Streamlining the IRB Reliance Process at a Single Institution


The Angeles Clinic and Research Institute, a Cedars-Sinai Affiliate

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.
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 Process Map