THE University of Vermont CANCER CENTER

NEW PROTOCOL - TRANSDISCIPLINARY TEAM (TDT) REVIEW
(To be completed the TDT Leader or their designee)

Transdisciplinary Team (TDT):

Title of Protocol:

Principal Investigator (PI):

Date of Review:

Disease Team Decision:

☐ Approved

☐ Disapproved

Comments:

Scientific Merit Score: _____

Scoring System:

4 - Excellent – Example: high profile clinical trial initiated by a UVMCC investigator with a novel therapy that may have substantial impact on disease

3 – Good – Examples: high profile cooperative group phase III or randomized phase II study with a UVMCC investigator as national PI; high profile industry sponsored or multi-institutional study with a UVMCC investigator as a national PI; high interest trial likely to impact disease

2 - Acceptable – Examples: high interest clinical trials less likely to impact disease or quality of life but ask an important question; studies with competing higher priority trials of interest that may address a gap in the disease team portfolio

1 - Not Scientifically Meritorious

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UVMMC ACCRUAL GOALS/PRIORITIZATION PLAN:

1. Does this study compete with another active study? ☐ No ☐ Yes

If yes, answer questions (a-c):

a) Please list other competing studies:

b) Please note how the studies' patient populations overlap and provide rationale for opening the current study:

c) Prioritization of study within existing portfolio of trials (if trials compete for the same patient population): ☐ N/A

1) First priority: _____

2) Second priority: _____

3) Third priority: _____

2. Accrual Goals: a) UVMMC Total Target Accrual (Single #, not range):

b) UVMMC Target Accrual per year (Single #, not a range):

(Note: Studies that do not meet ≥50% of annual accrual goal measured from the date the study is open to accrual will be recommended for closure. To allow assessment of accrual goals, only a specific number is allowed for questions 2a & 2b, not a range.)

3. How many patients/year would likely have been eligible for this trial when considering the past several years?

Was the cancer registry used for this estimate? ☐ Yes ☐ No

If yes, which years of the registry were reviewed?

If no, how was the number of potential patients/subjects determined?

4. What are the potential barriers to accrual and what preemptive steps can the research team take to minimize those barriers?

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By signing this form, the TDT leader (or their designee) attests that the disease team reviewed and discussed the protocol and agrees to support enrollment on the clinical trial. If the PI is the TDT team leader, an alternate team member should sign the TDT form. This completed form must be submitted to the Protocol Review and Monitoring Committee (PRMC) along with a completed protocol submission form (PSF).

TDT Leader (or designee):

Printed Name: _____

Signature: _____ Date: _____