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|  | Department of Health & Human Services | Public Health Service  National Institutes of Health  National Cancer Institute  Bethesda, Maryland 20892 |

# PROTOCOL STATUS UPDATE FORM

The National Cancer Institute, as a sponsor of clinical trials, reviews the status of each clinical trial on an ongoing basis. To help us update our records, prioritize resources, and evaluate development plans for each agent, please complete the form below to update NCI on the status and status date of your study.

**Please e-mail this form to the corresponding Protocol and Information Office:**

**DCP sponsored studies:** [**nci\_dcp\_pio@mail.nih.gov**](mailto:nci_dcp_pio@mail.nih.gov)

**DCTD/CTEP sponsored studies:** [**pio@ctep.nci.nih.gov**](mailto:pio@ctep.nci.nih.gov)

**NCI Protocol #:**

**Today’s Date:**

**Protocol Title:**

**Name of person completing this form:**

*Select each applicable change and provide the corresponding date. More than one status may be filled in:*

# PRIMARY COMPLETION DATE

Definition: The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated. The Primary Completion date must be on or after the Closed to Accrual and Treatment date and must be on or before the Completed date.

## **Required: Please choose either #1 or #2:**

**#1:** Anticipated primary completion date:

**#2:** Actual primary completion date:

# ****ACTIVE****

## **Date of status change:**

Definition: Trial is open to accrual. (Equivalent to the clinicaltrials.gov status definition of “Recruiting”)

# TEMPORARILY CLOSED TO ACCRUAL

## **Date of status change:**

Definition: Trial is temporarily not accruing. (Equivalent to the clinicaltrials.gov status definition of “Suspended”)

## **Required: Please choose one reason from the options below:**

Scheduled interim monitoring  Drug supply issues

Unacceptable toxicity  Other (specify):

# TEMPORARILY CLOSED TO ACCRUAL AND TREATMENT/ INTERVENTION

## **Date of status change:**

Definition: Trial is temporarily not accruing and patients are not receiving therapy/ intervention. (Equivalent to the clinicaltrials.gov status definition of “Suspended”)

## **Required: Please choose one reason from the options below:**

Scheduled interim monitoring  Drug supply issues

Unacceptable toxicity  Other (specify):

# CLOSED TO ACCRUAL, PATIENTS STILL ON TREATMENT/ INTERVENTION

## **Date of status change:**

Definition: The protocol has been closed to patient accrual. Patients are still receiving therapy/ intervention. (Equivalent to the clinicaltrials.gov status definition of “Active, Not Recruiting”)

## **Required: Please choose either #1 or #2:**

**#1:** Study has 90% of projected total accrual (if pilot, phase 0, 2, or 3) or Recommended Phase II Dose (RP2D) established (if phase 1)

**#2:** Study has less than 90% of projected total accrual (if pilot, phase 0, 2, or 3) or Recommended Phase II Dose (RP2D) not established (if phase 1)

## **Required for #2: Please select the reason. No more than one can be selected:**

Interim monitoring  External information

Drug supply issues  Unacceptable toxicity

Inadequate accrual rate  Other (specify):

# CLOSED TO ACCRUAL, ALL PATIENTS HAVE COMPLETED TREATMENT/ INTERVENTION

## **Date of status change:**

Definition: The protocol has been closed to patient accrual. All patients have completed therapy/ intervention, but patients are still being followed according to the primary objectives of the study. No additional investigational agents are needed for this study. (Equivalent to the clinicaltrials.gov status definition of “Active, Not Recruiting”)

# COMPLETED

## **Date of status change:**

Definition: The protocol has been closed to accrual, all patients have completed therapy, and the study has met its primary objectives.

# FDAAA/IRB COMPLETED

## **Date of status change:**

Definition: The study has concluded normally; participants are no longer being examined (including any long-term follow-up) or treated (i.e., last patient's last visit has occurred) and analysis of data has been completed. The FDAAA/IRB Completed date must be on or after the Completed date. (Equivalent to the clinicaltrials.gov status definition of “Completed”)

# ADMINISTRATIVELY COMPLETED

## **Date of status change:**

Definition: The protocol has been completed prematurely (e.g., due to poor accrual, insufficient drug supply). The trial is closed to further accrual and all patients have completed protocol treatment. (Equivalent to the clinicaltrials.gov status definition of “Terminated”)

## **Reason for Administratively Completed:**