

The Feinstein Institutes for Medical Research at Northwell Improves Investigator Communication Through Establishment of Central Office

The Feinstein Institutes for Medical Research at Northwell Health Applies CTTI's Investigator Qualification Recommendations

SUMMARY

The [Feinstein Institutes for Medical Research](#) is Northwell Health's research enterprise and home to five major research institutes and numerous centers of excellence of national standing. Northwell Health, a large health system of 23 hospitals and 5,000 researchers and staff, established a first-of-its-kind central administrative office, the Office of Research Policy and Training (RPT), to support centralized policy and learning and development for investigators and research professionals across the system's thousands of ongoing studies. CTTI's [Investigator Qualification Recommendations](#) were central to the Feinstein Institutes' effort.

GOAL(S)

The Feinstein Institutes for Medical Research is the home of research at Northwell Health. During the past several years, Northwell Health has grown into a massive health system with investigators and research professionals located throughout New York State. As the system grew, so did its research portfolio and onboarding of new researchers. By 2011, there was a need to streamline communication and align research policies and processes from the system's various research support offices to meet the needs of the growing organization. The goal was to centralize the overall approach of the support offices for research policies, training, and learning and development while still allowing the flexibility for each support office to leverage its own standard operating procedures and training when required. To address this challenge, the Feinstein Institutes created a position tasked with establishing a support office for the central administration of research policies and learning and development for the system.

CHALLENGES

This type of centralized research support office and learning and development are not traditionally considered as elements of the research infrastructure, so the Feinstein Institutes did not have a wealth of best practices to draw from. The novelty of such a support office also meant resource limitations, including financial constraints, lack of technology, and limited staff and expertise. In fact, the Feinstein Institutes' central office for research policy and learning and development began and stayed as a department of just one employee for several years.

SOLUTION(S)

Fortunately, that one employee also happened to be on the CTTI project team that collaborated to develop the Investigator Qualification Recommendations, which offer guidance on how to identify qualified investigators and their delegates while simultaneously reducing inefficiencies in training and better preparing for the quality conduct of clinical trials. With little other documentation to rely on, CTTI's recommendations would serve as a resource in developing the Feinstein Institutes' RPT office that has a mission to evaluate and manage centralized research policies and research training and professional development so that research employees meet regulatory, industry and institutional standards and requirements.

TAKING ACTION

RPT's creator envisioned a workplace full of curious minds with the flexibility to think differently, capitalize on opportunities, and work smarter while producing knowledge to cure disease. In conjunction with subject matter experts, the team began creating learning modules utilizing adult learning methodologies in a variety of in-person and online formats to ready investigators for Northwell research. They started with CTTI's Investigator Qualification Recommendations, which emphasize a move away from repetitive Good Clinical Practice (GCP) training alone, joining TransCelerate's GCP Mutual Recognition Program¹, and urging teams to migrate toward targeted programming and identification of gaps in knowledge or skills. With that in mind, RPT reached out to investigators and other research staff to better understand their learning needs and to help close gaps that pose risks during the conduct of clinical research. Feedback indicated that investigators and research staff needed a full menu of options to support their needs. The team also considered the learning style of investigators, many whom are also physicians and have grown accustomed to learning in specific ways. The Feinstein Institutes team is working toward mimicking that approach with the implementation of research orientation for Northwell Health employees new to research, as well as offering the option to attend grand rounds, high-level meetings, and "office hours" to speak and work through hot topics and issues. Each of these efforts emphasizes mentorship and coaching wherever possible, providing easily accessible research tools and on-demand services, as well as a variety of Continuing Medical Education (CME) accredited in-person and online classes for on-demand learning. RPT's return on investment and strategic planning is constantly assessed utilizing Kirkpatrick's Four Levels of Evaluation²: (1) reaction, 2) learning, 3) behavior change, and 4) results as a metric, targeting a minimum level three.

IMPACT

Utilizing a learning needs and risk-based approach to create targeted professional development for investigators allowed RPT to fulfill regulatory training requirements, while at the same time supporting lifelong learning and the professional growth of investigators. RPT currently serves as a central resource for research staff, principal investigators, coordinators, and the various research support offices (i.e., IRB, grants management, compliance, etc.) on policies, training, and learning and development across Northwell Health. Research investigators now have a streamlined and central location to proactively look for research policies and learning and development resources, make recommendations on how they envision improving their research qualifications, and empower themselves to be involved in their own professional development specific to research.

ADVICE

Clinical research is always moving, so once solid investigator learning and development is established, organizations should continue to reassess and tweak it on an ongoing basis. It is also helpful to use the Human Performance Improvement model³ in establishing learning materials-- that is, establish the root cause of a learning gap before you offer a solution. For example, a lapse in process adherence does not necessarily mean investigators need traditional classroom training on the process. There may be other gaps or challenges (such as operational, technological, or financial) that are root causes. In addition, this type of central research support office operates similarly to an internal consultant model where mutual respect, commitment, and open-mindedness are critical. Good and proactive communication and change readiness with leadership and the investigator community to establish their needs is essential to any learning and development effort.

CITATIONS

1. GCP Mutual Recognition [Internet]. Transcelerate. [cited 2020May25]. Available from: <https://transceleratebiopharmainc.com/gcp-training-attestation/>
2. Kirkpatrick's Four Levels of Evaluation [Internet]. [cited 2020Aug05]. Available from: <https://www.kirkpatrickpartners.com/Our-Philosophy/The-Kirkpatrick-Model>
3. Human Performance Improvement Model. [Internet]. [cited 2020Aug05]. Available from: <https://www.td.org/insights/what-is-human-performance-improvement>

ORGANIZATION

Northwell Health

CONTACT

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ORGANIZATION TYPE

Academia

IMPLEMENTATION DATE

2013

TOPIC

Investigators & Sites

RELATED CTTI PROJECT

[Investigator Qualification](#)

CTTI RESOURCES

[CTTI Recommendations: Identifying Qualified Investigators and Their Delegates to Conduct Sponsored Clinical Trials](#)

ADDITIONAL RESOURCES

Arango J., Chuck T., Ellenberg S., Foltz B., Gorman C., McHale S., Merchant K., Selter J., Shapley S., & Wild G. Good Clinical Practice training: identifying key elements and strategies for increasing training efficiency. *Ther Innov Regul Sci* 50, 480–486 (2016).

Bechtel J., Chuck T., Forrest A., Hildebrand C., Panhuis J., Pattee SR., Comic-Savic S., & Swezey T. Improving the quality conduct and efficiency of clinical trials with training: Recommendations for preparedness and qualification of investigators and delegates. *Contemporary Clinical Trials* 89 (2020).

Swezey T., McGuire F.H., Hurley P., Panhuis J., Goldstein K., Chuck T., Dombeck C., Perry B., Brennan C., Phrsai N., Corneli A.. More than a box to check: Research sponsor and clinical investigator perspectives on making GCP training relevant. *Contemporary Clinical Trials Communications* (2020).