1. **This amendment is being submitted as:**

Expedited Amendment Review *(all changes fall under expedited amendment review)*

Full Amendment Review *(at least 1 change falls under the criteria for full amendment review)*

1. **Please mark off *all* of the changes corresponding to this amendment. If an amendment DART form is required based upon the table below, please complete form starting on page 2:**

|  | **Type of Amendment**  **Description/example**  **(not inclusive of all examples)** | **Review Type** | | **Amendment DART Form Required – See page 2** |
| --- | --- | --- | --- | --- |
| **Expedited Amendment Review** | **Full Amendment Review** |
| **Study Design Changes** | Activating an additional arm/cohort | n/a |  | Yes\* |
| Addition of a phase | n/a |  | Yes\* |
| Protocol is a Phase I/II study and is moving from Phase I to Phase II\* | n/a |  | Yes\* |
| **Eligibility** | Significant changes such as adding or opening/ activating an additional or new disease areas**\*** or updates reflecting a change in standard of care, etc. | n/a |  | Yes\* |
| **Study Drug** | Adding and/ or removing an intervention (drug, surgery, radiation, etc.) | n/a |  | Yes |
| Changes made to drug dosage and/or schedule |  | n/a | No |
| **Statistical/ Analysis Plan** | Changes have been made to any of the following:   * Study Endpoints * Power analysis * Sample size |  | n/a | No |
| **Methods of response evaluation** | Changes made to the methods of response evaluation |  | n/a | No |
| **Study Objectives** | Changes made to the primary and/or secondary study objectives |  | n/a | No |

\*These changes require an updated DART Form to be submitted with the amendment. *Note:* Phase II, III and IV studies enrolling in additional disease areas (including Phase I/II studies moving from Phase I to Phase II) require sign off from the DART Leader of any disease targeted.

1. **Has this study been activated at Yale?** Yes  No
2. **Is the study permanently closed to accrual at Yale?** Yes  No
3. **Is this amendment approved by the IRB of record?**  Yes\*  No

\*To ensure expeditious processing, please alert the Office of Quality Assurance and Monitoring via email when submitted at [prc.ycc.committees@yale.edu](mailto:prc.ycc.committees@yale.edu).

1. **Does amendment seek to enroll participants from underrepresented populations?**  Yes  No

**If no, provide a rationale:**

1. **Competing Protocols?**  Yes  No

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **HIC #** | **Date Open to Accrual** | **Accrual Goal** | **# Enrolled to Date at Yale** | **Expected Closure Date** | **Comment on how priority will be assigned** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

1. **Supporting Documents uploaded to ePRMS:**

Protocol (tracked version)

Protocol (clean version)

Summary of changes document for protocol (if not provided by sponsor, one must be developed)

Investigator’s Brochure (only if accompanying an amendment to the protocol)

Summary of changes document for the Investigator’s Brochure (if available)

Sponsor correspondence (if amendment is initiated by external sponsor)

Updated DART Form (if applicable for Full Amendment Review as indicated above)

**Comments:**

**PI Name: PI Signature: Date:**

**DART Leader: DART Leader Signature: Date:**