*See Figure 1.0 for the percentage of target accrual rate formula and Figure 2.0 for the Accrual Monitoring assessment schedule.*

Accrual Monitoring History:

**Section II: Principal Investigator Assessment and Justification**

1. Overall Assessment:

Agree with recommendation to close the study to accrual permanently.

Disagree with recommendation to close the study to accrual permanently. Please answer questions below.

1. Why should the study remain open to accrual?
2. What strategies will be used to increase accrual in the next three (3) months?
3. Are there competing protocols? *(If yes, complete the table below for all competing protocols.)*

\_\_ Yes

\_\_ No

| **HIC #** | **Short Title** | **Date Open to Accrual** | **Accrual Goal** | **# Enrolled to Date** | **Expected Closure Date** | **Comments on how priority will be assigned** |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**FOR OFFICE USE ONLY:**

**PRC Reviewer’s Name:**

Principal Investigator did not provide a response.

**Recommended Decision:**

Recommend closure

Do not recommend closure

Re-evaluate in three (3) months

Re-evaluate in six (6) months

*Provide explanation:*

**Additional Comments** *(optional)*:

**Addendum 1: Re-review Following Extension**

**FOR OFFICE USE ONLY:**

Date of Re-Review:

Duration of Extension:

Accrual during Extension:

Percentage of Target Accrual Rate:

**Recommended Decision:**

Recommend closure

Do not recommend closure

*Provide explanation:*

# Figure 1.0 Percentage of Target Accrual Rate Calculation

Calculation of Percentage of Target Accrual Rate:

Actual Accrual Target Accrual Goal

÷

Current # of days open Expected Duration (days)

= .2420 or 24%

365

377

÷

8

2

**Example:** A trial has an expected accrual duration of *365* days with an expected accrual of *8*

study participants. At the time of review, the trial has been open *377* days with *2* accruals to date. Since the trial has been open for more than 12 months with only 24% of the target accrual rate reached, the trial will be issued a closure notice.

# Figure 2.0 Accrual Monitoring Assessment Schedule from Accrual Monitoring Policy

|  |  |  |
| --- | --- | --- |
| **Assessment Time** | **Percentage of Target Accrual Rate** | **Action** |
| 3 months | 0% | Notice |
| 6 months | 0% | Warning |
| 9 months | 0% | Closure Recommendation |
| 9 months | < 30% | Warning |
| 12 months | < 30% | Closure Recommendation |
| 15 months | < 40% | Warning |
| 18 months | < 40% | Closure Recommendation |
| 21 months | < 50% | Warning |
| 24 months | < 50% | Closure Recommendation |

After 24 months open, trials continue to be evaluated for accrual rate and will receive warning letters at 27 and 33 months and closure recommendations at 30 and 36 months if not meeting > 50% of target accrual. Studies open to accrual longer than 36 months will continue to be evaluated for accrual rate every six months. Those studies not meeting > 75% of target accrual will receive warning letters and may receive a closure recommendation at the discretion of the PRMS.