THE University of Vermont CANCER CENTER

UVM Cancer Center Protocol Submission Form

Section 1

Trial Sponsor:		**Sponsor's Protocol #:**	
Full Trial Title:			
Principal Investigator:			
Sub-Investigator(s):			
Affiliate Site Principal Investigator:			

Will Use CTO Resources: ◉ Yes ○ No

Primary TDT:
○ Breast ○ Cutaneous ○ Upper GI/HB ○ Lower GI ○ Gyn ○ Heme ◉ Head & Neck
○ GU ○ Lung ○ Neuro ○ Sarcoma ○ Pediatric ○ Supportive Care/Survivorship
○ Endocrine

Associated TDTs Involved:
○ Breast ○ Cutaneous ○ Upper GI/HB ○Lower GI ○ Gyn ○ Heme ◉ Head & Neck
○ GU ○ Lung ○ Neuro ◉ Sarcoma ○ Pediatric ○ Supportive Care/Survivorship
◉ Endocrine

Clinical Research Category: ○ Interventional ◉ Observational ○ Ancillary ○ Correlative

Primary Study Purpose Category:
○ Treatment ○ Diagnostic ○ Prevention ○ Screening
○ Supportive Care ○ Basic Science ◉Health Services ○ Device Feasibility ○ Other

Study Specific Category:
To Guide Protocol Review
◉ Investigator-Initiated Observational Study
◉ Investigator-Initiated Ancillary or Correlative Study
○ Investigator Initiated Interventional Trial ◉ NCTN Trial
◉ Industry Sponsored Trial

Section 2 - Science, Recognition, and Alignment with UVM Cancer Center Goals

1. What preliminary data exists to support this study's aims and hypothesis/hypotheses?

2. Describe the patient population defined by the inclusion/exclusion criteria and describe any potential biases (e.g., age, sex, demographic data, disease state, etc.).

3. What is the predicted outcome (e.g., expected change in primary endpoint measure) and how might it impact future patient care?

4. Please document how your involvement as PI for this trial will provide scientific recognition/credit for you and/or the UVM Cancer Center and/or support UVM strategic goals. **Please check all boxes below that apply to this protocol:**

☐ Targets disease with no good standard of care options.
☐ Targets rare tumor/disease with unmet need (A **rare disease** is generally considered to be a **disease** that affects fewer than 6 per 100,000 people in the United States at any given time).
☐ Patient population for whom there is an unmet need.
☐ NCTN/Cooperative group trial.
☐ Based on UVM translational work.
☐ Authorship expected through involvement in the trial.
☐ Will provide pilot data for future grants.

Grant description, if known:

☐ Requested by Affiliate Site to meet credit requirements for NCTN participation.
☐ Other, and/or comments

Section 3 - Trial Categories

Investigator-Initiated Trial (IIT): ◉ Yes ○ No (If yes, answer questions # 1-7)

1. ◉ Single site (UVMMC only) ○ Planned Multi-site
   If Multi-site, please identify Potential Participating Sites:

2. Name of biostatistician providing consultation:

3. Investigator-Initiated at *another* Institution:

   ◉ Yes, and the sponsor is: ○ No

4. Study-wide Planned Accrual at UVMMC:

5. Does this protocol involve the use of an investigational drug(s), device, or biologic(s)? ◉ Yes ○ No
   If yes: Drug name, biologic name, or device name: aaaa
   IND/IDE #:
   Please provide copy of the IND or IDE letter if you are the IND/IDE holder.

6. Specific Funding Source:

NCTN Cooperative Group Trial: ○ Yes ◉ No (If yes, answer questions # 1-3)

1. # of patients enrolled nationally/study-wide to date:
2. Study-wide Accrual Goal:
3. Projected date of study closure based on accrual rate:

Industry Sponsored Trial: ○ Yes ○ No (If yes, answer questions # 1-4)

1. Has a Pre-study Site Selection Visit (PSSV) occurred with confirmation of site-selection?
   ○ Yes ◉ No
2. Has a CTO Resource Allocation and Evaluation (RAE) review occurred with confirmation of approval? ◉ Yes ○ No
3. # of patients enrolled to date study-wide:
4. Study-wide Accrual Goal:
5. Projected Date of Study Closure: