Instructions for Completing the TDT Protocol Submission Form

SUBMITTING THE APPLICATION

1. The PI must complete this application.
2. If no formal TDT exists for this 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 and TDT, and their interpretation of the relevant section of the protocol, not an abridged carbon copy of the protocol.
4. Once the TDT Leader and TDT members have reviewed and signed this form, the Research Coordinator is responsible for sending the application to PRMC as part of the initial submission of protocol documents.

TRANSDISCIPLINARY TEAM (TDT) PROTOCOL SUBMISSION FORM

Primary TDT: ☐ **Breast** ☐ **Cutaneous Oncology** ☐ **GI** ☐ **GU** ☐ **GYN** ☐ **Heme** ☐ **H&N** ☐ **Neuro** ☐ **Pediatrics** ☐ **Sarcoma** ☐ **Thoracic** ☐ **N/A** **Other:**

Associated TDTs also involved: ☐ **Breast** ☐ **Cutaneous Oncology** ☐ **GI** ☐ **GU** ☐ **GYN** ☐ **Heme** ☐ **H&N** ☐ **Neuro** ☐ **Pediatrics** ☐ **Sarcoma** ☐ **Thoracic** ☐ **N/A** **Other:**

Date(s) Presented at TDT(s):

Trial Sponsor Name

Protocol Number (i.e., S1700, CBGJ398US1202, etc)

Full Trial Title:

Is this a First in Man (FIM) trial? ☒ No ☐ Yes

A. SCIENTIFIC

1. **Is this study based on appropriate preliminary data?**

2. **Is the study population without bias and include a diverse population including age, sex, demographic data, disease state? If no, please explain.**

3. **Will the endpoints of the study directly impact future patient care? If not, what scientific contribution will this study make to the literature?**

4. **What is the predicted/expected change in primary endopoint that serves to power the study? Is this clinically significant?**

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 and explained below:

☐ Targets disease with no good standard of care options.

☐ Targets rare tumor/disease with unmet need.

☐ Cooperative group: PI serves as national protocol team member.

☐ Based on UVM translational work.

☐ Will provide a pilot data for future grants. (PI must articulate below what grant they are anticipating using it for.)

☐ Authorship expected through involvement in the trial.

C. PROTOCOL DETAILS

Principal Investigator Name & Title:

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 "TDT Application 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
   Sponsor institution:
4. *Study-wide Accrual Goal*:

NCTN Cooperative Group Trial: ◯ No ◯ Yes *If yes, answer questions # 1-3*

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

1. *# of patients enrolled nationally/study-wide to date:*
2. *Study-wide Accrual Goal:*
3. *When does the sponsor plan to close the study?*

Industry Sponsored Trial: ◯ No ◯ Yes *If yes, answer questions # 1-4*

(For assistance see ClinicalTrials.gov & clinical coordinator)

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?*

D. UVMMC ACCRUAL GOALS/PRIORITIZATION PLAN:

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

If yes, please provide rationale for opening this study:

Please list other competing studies:

UVMMC Total Target Accrual (#):

UVMMC Target Accrual per year (#):

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?

E. FUNDING SUPPORT

At this time funding is anticipated to be: ☐ Complete ☐ Partial ☐ Unfunded

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

F. RESOURCE UTILIZATION

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

☐ Research Coordinator from UVMCC CTO ☐ Biostatistics ☐ UVMCC BioBank
☐ Research Nursing ☐ Bioinformatics ☐ Cancer Translational Research Laboratory
☐ Advanced Genome Technologies Core ☐ Microscopy imaging ☐ Other (describe in comments)

Additional comments about any of the above UVMCC resources:

b. Does the protocol utilize UVM Medical Center resources (mark those that apply with an X)?

☐ Pathology (blocks, slides, etc.) ☐ Radiology (attach completed Radiology Research Support Form)
☐ Pharmacy ☐ Clinical Research Center (CRC) ☐ Other (describe in comments)

Additional comments about any of the above Medical Center resources:

TDT Membership Review Documentation: *Signed by TDT Members and PI*

*****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 Application, Protocol, and Summary Sheet were presented and vetted by the Transdisciplinary Team on _____.

PI Signature: _____ **Date:** _____

TDT Leader Signature: _____ **Date:** _____

Associated TDT Members (if applicable):

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

☐ **Medical Oncology:**

Representative 1: _____ **Date:** _____

Representative 2: _____ **Date:** _____

Representative 3: _____ **Date:** _____

☐ **Surgery:**

Representative 1: _____ **Date:** _____

Representative 2: _____ **Date:** _____

Representative 3: _____ **Date:** _____

☐ **Radiation Oncology:**

Representative 1: _____ **Date:** _____

Representative 2: _____ **Date:** _____

Representative 3: _____ **Date:** _____

☐ **Pathology and Laboratory Medicine:**

Representative 1: _____ **Date:** _____

Representative 2: _____ **Date:** _____

Representative 3: _____ **Date:** _____

☐ **Radiology:**

Representative 1: _____ **Date:** _____

Representative 2: _____ **Date:** _____

Representative 3: _____ **Date:** _____

☐ **Other:**

Representative 1: _____ **Date:** _____ **Division/Dept**_____

Representative 2: _____ **Date:** _____ **Division/Dept**_____

Representative 3: _____ **Date:** _____ **Division/Dept**_____

TDT 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.