

Trial Oversight, Transition Policy to Incoming IU Investigators

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1. Background

Indiana University (IU) has a well-established multicenter program. It acts as IUs CRO (Contract Research Organization), allowing Principal Investigators (PIs) to conduct Multisite IU-led Investigator-Initiated Trials (IITs). In recent years, the multicenter team has experienced an uptick in study transfers among new PIs recruited to IU. As PIs transition to IU, many have scientifically relevant IITs they would like to continue to explore. The PIs transfers the lead site responsibilities to IU to continue their research. Because of this, we develop processes to make the transition smooth for the PI while ensuring data integrity and patient safety remain top priorities.

2. Goals

The goal is to streamline the study transition process from the transferring institution to IU while maintaining the integrity of the study and its data and ensuring subject safety. Streamlining this process will allow for shorter enrollment holds, allowing PIs to meet accrual goals and funder expectations even while they transfer their active trials to a new institution.

3. Solutions and Methods

A Standard Operating Procedure (SOP) was created that lists, in a checklist format, all items required for an effective and efficient transition. The SOP discusses roles, tasks, and associated policies and procedures. The Multicenter Team Manager meets with the PI and transferring site before the transfer, during PI orientation, and throughout the transition phase to discuss plans, expectations, and requirements. The transition SOP discusses all aspects, including but not limited to Protocol and study document transfer and re-writes, Institutional Review Board approvals, prior monitoring and auditing reports, Investigational New Drug transfers, fund and contract transfers, safety letters and Investigator brochures, subject data, transfer of samples and drug, etc. During the transition, the Multicenter Team Manager maintains continuous and open communication with the PI and the transferring site, assigning a staff member to assist with the transition and ultimately be assigned the Project Manager role for the trial. In most cases, the transferring site plans to remain on study as a participating site. PIs often want to add additional sites to increase accrual and patient population inclusivity.

4. Outcomes

The SOP was finalized in August 2023. We have successfully transitioned one trial and are currently transitioning a high-risk, six-site trial. The SOP allows continuous open communication and direct expectations and processes. The SOP has minimized delays and confusion and improved timelines for all parties.

5. Lessons Learned and Future Directions

Standard practice and clear expectations are imperative for a smooth transition, ultimately allowing for better access to subjects and innovative trials being shared nationwide. Before the SOP, study transfers did occur; however, with this SOP, study transfers have become more streamlined. As PIs continue to transfer institutions, the need for a standard process will continue to evolve. As always, IU remains open to suggestions and improvements as we work towards a cure.