AACI CRI
Clinical Research Innovation

Principal Investigator (PI) Onboarding and Training, Maintaining, and Offboarding Checklists

The CRI Education and Operations Subcommittee identified a need to create a templated checklist for Principal Investigator (PI) training within academic cancer centers, ensuring consistency, efficacy, and accountability throughout the entire PI lifecycle. The framework encompasses onboarding tasks, communication expectations, ongoing training, and offboarding procedures, tailored to the unique demands of cancer research. By utilizing this resource as a template, academic cancer centers can cultivate their own procedures to ensure well-trained, supported, and empowered PIs that can focus on advancing cancer research and improving patient outcomes.

	What to do before a new PIs arrival
☐	Find out as early as possible if a new investigator is coming to the team.
☐	Identify if the new investigator is from a different cancer center with experience or new to clinical research.
☐	Develop a mentorship program if not already established or enroll new PI in a mentorship program to share valuable resources such as expectations, tips, and electronic resources for team connections and research structure at the institution.
☐	• During the program PIs will learn about source documentation, PI oversight, negotiating budgets, relationships with other departments, monitoring and auditing, Food and Drug Administration (FDA) inspections, institution and state regulations, and more.
☐	If the PI has clinical research experience, identify if they are bringing trials with them.
☐	Collect contact information to create institutional email address.
☐	• If possible, obtain access to electronic medical record (EMR), protocol management systems, electronic institutional review boards (IRBs), etc.

	What to do after their arrival Items are to be completed before participating in research (suggested completion time is 2 weeks)
☐	PI must show understanding of the requirements for clinical research including but not exclusive to specific training on human subject protection (HSP), good clinical practice (GCP), research foundations, scientific review committees, practice of clinical research by the NIH, etc.
☐	• To assess understanding use checklist, training modules, meetings with clinical trial leadership, and/or competencies.
☐	• Provide PI with an investigator manual or standard operation procedures (SOPs)

☐	If unable to obtain access prior to arrival, obtain access to EMR, protocol management systems, electronic IRBs, Shared Investigator Platform (SIP), databases, etc.
☐	Register or transfer PI as an NCI-investigator, specifically in the Cancer Therapy Evaluation Program (CTEP)
☐	Provide an investigator start form or training plan checklist that details and tracks courses such as GCP, HSP, Responsible Conduct of Research (RCR), Conflict of Interest (COI) (CITI training), RECIST training, Diversity, Equity, and Inclusion (DEI) training (if applicable), human resource (HR) courses, and other platform training specific to the cancer center.
☐	Schedule meetings for PI to meet with other departments within the research teams.
☐	Collect the PIs curriculum vitae (CV), medical license, and handwriting sample as applicable to the institution.
☐	Register the PI on the institutions part 11 compliant signature platform (if applicable)
☐	Update contact information across communication platforms and webpages.
☐	Provide an overview of the study-start up process.
☐	Determine which trials new investigator should be added to. Ensure listed on APL and DOA, and that appropriate study specific training has been completed and documented PRIOR to consenting or participating on studies in any capacity.
☐	Share opportunities to get involved in institutional research committees (e.g., IRB, data safety monitoring, protocol review and monitoring).

	Maintaining
☐	Administer periodic training for new PIs.
☐	Continue to develop and share resources such as clinical trial tool kits, documents for site practices, links, workflow changes, etc. for future reference.
☐	Offer research meetings or workshops for either the division or department to allow questions and answers and to learn amongst peers.
☐	Offer leadership training for continued growth and development.
☐	Reregister PI annually in CTEP.
☐	Update annually the PI COI disclosure and trainings per institutional policy.
☐	Maintain HSP and GCP training as applicable.
☐	Provide the PIs with a list of all the open studies for them to track.
☐	Continue to update studies and report results, adverse events (AEs), or modifications to studies in Clinicaltrial.gov.

	Offboarding
☐	The PI is to provide a list of studies that are not managed by clinical trials office (CTO) to either the department administrator, research administrator, division head, or CTO contact.
☐	• These studies usually are chart reviews, ancillary/correlative/lab, or registry type trials that the PI managed on their own or with a fellow.
☐	• Make sure those studies are either closed with the IRB or assigned to someone else.
☐	Work with CTO on all active studies they manage, discuss who the new PI will be, ensure discussion is had with the new PI, and start the process of study transfer in case there are questions that need to be addressed prior to the PI leaving the institution.
☐	• Discuss with the PI an official offboard date (ensure new PI starts immediately).
☐	• Make sure all of the PI responsibilities are completed up until that official offboard date including but not exclusive to sign off (electronic and wet) on CRFs, logs,

☐ ☐ ☐ ☐	IRB/deviations reporting closed out, issues identified at audits or inspections have been addressed, CAPAs in place, etc. • Send study sponsors an email regarding the change in PIs on study trials. ○ Make sure to obtain approval from sponsor for new PI and have an agreement that the change is appropriate. • Ensure contract is updated with new PI if named in it. • Re-consent patients across trials as necessary.
☐	Make sure someone in the CTO has access to all of the data and samples for any/all of the trials the PI was responsible for.
☐	Ensure access to CTMS and other platforms are discontinued after last day.
☐ ☐	If the PI wants to open a study at the new institution, make sure appropriate contracts, Material Transfer Agreements (MTAs), IRB, etc. are in place. • Ensure they know they cannot take specimens or data with them unless appropriate contracts and regulatory documents are in place.
☐	Collect contact information for the new institution if needed to contact PI in the future.