THE University of Vermont CANCER CENTER

Instructions for Completing the UVMCC Clinical Research Protocol Submission Form

SUBMITTING THE APPLICATION

1. The Principal Investigator (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. Scientific details are meant to be synoptic and incorporate the perspective of the local PI, Transdisciplinary Team (TDT) or investigator group, and their interpretation of the relevant section of the protocol, not an abridged carbon copy of the protocol.
3. It is expected that the protocol and this completed form will be reviewed by the Investigator Team/TDT at a research meeting involving all stakeholders and/or core collaborators, prior to obtaining the requisite TDT Leader endorsement signature on the New Protocol TDT Review form. If no formal TDT exists for a protocol, the PI should complete the form, and have it presented to at least 2 collaborators who are key to the trial's success. The collaborators will need to sign this PSF to acknowledge support (see below). A New Protocol TDT Review form will not be needed in this case.
4. This completed form accompanied by a completed New Protocol TDT Review form must be submitted with the protocol package to the UVM Cancer Center Protocol Review and Monitoring Committee (PRMC) as part of the initial submission.

INVESTIGATOR INITIATED STUDIES

Protocol templates should be used for all investigator-initiated studies (IITs). The Cancer Center Clinical Trials Office has protocol templates available and will provide protocol development support for investigators. Please contact DeAnna DeMars-Cox for assistance at Deanna.demars-cox@med.uvm.edu

UVMCC CLINICAL RESEARCH PROTOCOL SUBMISSION FORM

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

Primary TDT: ○ Breast ○ Cutaneous ○ GI ○ GU ○ Gyn ○ Heme Malignancy ○ Head & Neck ○ Lung ○ Neuro ○ Sarcoma ○ Pediatric ○ Supportive Care/Survivorship

Affiliate Site Request: ○ N/A ○ Central Vermont Medical Center

Associated TDTs also involved: ☐ Breast ☐ Cutaneous ☐ GI ☐ GU ☐ Gyn ☐ Heme ☐ Head & Neck ☐ Lung ☐ Neuro ☐ Sarcoma ☐ Pediatric ☐ Supportive Care/Survivorship

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 GOAL

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:

C. PROTOCOL DETAILS

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

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

*Definitions:

Interventional: Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, 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: Studies that focus on cancer patients and healthy populations and involve no prospective intervention or alteration in the status of the participants. Biomedical and/or health outcomes 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: Studies that 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 only include 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.

Treatment (TRE): Protocol designed to evaluate one or more interventions for treating a disease, syndrome, or condition. Note: This equates to therapeutic trials in previous versions of the guidelines.

Diagnostic (DIA): Protocol designed to evaluate one of more interventions aimed at identifying a disease or health condition.

Prevention (PRE): Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.

Screening (SCR): 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 (SUP): 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 (BAS): Protocol designed to examine the basic mechanisms of action (e.g., physiology, biomechanics) of an intervention.

Health Services Research (HSR): Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.

Other (OTH): Not in other categories

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Investigator-Initiated Trial (IIT): ◯No ◯Yes (If yes, answer questions # 1-6)

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 the UVMCC Biostatistics Core Facility for contact information.
3. Investigator-Initiated at *another* Institution: ◯No ◯Yes, and the sponsor is:
4. Study-wide Planned Accrual:
5. Does this protocol involve the use of an investigational drug(s), device, or biologic(s)? ◯No ◯Yes
   If yes: Drug name, biologic name, or device name:
   IND/IDE #:
   Please provide copy of the IND or IDE letter if you are the IND/IDE holder.
6. Specific Funding Source:

D. NCTN or Industry Sponsored

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?
   ◯Yes ◯No
2. # of patients enrolled to date study-wide:
3. Study-wide Accrual Goal:
4. Projected Date of Study Closure:

*(**For assistance, please contact the Cancer Center Clinical Trials Office)*

PI Printed Name: _____

PI Signature: _____ Date: _____

If no formal TDT exists for the protocol, please obtain signatures from at least 2 collaborators who are key to the success of the study.

Collaborating Physician/Individual:

Department: _____

Printed Name: _____

Signature: _____ Date:_____

Collaborating Physician/Individual:

Department: _____

Printed Name: _____

Signature: _____ Date:_____