Category: Trial Start-up, Activation, Regulatory, and Protocol Development – Work in progress

Streamlining the IRB Reliance Process at a Single Institution

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1. Background

As cancer clinical trials grow more complex, ensuring the safety of trial participants through institutional review board (IRB) review and approval becomes increasingly critical. Since most clinical research studies are conducted across multiple institutions, each institution must undergo an IRB review. However, to reduce the need for numerous IRB approvals in cancer cooperative group studies, the Code of Federal Regulations ("CFR"), 45 CFR Part 46.114 (b)(1) requires that any institution involved in cooperative group research rely on a single IRB, the Central IRB (CIRB). Additionally, 45 CRF 46.114 (c) allows institutions to enter a joint review to minimize duplication of effort if the study is not a cancer-cooperative group study. The Angeles Clinic and Research Institute (TACRI), a Cedars-Sinai Affiliate, works with the Cedars-Sinai IRB (CS-IRB) as the local IRB and is committed to utilizing the reliance process to reduce redundancy and optimize efficiency.

2. Goals

TACRI's area of expertise covers multiple oncology diseases, including conducting multiple phase 1 clinical trials funded by sponsors and investigator-initiated trials across various centers. To facilitate sponsor-funded trials, we utilize a reliance process that involves working with CS-IRB as the local IRB and WIRB-Copernicus Group IRB (WCG) or Advarra as the external IRB of record. Both entities have an established reliance agreement with us. Our primary objectives are as follows:

- Foster greater collaboration between sponsors/CROs and their external IRBs.
- Enhance education and training on the reliance process to improve IRB efficiencies, streamline the review process between various stakeholders, and remain compliant with regulatory changes.
- Monitor our processes and communication closely to ensure no negative impacts on the turnaround times.
- Evaluate whether the reliance process can improve site activation timelines for clinical trials.

3. Solutions and Methods

1. To better understand our processes, we created a process map of our current state utilizing the reliance process to identify any barriers or gaps. (Process Map attached)
2. Following the process mapping exercise, we developed an A3 utilizing lean methodology to identify the problem, outline root causes and an action plan. (A3 attached)
3. We created a training session for the TACRI team, which was shared with CS-IRB on the reliance process regulatory history, current regulations, and potential future changes. In addition, the training included the A3 and action plan.

4. Outcomes

Through this project, we increased collaboration with key stakeholders across TACRI and the Cedars-Sinai enterprise. We developed a training program for the TACRI clinical research staff on the reasons for a reliance process, which includes all the policies and procedures already created by the reliance specialists at the Cedars-Sinai IRB.

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We noted that Cedars-Sinai has multiple reliance agreements in place, which allowed TACRI to immediately expand our collaborations with other external IRBs and partner with sponsors when they work with their IRB of choice.

The current action plan is in process and continually being monitored.

5. Lessons Learned and Future Directions

Our experience has helped us understand the benefits of a streamlined IRB reliance process. Through our training program and A3 process, all our key stakeholders are involved in identifying redundant steps to eliminate.

Figure

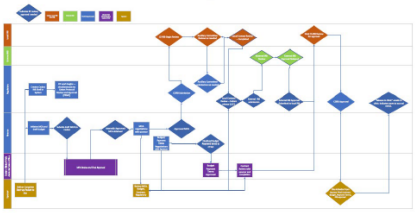
A3

A 3 Title: IRB Reliance Process at TACRI

Team Members: Brenda Hann, Julian Blake, Crystal Jenkins Edmond

1. Problem – Complicated communications leading to delays and frequent rework for study start

Reliance Process Single Center March 2024



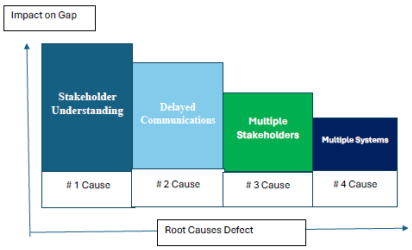
2. Root Causes:

Multiple key stakeholders	Stakeholder understanding of the reliance process at Cedars-Sinai	Delayed follow-up in communications	Multiple systems to use
Sponsor, IRBs, Finance, Regulatory, Liaisons, Clinical, MDs, and multiple internal departments involved in the process	The sponsor prefers the reliance process to utilize one IRB.	Communication with multiple parties is easy to lose, especially where and when the last communication occurred.	Communications can come from multiple systems and in many forms, such as voice mail, paper, and electronic.
Clinical Research complexity involves multiple touch points, with various interests in outcomes, and can lead to additional redundancies.	Local context is up to the local IRBs, who have the final oversight and are held to this compliance standard.	Unclear what the various roles and the ideal person to communicate with from all stakeholders	Each Stakeholder group has its required system for tracking purposes, and the systems do not talk to each other.
Changes in clinical research structure and access always add additional stakeholders.	Current regulations hold the local IRB accountable	Various roles and the process are not part of standard work and are not communicated in advance with key stakeholders	Each Stakeholder is invested in their systems.
There is no uniform process to determine the number of key stakeholders.		A plan for streamlined communication is not an everyday part of start-up communications.	

4. Action Plan

Goals:	Actions:	By Who:	By When:
Reliance Training Program	Create a general review of the reliance process, including the history and how compliance works, along with flexibility with changing regulations for updates.	Brenda Hann	June 2024
Monitoring delayed communications streamlining a plan for improved communication between internal and external stakeholders	Begin a plan to streamline roles, responsibilities, and how to track communications for improved workflow.	Julian Blake, Crystal Jenkins, Edmond	January 2025
Minimize the number of stakeholders.	Include all IRBs the sponsor chooses, if Cedars already has a reliance agreement in place, and if it is feasible, startup with one test case.	Julian Blake	June 2024
Understand various systems, add improved systems, and understand how they interact.	Review current systems and look for improvements for streamlined communications.	All stakeholders, TACRI Lead for our internal processes	January 2025

3. Pareto:



Process Map