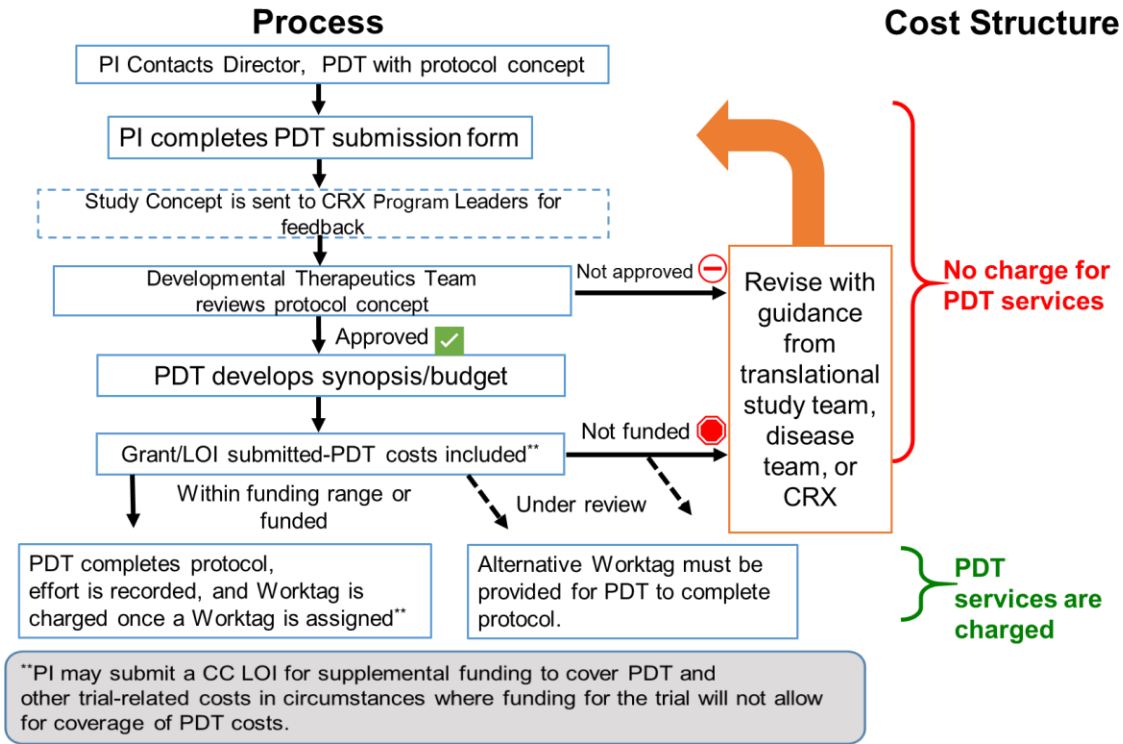


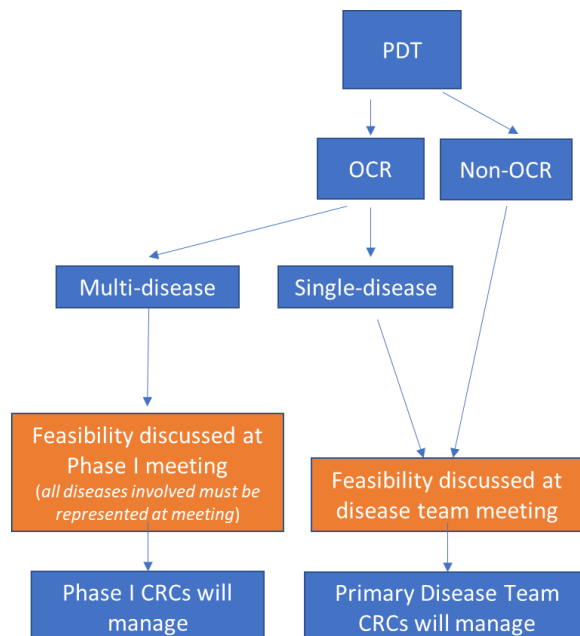
UVA Cancer Center Investigator-Initiated Trial (IIT) Support



Additional Guidance for Requesting Protocol Development Services

Pre-LOI/Grant Submission

PI completes an IIT request form in the [Oncology Clinical Trials Tracker through RedCap](#). Directions for obtaining a RedCap account may be found [here](#). The IIT request form contains several of the questions that should be addressed during the initial feasibility review of the study concept. The IIT request form will be routed through RedCap to the Director of the PDT ([Kim Bullock](#)). Feasibility reviews should be completed as follows:



1. The PI may choose to reach out to the [Cancer Therapeutic Program](#) leaders to receive feedback from their peers in the Cancer Therapeutics Program. Discussions amongst program members can help foster collaborations and provide opportunities to explore potential synergies between clinical research projects.
2. IIT concepts will be reviewed by faculty on the Developmental Therapeutics (DT) Team. Concepts will be reviewed via email or at a DT meeting if further discussion is needed.
 - Areas of focus will include study objectives, endpoints, rationale, patient population, and funding
3. Once a concept is approved by the DT team, the PI will work with PDT to develop a synopsis and budget. The budget will include protocol-development costs and all corresponding protocol-related costs (e.g., other personnel and clinical costs).
4. If the concept is not approved by the DT team, the PI has the option to revise the concept with guidance from the translational research team, the corresponding disease team, or the Cancer Therapeutics team (CRX).
5. The grant/LOI and budget will be submitted to the funding agency.

To apply for internal Cancer Center funding for IITs, [please find the application here](#). Applications are due on the first Wednesdays of every April, August, and December. The [Protocol Development Team \(PDT\)](#) can help with the completion of the IIT LOI form (under "Supporting Documents"). Please email Kim Bullock (kb9d@uvahealth.org) if you need assistance.

Post-Submission

1. After the PI has been notified that their grant/LOI is in funding range or has been approved, the PDT will begin working on the protocol. Effort will be recorded in OnCore for PDT staff and as a percent effort for the Director, PDT, and the PI's Worktag will be billed for services.
2. If the project is not selected for funding and the PI wants to move forward with the protocol, or the PI requests that work begin on the protocol before a decision has been made by the funding agency, the PI will provide a Worktag to cover the costs of the PDT. These funds could come from start-up, philanthropy, RG accounts, etc.