Instructions for Completing the UVMCC Clinical Research Protocol Submission Form

SUBMITTING THE APPLICATION

1. The PI must complete this application. National Clinical Trials Network (NCTN) Protocols only opening at Affiliate Sites can be completed by the local PI and reviewed by a designated PI at UVMMC for submission.
2. If no formal TDT exists for a protocol, please complete the form and have it presented to and signed by at least 2 other reviewers or collaborators who are key to its success or who are experts in the relevant field.
3. Scientific details are meant to be synoptic and incorporate the perspective of the local PI, TDT or investigator group, and their interpretation of the relevant section of the protocol, not an abridged carbon copy of the protocol.
4. It is expected that the protocol and this completed form will be reviewed by the Investigator Team/TDT at a research meeting involving all stakeholder or core collaborators, prior to obtaining requisite endorsement signatures.
5. Once the PI, collaborators, and TDT Leader (if applicable) have reviewed and signed this form, the Research Coordinator is responsible for sending the application to the UVM Cancer Center Protocol Review and Monitoring Committee (PRMC) as part of the initial submission of protocol documents.

UVMCC CLINICAL RESEARCH PROTOCOL SUBMISSION FORM

Primary TDT: ☐ **Breast** ☐ **Cutaneous Onc.** ☐ **GI** ☐ **GU** ☐ **Gyn** ☐ **Heme** ☐ **Head & Neck** ☐ **Lung** ☐ **Neuro** ☐ **Sarcoma** ☐ **Pediatric** ☐ **Glens Falls Affiliate Site Request** ☐ **Central VT Med. Center Affiliate Site Request** ☐ **N/A** ☐ **Other:**

Associated TDTs also involved: ☐ **Breast** ☐ **Cutaneous Onc.** ☐ **GI** ☐ **GU** ☐ **Gyn** ☐ **Heme** ☐ **Head & Neck** ☐ **Lung** ☐ **Neuro** ☐ **Sarcoma** ☐ **Pediatric** ☐ **GF Affiliate Site** ☐ **CVMC Affiliate Site** ☐ **N/A** ☐ **Other:**

Date(s) Presented at TDT(s):

Trial Sponsor Name: **Sponsor's Protocol Number (i.e., S1700, AAQ786):**

Full Trial Title:

Is this a First-in-Human (FIH) trial? ☐ No ☐ Yes

A. SCIENTIFIC

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?**

B. SCIENTIFIC RECOGNITION &/OR STRATEGIC GOALS

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.
- ☐ 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 a pilot data for future grants. (PI must articulate below what grant they are anticipating using it for)
- ☐ Requested by Affiliate Site to meet credit requirements for NCTN participation.
- ☐ Other, and/or comments:

C. PROTOCOL DETAILS

Principal Investigator Name & Title:

Sub-Investigator(s) Name(s) & Title(s):

Clinical Research Category*: ◯ Interventional ◯ Observational ◯ Ancillary/Correlative

Primary Purpose of the Study*: ◯ Treatment ◯ Diagnostic ◯ Prevention ◯ Screening ◯ Supportive Care ◯ Basic Science ◯ Health Services Research ◯ Other

*(*See NCI definitions of each category/purpose on "UVMCC Clinical Research Form Addendum 1" on the last page)*

Date Study Opened (Nationally): ☐ N/A

Investigator-Initiated Trial (IIT): ◯ No ◯ Yes If yes, answer questions # 1-4

1. ☐ Single site (UVMMC only) ☐ Planned Multi-site
   If Multi-site, please identify Potential Participating Sites:
2. The PRMC expects that researchers have consulted with a statistician about their study.
   Name of biostatistician providing consultation:
   If you need biostatistical support, please visit UVMCC Biostatistics Core Facility website for contact information.
3. Investigator-Initiated at *another* Institution: ☐ No ☐ Yes, and the sponsor institution is:
4. Study-wide Accrual Goal:

NCTN Cooperative Group Trial:** ◯ No ◯ Yes 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:** ◯ No ◯ Yes If yes, answer questions # 1-4:

1. Has a Pre-study Site Selection Visit (PSSV) occurred with confirmation of site-selection? ☐ No ☐ Yes
2. # of patients enrolled to date study-wide:
3. Study-wide Accrual Goal:
4. When does the sponsor plan to close the study?

*(**For assistance see CTSU.org and/or ClinicalTrials.gov & clinical coordinator)*

D. UVMMC ACCRUAL GOALS/PRIORITIZATION PLAN:

1. **Does this study compete with another active study?** ◯ No ◯ Yes If yes, answer questions a) and b):
   a) Please list other competing studies:

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

2. **Accrual Goals:** a) UVMMC (or Affiliate Site) Total Target Accrual (#):
   b) UVMMC (or Affiliate Site) Target Accrual per year (#):
3. **How many patients/year would likely have been eligible for this trial over 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 your research team take to minimize those barriers?**
5. **If this is an Interventional Treatment study, how do the options on this trial fit into the group's current treatment algorithm for these patients?**

E. FUNDING SUPPORT

At this time funding is anticipated to be: ◯ Complete ◯ Partial ◯ Unfunded ◯ Not Applicable (for NCTN studies)

If partial or unfunded, please list plans to obtain support:

F. RESOURCE UTILIZATION

1. **Does the protocol utilize any of the following UVM Cancer Center resources (mark those that apply with an X)?**

☐ Research Nursing ☐ Biostatistics ☐ UVMCC BioBank
☐ Vermont Integrative Genomics Resource ☐ Microscopy imaging ☐ Cancer Translational Research Laboratory
☐ CTO Laboratory Specialist (i.e. PK samples) ☐ Other (describe in comments) ☐ Bioinformatics
☐ Full support from UVMCC Clinical Trials Office (CTO): includes an assigned Clinical Research Coordinator* and Regulatory Specialist *(*Coordinator assignment will be finalized by the CTO.)*
☐ Partial support from UVMCC CTO: Regulatory documentation support
☐ No UVMCC resources

Additional comments about any of the above UVMCC resources:

2. **Does the protocol utilize any of the following UVM Medical Center resources (mark those that apply with an X)?**

☐ Pathology (blocks, slides, etc.) ☐ Clinical Research Center (CRC) ☐ Radiology
☐ Pharmacy ☐ Other (describe in comments)
☐ No UVMMC resources

Additional comments about any of the above Medical Center resources:

COLLABORATOR REVIEW DOCUMENTATION

Signed by PI & Investigator Team Members upon whom study success depends upon

*****By signing this form, the TDT member/collaborator attests that he/she has read the completed form in full, and agrees to support enrollment on the described clinical trial.*****

This Form and Protocol were presented and vetted by the Investigator Team on: _____. *(date)*

PI: Printed Name:_____ Signature:_____ Date:_____

TDT Leader (or Site PI for NCTN trials):

Printed Name:_____ Signature:_____ Date:_____

Collaborating Investigators:

Please check all that apply and obtain signatures from all members of each modality that may be involved in this study. Use the "Additional" section for investigator groups/collaborations that do not fall in the traditional TDT categories and fill in the department name.

☐ **Medical Oncology:**

Representative 1: Printed Name:_____ Signature:_____ Date:_____

Representative 2: Printed Name:_____ Signature:_____ Date:_____

☐ **Surgery:**

Representative 1: Printed Name:_____ Signature:_____ Date:_____

Representative 2: Printed Name:_____ Signature:_____ Date:_____

☐ **Radiation Oncology:**

Representative 1: Printed Name:_____ Signature:_____ Date:_____

Representative 2: Printed Name:_____ Signature:_____ Date:_____

☐ **Pathology and Laboratory Medicine:**

Representative 1: Printed Name:_____ Signature:_____ Date:_____

☐ **Radiology:**

Representative 1: Printed Name:_____ Signature:_____ Date:_____

☐ **Additional Core Team Members**

Representative: Printed Name:_____ Signature:_____ Date:_____

Dept/Division/Site: _____

Representative: Printed Name:_____ Signature:_____ Date:_____

Dept/Division/Site: _____

Representative: Printed Name:_____ Signature:_____ Date:_____

Dept/Division/Site: _____

Representative: Printed Name:_____ Signature:_____ Date:_____

Dept/Division/Site: _____

Representative: Printed Name:_____ Signature:_____ Date:_____

Dept/Division/Site: _____

UVMCC Clinical Research Form Addendum 1 – NCI Definitions

Clinical Research Category	NCI Definition
Interventional	Study participants are assigned by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, therapeutic, behavioral or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed**.**
Observational	The study focuses on cancer patients and healthy populations that involve no intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.
Ancillary or Correlative	**Ancillary:** studies are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported. **Correlative:** laboratory based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.

Primary Purpose	NCI Definition
Treatment	Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition.
Diagnostic	Protocol designed to evaluate one of more interventions aimed at identifying a disease or health condition.
Health Services Research	Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.
Prevention	Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.
Screening	Protocol designed to assess or examine methods of identifying a condition (or risk factor for a condition) in people who are not yet known to have the condition (or risk factor).
Supportive Care	Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects, or mitigate against a decline in the participant's health or function. In general, supportive care interventions are not intended to cure a disease.
Basic Science	Protocol designed to examine the basic mechanisms of action (*e.g.*, physiology, biomechanics) of an intervention.