THE University of Vermont CANCER CENTER

Investigator Instructions for Protocol Submission Form (PSF) Completion

1. The Principal Investigator (PI) must complete the PSF accurately and in its entirety. Please refer to the FAQ section for additional information.
2. UVMCC-approved protocol templates should be used for all investigator-initiated trials (IITs). Please contact the UVMCC CTO Protocol Writer for assistance with IIT protocol and budget development. If you need biostatistician support, please visit the UVMCC Biostatistics Core Facility for contact information.
3. The designated PI at UVMCC must submit this form on behalf of the local PI at an affiliate site for National Clinical Trials Network (NCTN) Protocols.
4. Scientific details (form section 2) are meant to be synoptic, providing the perspective of the UVMCC PI.
5. It is expected that the protocol and this completed form will be submitted by the PI to the relevant TDT Leader for First Stage Review prior to the meeting.
6. A complete submission by the TDT Leader to the New Study Intake & PRMC Coordinator (prmc@med.uvm.edu) includes:
    a. Protocol
    b. PSF – completed and signed
    c. TDT Form – completed and signed

Frequently Asked Questions

For what categories of clinical research do I need to complete the PSF?

1. Is this an Investigator Initiated Interventional Trial?

If yes, First Stage Review, Cancer Center Registration and PRMC review are required. *Complete the entire PSF.*

2. Is this an NCTN or Industry Sponsor Trial?

If yes, First Stage Review, Cancer Center Registration and PRMC review are required. *Complete the entire PSF.*

3. Is this an Archived Tissue Study, Retrospective Chart Review, or Quality Assurance/Improvement Study?

If yes, *do not complete the PSF* unless you are requesting First Stage Review by a TDT. Please note, that an IRB submission may be required if the study is considered to be human subjects research by the UVM IRB. This will impact the research category and activation steps (see PRMS Pathways).

4. Is this an Investigator-Initiated Observational, Ancillary, or Correlative Study?

If yes, Cancer Center Registration is required. First Stage Review and PRMC review are not required. A PSF is required for the following scenarios:

- If your protocol does not require CTO resources or optional First Stage review, *complete only section 1 of the PSF*. The PI is responsible for submitting it directly to the New Study Intake & PRMC Coordinator.
- If your protocol requires CTO resources and/or optional First Stage Review, *complete the entire PSF*.

Study Type		First Stage Review	Cancer Center Registration	PRMC Review	PSF completion
Investigator-Initiated Interventional		Yes	Yes	Yes	Yes
NCTN		Yes	Yes	Yes	Yes
Industry-sponsored		Yes	Yes	Yes	Yes
Archived tissue		Optional	No	No	No *
Retrospective Chart Review		Optional	No	No	No *
QA/QI		Optional	No	No	No *
Investigator-initiated Observational, Ancillary or Correlative	**CTO Resources requested**	Optional	Yes	No	Yes
	CTO Resources not requested	Optional	Yes	No	Section 1 only *

* If optional First Stage Review requested by PI, fill the entire PSF.

Where can I find protocol templates?
The UVMCC Clinical Trials Office has protocol templates available and can provide protocol development support for investigators. Do not use the IRB Submission Form for this purpose. Please contact the UVMCC Oncology Clinical Trials Specialist (emma.armstrong@uvmhealth.org) for access to templates and assistance.

What are the NCI Clinical Research Category 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 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 - 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 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.

What are the NCI Primary Study Purpose Category definitions?
Treatment - Protocol designed to evaluate one or more interventions for treating cancer.
Note: This equates to therapeutic trials in previous versions of the guidelines.
Diagnostic - Protocol designed to evaluate one or more interventions aimed at identifying cancer or pre-cancerous condition.
Prevention - Protocol designed to assess one or more interventions aimed at preventing the development of cancer.
Screening - Protocol designed to assess or examine methods of identifying a cancer, pre-cancerous condition, or risk factor for cancer in people who are not yet known to have the condition.
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.
Health Services Research - Protocol designed to evaluate the delivery, processes, management, organization, or financing of health care.
Device Feasibility - Intervention of a device product is being evaluated in a small clinical trial (generally fewer than 10 participants) to determine the feasibility of the product; primary intent is feasibility and not health outcomes.
Other - Any purpose not described above.

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Clinical Trial Office Resources

Pre-Study

- Assistance with protocol development, writing or budget development
- CDA coordination for industry studies or multi-site IITs
- Site feasibility questionnaire and site visit for industry studies or multi-site IITs
- Regulatory activities and preparation of documents for IRB submission
- FDA submission for IITs, if required
- Assistance with Data Safety and Monitoring Plan creation
- Pre-Award Industry Clinical Trial Agreement, and Budget/Contract Negotiation Oversight
- Investigational Pharmacy Support including Beacon Builds
- Data Usage & Material Transfer Agreements
- Database Development
- Coordination of EPIC and Oncore Study Builds
- Study Initiation Visit (SIV) coordination

Review

- Resource Allocation Evaluation by CTO and UVMMC
- Coordination of Ancillary reviews including Radiology, Institutional Biosafety Committee, Radiation Safety Committee, Pharmacy and UVMCC Shared Resources
- Quality Assurance oversight and implementation of the Data Safety and Monitoring Plan
- TDT (disease team) First Stage Review coordination support
- PRMC review and accrual monitoring
- Assistance with clinicaltrials.gov registration
- Accelerated/Emergency PRMC review for special circumstances

On Study

- Source Documentation Development of case report forms
- Data Management Services including coordination in Oncore and through industry platforms
- Tumor Measurement read Coordination through Yunu Platform
- Ongoing regulatory activities for modifications, amendments, continuing reviews, and Reportable New Information with IRBs of Record
- Quality Assurance support with monitoring and auditing of Safety, Adverse Events/Serious Adverse Events, Noncompliance, and Unanticipated Problems.
- Data Safety and Monitor Plan implementation for IITs
- Industry Budget Development and Negotiation Amendment Oversight
- Industry Clinical Trial Agreement Negotiation and Execution Amendment Oversight
- Oversight for monitoring visits including Study Initiation Visits, Interim Monitoring Visits, and Study Closeout Visits