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BACKGROUND

Scientific review of clinical protocols is an NCI expectation for cancer centers¹. Processes as to which types of protocols required first-stage review, which types of protocols were exempt from the protocol review and monitoring committee (PRMC) review, and how these operations and composition differed were poorly defined at the University of Vermont Cancer Center (UVMCC).

This led to confusion and frustration on the part of investigators, delays in study development and evaluation, and a breakdown in collaboration among investigators and clinical trials office (CTO) staff.

GOALS

To develop a navigation tool for investigators and transdisciplinary team (TDT, disease-focused first stage review groups) leaders that:

- define and improve the efficiency of protocol review,
- shortens study processing times, reduces stakeholder confusion and frustration, and
- supports and improves collaboration among investigators and clinical trials office staff.

In Slide Show mode: Click on selection to see protocol flow pathway No Cancer Center registration or review Archived tissue study Cancer Center registration required Exempt from PRMC review Requires CTO review if using CTO resources PRMC review required NCTN trial Investigator-Initiated Observational or Ancillary/Correlative Study NOT using CTO resources Investigator-Initiated Industry Trial Investigator-Initiated Interventional Trial NOT using CTO resources Investigator-Initiated Interventional Trial NOT using CTO resources



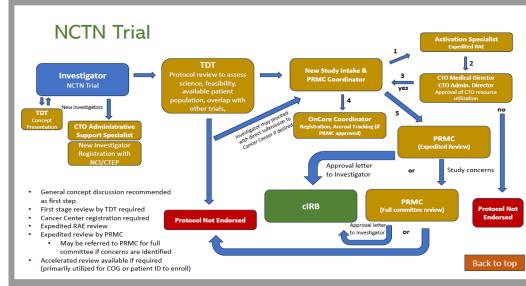


Figure 3: UVMCC PRMS Pathways for Industry-Sponsored Trials

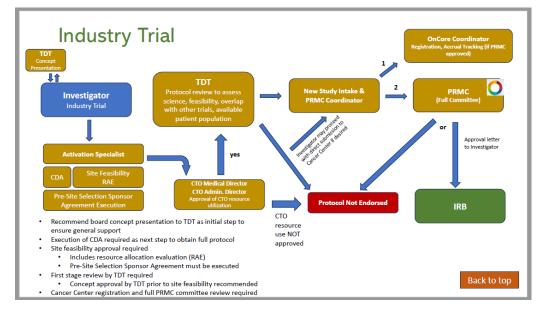


Figure 4: UVMCC PRMS Pathways for Interventional Investigator-Initiated Trials with CTO Resources

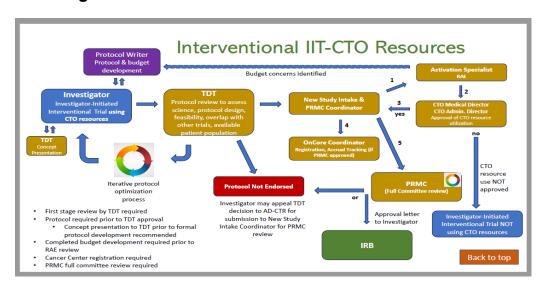


Figure 5: List of UVMCC CTO Trial Resources for Investigators

CTO Resources		
Pre Study	Review	On Study
 Assistance with protocol development, writing or budget development 	Resource Allocation Evaluation by CTO and UVMMC	 Clinical research coordinator support for screening, enrollment and patient follow-up
CDA coordination for industry studies or multi-site IITs		
Site feasibility questionnaire and site visit for industry studies or multi-site IITs	 Coordination of Ancillary reviews including Radiology, IBC etc 	 Source Documentation Development of case report forms
 Regulatory activities and preparation of documents for IRB submission 	Quality Assurance oversight and	 Data Management Services including coordination in Oncore and through industry platforms
FDA submission for IITs if required	implementation of the Data Safety and Monitoring Plan	
Assistance with Data Safety and Monitoring Plan creation	and Worldoning Flam	RECIST read Coordination through Yunu Platform
 Pre-Award Industry Clinical Trial Agreement, and Budget/Contract Negotiation Oversight 	TDT (disease team) review and input	 Ongoing regulatory activities for modifications, amendments, continuing reviews, and Reportable
 Completion of Sponsor Questionnaires & Conduct of Pre-Site Visits for Industry Sponsors 	PRMC review and accrual monitoring	New Events with IRBs of Record
Investigational Pharmacy Support including Beacon Builds	Assistance with Clinicaltrials.gov	 Quality Assurance support with monitoring, auditing, Adverse Events/Serious Adverse Events,
Data Usage & Material Transfer Agreements	registration	& Data Safety and Monitor Plan implementation
Database Development	Accelerated/Emergency PRMC	Industry Budget Development and Negotiation Amendment Oversight
 Coordination of EPIC and Oncore Study Builds 	review for special circumstances	And the overlaging
Study Initiation Visit (SIV) coordination		Industry Clinical Trial Agreement Negotiation and
Cancer C	enter Data & Safety Monitoring Committee	Execution Amendment Oversight
is availah	le for investigator-initiated trials	Back to to

METHODS & SOLUTIONS

We developed a user-friendly web-based navigation tool that clearly defined delineated pathways of study review for investigator-initiated, national cooperative group, and industry trials, and it guided appropriate review pathways for non-interventional and correlative research studies.

OUTCOMES

Immediate implementation outcomes included:

- investigators and TDT leaders
 developed an improved
 understanding and acceptance of
 NCI review processes;
- investigators developed an improved understanding of the role of the clinical trials office in the protocol review process;
- a clearly defined and delineated point of entry to the protocol review and monitoring system.

Anticipated outcomes for which data is currently being collected:

- 1) improved process review timelines for studies, particularly investigator-initiated trials;
- 2) greater acceptance of TDT leadership role and responsibilities in the first stage review process.

LESSONS LEARNED & FUTURE DIRECTIONS

- ➤ Before the navigation tool implementation, investigators were not cognizant of the various activities performed by the clinical trials office staff or the amount of effort in shepherding protocols through the system.
- ➤ Confusion about the processes led to frustration and reduced enthusiasm to develop and activate trials.
- Since this time, investigators have had less confusion and frustration, and improved collaboration among the clinical trials office staff.
- Further, the navigation tool has resulted in an increased number of protocols in development. When implementing new tools, early investigator education is pivotal to enhancing engagement, collaboration, and robust clinical trials efforts.

ACKNOWLEDGEMENTS

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- UVMCC Clinical Trials Office
- UVM Institutional Review Board
- Faculty & Staff across TDTs participating in the implementation

REFERENCES

1. https://grants.nih.gov/grants/guide/pa-files/PAR-21-321.html

