



Trial Oversight, Transition Policy to Incoming IU Investigators

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Background

Indiana University (IU) has a well-established Multicenter (MC) program. The program acts as IUs Contract Research Organization (CRO), allowing Principal Investigators (PIs) to conduct multisite IU-led Investigator Initiated Trials (IITs). In recent years, the MC 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 transfer 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.

Goals



Refine transfer process to allow for shorter enrollment holds.



Maintain the integrity of the study and its data



Ensure subject safety



Streamline the study transition process.

Solutions & Methods

- A Standard Operating Procedure (SOP) was created that lists out all items required for an efficient transition. The SOP covers:
 - ✓ Role expectations and tasks
 - ✓ Associated Policies and Procedures
 - ✓ Protocol and study document transfer and rewrites
 - ✓ IRB approvals
 - ✓ Prior monitoring and auditing reports
 - ✓ IND transfers
 - ✓ Funding and contract transfers
 - ✓ Safety Letters and Investigator Brochures
 - ✓ Subject Data
 - ✓ Transfer of samples and drug
- MC Team Manager (MTM) meets with the PI through all phases of study transfer.
- MTM will assign a Project Manager to the study.
- In most cases the transferring site will plan to remain on study as a participating site.
- PIs often want to add additional sites to increase accrual and patient population inclusivity.

Outcomes

- The SOP was finalized in August 2023
- The IU Team has successfully transitioned one trial and are actively transitioning a high-risk, six site trial.
- Continuous, open communication and direct expectations are clear as a result of this SOP. The SOP has minimized confusion and improved timelines for all parties.

Lessons Learned

- Standard practice and clear expectations are imperative, ultimately allowing for better access to trials nationwide.
- Study transfer times have become more streamlined since the implementation of the SOP

Future Directions

- As PIs continue to move institutions, the need for a standard process will continue to evolve.
- IU remains open to suggestions and improvements as we work towards a cure.

