THE University of Vermont CANCER CENTER

# UVM Cancer Center Protocol Submission Form

## Section 1

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|---|---|---|---|
| **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: