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.

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:**