

Closing the Loop and Boosting Revenue: Leveraging Outstanding Financials to Incentivize IRB Final Closures

J. Moehle, J. Ballard, L. Hayes, J. Reed

Huntsman Cancer Institute at the University of Utah

1. Background

In the last six months, the Huntsman Cancer Institute clinical trials office (CTO) Finance and Regulatory teams have embarked on a transformative initiative to ensure financial invoices at trial sites are current, paid, and reconciled before institutional review board (IRB) Final Closure. This approach creates a nexus between financial management, regulatory compliance, and operational efficiency.

2. Goals

The primary objective remains the same – ensure full payment contractually obligated to sites from sponsors/contract research organization (CROs). An additional goal is introduced: incentivize sponsors and CROs to promptly resolve financial discrepancies, ensuring full compensation to the site before proceeding with IRB Final Closure.

3. Solutions and Methods

Building on initial strategies, this introduced a deliberate halt in IRB Final Closure for studies with unresolved financial matters. This pause acts as a motivator for sponsors and CROs to address accounting issues promptly, resulting in accurate and reconciled invoices and thorough dispute resolution before proceeding.

4. Outcomes

Approximately 25 percent of studies ready for IRB Final Closure experienced a temporary halt, leading to either swift resolution of financial matters or the submission of a Continuing Review. This intentional delay not only expedited resolution but significantly increased revenue streams for the institution as sponsors prioritized settling outstanding payments. Up to \$500,000 (\$500K) has been recovered that may have been more difficult to collect should IRB Final Closure have proceeded.

5. Lessons Learned and Future Directions

This process has emphasized the effectiveness of using IRB Final Closure as leverage for timely financial resolution. The deliberate withholding of closure motivated sponsors and CROs to prioritize the swift resolution of accounting matters, fostering a collaborative and accountable research environment.

Future directions involve refining and standardizing the approach to temporarily halting IRB Final Closure, continually evaluating the impact on revenue streams and overall trial efficiency. Collaboration with sponsors and CROs to establish best practices for financial management in clinical trials remains crucial.