Disease Aligned Research Team (DART) Protocol Review Form

Version: 5
Revised: 9/25/2018

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Date Reviewed by DART: ________________________  Principal Investigator: ________________________

Group PI: ________________________
if applicable

DART Mentor for PI: ________________________
if applicable

HIC #: ________________________
if applicable

Team Members Present:

☐ Name: ________________________  ☐ Name: ________________________

☐ Name: ________________________  ☐ Name: ________________________

☐ Name: ________________________  ☐ Name: ________________________

☐ Name: ________________________  ☐ Name: ________________________

Study Title: ________________________

Protocol #: ________________________  Sponsor Name: ________________________
(Sponsor or NCTN)

Protocol Type: ________________________  Data Table 4 Report Type: ________________________

Funding Source:
☐ NCI
☐ NCTN
☐ ETCTN

Other: ________________________

☐ Industry
☐ IIT
☐ Industry
☐ YCC
☐ Grant or other funds:

Please list: ________________________

Approved by DART: ☐ Yes  ☐ No

If no, please provide a brief rationale and then proceed to the bottom of this form and provide a signature.

______________________________
STUDY INFORMATION

Rationale for Study Design/Hypothesis:
The Principal Investigator should comment on the scientific merit of the study and specifically address how the study fits into the DART Portfolio. For example, why is this an interesting or novel scientific proposal and why should we conduct this research at Yale?

Research Center (RC) Accrual Goal
RC Upper Accrual Goal:
RC Lower Accrual Goal:
RC Annual Accrual Goal:

If the study includes multiple phases, indicate in which phase(s) Yale will participate.

If the study includes multiple phases, indicate how many subjects you expect to enroll in each phase.

If the study will enroll multiple disease cohorts, indicate to which disease cohort(s) Yale will enroll.

National open to accrual date:
Current national accrual:

ACCRUAL CONSIDERATIONS

☐ Rare Disease*
☐ Rare Molecular Subtype*
☐ N/A

*Per the NCI, incidence rate ≤ 6 newly diagnosed persons out of a population of 100,000 persons per year (≤ 6/100,000 per year).

If you have selected that the trial includes a rare disease or a molecular subtype, provide supporting evidence (i.e. population incidence below):

If the study targets a rare cancer, please provide your justification and rationale for opening this trial at Yale Cancer Center.
INCLUSION OF CARE CENTERS

☐ Yes

☐ No

If no, please provide a brief rationale:

Has the sponsor approved Care Center Participation?  ☐ Yes  ☐ No  ☐ Pending

If pending, has the sponsor been contacted about inclusion of care centers?  ☐ Yes  ☐ No

Are there any restrictions/special considerations for Care Center participation? (i.e. only certain number of Care Centers allowed to participate, certain procedures being done at main campus or not being done at all participating care Centers, etc.)

IMPORTANCE OF STUDY TO YALE CANCER CENTER AND TO DART

Rationale for DART endorsement:

Describe what gap in the DART portfolio this study is filling or how this study is adding to the portfolio.

Competing Protocols:  ☐ Yes  ☐ No

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<tr>
<th>HIC #</th>
<th>Study Title</th>
<th>Date Open to Accrual</th>
<th>Accrual Goal</th>
<th># Enrolled to Date</th>
<th>Expected Closure</th>
<th>Comment on how priority will be assigned</th>
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Role of Yale Investigators and Scientists in this trial:

☐ Lead Investigator for the entire study at all sites

Principal Investigator:

☐ Yale study investigators formed the rationale or proposed the concept

☐ Yale study investigators provided substantial assistance and input for design of the trial

☐ Rationale for the study is based on data developed in Yale laboratories

☐ Other:

□

Comments:

☐

PI Name: ____________________________ PI Signature: ____________________________ Date: ____________

DART Leader: ____________________________ DART Signature: ____________________________ Date: ____________