Creating a Regional IRB: An Innovative and Collaborative Approach to Protect Research Participants, Serve the Community, and Enhance the Human Research Enterprise in the Same Geographical Area

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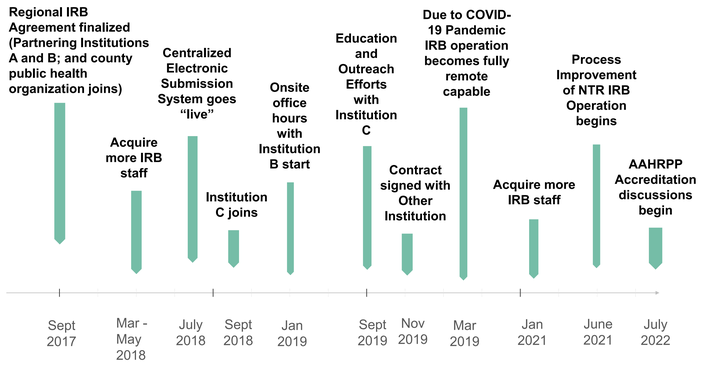
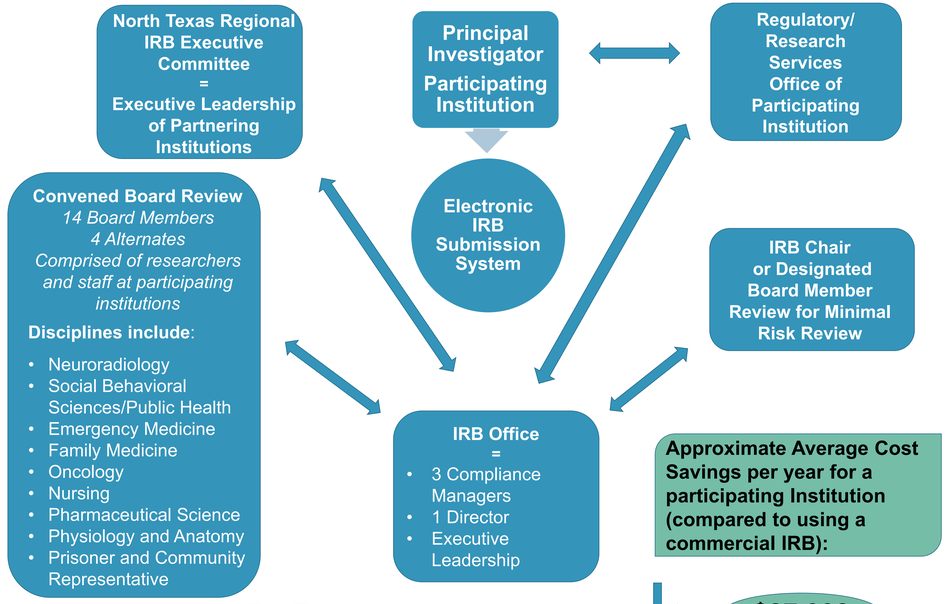
BACKGROUND

The multi-city region has many different institutions (hospitals, clinics, universities and foundations) conducting human subject research, resulting in researchers from various institutions collaborating on a study. However, having to submit projects to multiple IRBs for approval slowed down the process, and created administrative challenges.

PROGRAM DESCRIPTION

The North Texas Regional (NTR) IRB was established in September 2017 with the intention of creating a community IRB that not only serves many institutions but also provides a simplified landscape for fostering partnerships among researchers in the North Texas area. The regional IRB operates a multi-site human research protection program to review and approve all research involving human subjects, whether they be clinical/biomedical or social/behavioral projects. This program has two important components: the administrative support and outreach regarding the protection of human subjects by the IRB office and the regulatory review and approval provided by the NTR IRB itself (the IRB office is physically located at UNTHSC). There are currently two main institutions involved in the partnership (JPS and UNTHSC), and three others who obtain fee-for-service reviews. Success of the program is reviewed by the volume of submissions from the partnering institutions, as well as the research collaborations that occur as a result of this simplified, non-duplicative IRB-review process.





Approximate Average Cost Savings per year for a participating Institution (compared to using a commercial IRB):

$27,338

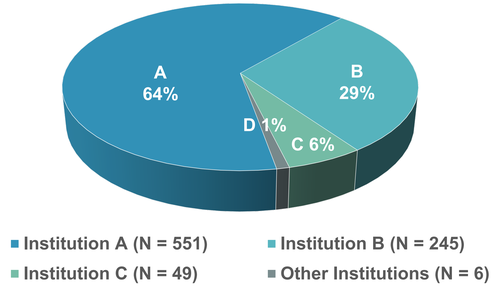
"The collaborative experience working with the NTR IRB has been unparalleled and they clearly have a sincere interest in facilitating successful research projects."

- Quote from a NTR IRB Board Member

"Having a regional IRB has been a tremendous help for improving efficiency and decreasing time spent on regulatory processes! It is not only easier to collaborate between our two institutions, but it is also easier to collaborate on projects that include additional institutions."

- Quote from a Principal Investigator affiliated with the NTR IRB

New Projects (since NTR IRB was established) N = 850



PROGRAM ASSESSMENT

Upon establishment of the NTR IRB, there was initial hesitation from investigators submitting projects for the first time. Challenges in the first year included investigators having limited knowledge of the federal regulations, the process for submitting projects, what was required as part of IRB approval, and the perceived ownership of the NTR IRB. To help alleviate confusion and challenges, officials/administrative teams at each of the collaborating institutions established regular communications and check-in meetings, implemented use of monthly, in-person IRB office hours, conducted in-person trainings, and provided 1:1 customized guidance and resources. Between 2017 and 2021, average annual new study submissions from the collaborating institution gradually increased (from 50 to almost 150). Additionally, participation in the NTR IRB promoted cost-savings (cost per protocol is almost $1000 less than using a commercial IRB), and facilitated several research partnerships (about 10 thus far). Furthermore, researchers from each collaborating institution serve on the IRB providing an array of expertise, and overall researchers in recent years have touted the benefits of having a regional IRB and the services included.

LIMITATIONS

Given the nature of traditional IRB structures, establishing new partners into the regional IRB has remained a challenge. In order to remain as a true regional IRB, additional institutions/organizations will need to be included, which will allow for furthering of research opportunities within the geographical area.

DISCUSSION

Establishment of a regional IRB provides many benefits, in addition to the ones outlined above. First, it satisfies the NIH single-IRB-review recommendation for multi-site studies. Second, it allows for inter-institutional collaboration which underscores translational research, in turn creating partnerships which would not have otherwise occurred. Finally, these partnerships allow for an increase in research opportunities, with the ultimate goal of creating a healthier community.