

Northwell Health Establishes Single IRB to Improve Trial Oversight and Execution

Northwell Health Applies CTTI's Single IRB Recommendations

SUMMARY

Northwell Health, a large health system of 23 hospitals, needed to put procedures in place to have oversight of studies as a single IRB because its researchers were working with Community Health Centers that wanted to rely on Northwell IRB as the single IRB for their studies. Furthermore, Northwell had many studies using external IRBs, which required a central program to maintain oversight. Finally, Northwell HRPP wanted to assure they were prepared for the National Institutes of Health's (NIH) 2018 single IRB mandate. Here is how they did it, what challenges they faced, and lessons learned to share with other colleagues in a similar position.

GOAL(S)

The Human Research Protection Program (HRPP) at Northwell Health supports, facilitates and promotes the ethical and safe conduct of research with human subjects in Northwell studies across 23 hospitals. In the early 2010's, as Northwell Health was continuously bringing on new hospitals with research portfolios, each hospital had different needs. Some researchers were used to relying on outside IRBs while others were asking Northwell IRB to serve as the IRB of record. Northwell wanted to establish a robust central IRB to ensure better oversight and control over its research efforts.

CHALLENGES

Bringing 23 care centers into alignment with a single process is a massive effort, and it was complicated by the fact that multiple studies were ongoing at the time of implementation. The Northwell team had to conduct this project in a way that did not delay timelines for ongoing work. In addition, there was a false understanding by investigators that using an external IRB required less responsibility on their part. The HRPP team needed to educate study teams in order to effectively launch the single IRB plan.

SOLUTION(S)

The director of Northwell Health's HRPP was also on the CTTI project team that collaborated to develop CTTI's Single IRB Recommendations. This was an asset, in that she knew not only the recommendations for single IRB, but also the resources-- nearly all of which would become instrumental in Northwell's effort to establish a single IRB and a central process for managing all research, regardless of reviewing IRB.

TAKING ACTION

One of the first resource documents the Northwell Health team referenced was CTTI's IRB Agreement template, which enables reliance on a study-by-study basis, clearly defining roles and responsibilities. The team developed a template specific to Northwell's needs based on the CTTI template, which served as the baseline for the single IRB implementation. The team also heavily relied on CTTI's Considerations Document of the responsibilities of the reviewing IRB vs the relying institution, which was instrumental in helping Northwell's investigators understand expectations. Training across 23 institutions was a massive effort for Northwell. The concept of being a reviewing IRB or a relying institution was confusing for staff, and different individuals understood the concepts differently across hospital systems. The line of communication between reviewing IRBs, relying institutions, and site investigators had to be clear. For example, if Northwell was the reviewing IRB, Northwell IRB had to define communication protocols with investigators at each site when serving as the single IRB of record.

IMPACT

Northwell Health began serving as a single IRB and actively relying on external IRBs in 2015, three years before the NIH Smart IRB mandate went into effect. As a result, they were ahead of the game and did not need to make any changes when the mandate came down. The director of Northwell's HRPP feels strongly that Northwell would have missed out on numerous studies had they not implemented the change.

ADVICE

Establishing centralized processes to maintain oversight (regardless of IRB of record) across a large health system is a massive endeavor and ongoing effort. Even five years in, the Northwell Health team still encounters questions it must resolve. For example, from an institutional perspective, the amount of oversight required is a balance. If an event occurs in a study, how much information does Northwell need to see as a relying institution, and at what point do they need to see it? In being a reviewing and relying IRB, there are also many different agreements floating around, and tracking which studies use what authorization agreement is an ongoing challenge. However, the overall effort was, from Northwell's perspective, a hugely necessary and beneficial one.

ORGANIZATION

Northwell Health

CONTACT

Hallie Kassan

ORGANIZATION TYPE

Healthcare Delivery/Payer

IMPLEMENTATION DATE

2015

TOPIC

Single IRB

RELATED CTTI PROJECT

[Single IRB](#)

CTTI RESOURCES

[Use of Central IRBs for Multicenter Clinical Trials: Recommendations](#)