The Children's Hospital of Philadelphia established the CTO in 1999 as part of the institution's emphasis on clinical research. Since that time, the CTO has experienced rapid growth and now offers a wide array of services to the Hospital and research community.

The CTO advances the quality and quantity of clinical research at Children's Hospital and its associated network. Specifically, the CTO supports research at the Hospital by developing and completing submissions to the Hospital's IRB; assisting in the preparation of IND and IDE application submissions to the FDA; conducting clinical research studies under the guidance of principal investigators; and developing budgets and providing research training for investigators, study coordinators and administrative staff.

The CTO works in partnership with investigators to ensure the protection of human subjects in accordance with GCP, federal, state and/or local regulations and the requirements of the study sponsor.

**CTO Administration**

Lisa A. Speicher, Ph.D.
Director, Clinical Trials Office

Nirmala Thevathasan, MPH, CCRC
Associate Director, Clinical Trials Office

For more information on the CTO or any of our services, please visit our Web site at http://stokes.chop.edu/programs/cto/index.php or contact us at the address or phone number below.

The Clinical Trials Office
The Children's Hospital of Philadelphia
34th Street and Civic Center Boulevard
Philadelphia, PA 19104-4399
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Excellence in the Administration and Management of Pediatric Clinical Studies

The Children's Hospital of Philadelphia®
Hope lives here.
The Clinical Trials Office (CTO) at The Children’s Hospital of Philadelphia is a centralized office that provides resources and assistance to clinical research investigators, enabling them to carry out clinical research in a manner consistent with the Hospital’s goals — excellent patient care, top-quality education, and innovative research. The CTO serves as the central focal point for clinical research activity at Children's Hospital and provides leadership, collegiality, and guidance to all study coordinators and other personnel. The CTO provides a variety of services that benefit both novice and experienced clinical researchers. With expertise in implementing, conducting, and monitoring clinical trials, the CTO ensures the excellence and compliance of clinical research trials.

The Value of Diversity

The CTO employs professionals with diverse backgrounds and various levels of education and experience. Our staff is composed of registered nurses, respiratory therapists, dieticians and other health care professionals. Staff members hold advanced degrees in a variety of disciplines including psychology, public health, business, education and clinical research. This broad range of experience and knowledge provides a solid foundation for a quality- and compliance-driven clinical research program.

Overview of Services

- Assign experienced clinical research staff to work collaboratively with principal investigators and study teams to initiate and facilitate quality research and data
  - Study coordinators are available on a full-time, part-time or fee-for-service basis
  - Clinical project managers and clinical research associates (monitors) are also available
- Facilitate study feasibility and study placement decisions
- Participate in the most current clinical research on common and rare pediatric diseases and conditions
- Provide expertise in all phases of drug trials, device trials, data collection studies and interview-based studies
- Provide operational and regulatory support for investigator-initiated and industry-sponsored studies that may require an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application
- Assist with Institutional Review Board (IRB) and other regulatory submissions
- Develop protocols
- Serve as an initial liaison with pharmaceutical companies
- Train new and seasoned coordinators
- Ensure trials are conducted following Good Clinical Practice (GCP) guidelines, Food and Drug Administration (FDA) regulatory guidelines, and International Committee for Harmonization (ICH) guidelines

The CTO frequently assists industry sponsors and academic centers by identifying potential site investigators at Children's Hospital. An investigator who would like to conduct a clinical trial or has been contacted by an industry sponsor or academic center to conduct a clinical trial should contact the CTO for assistance.

The CTO supports projects funded by a variety of sources including, but not limited to, National Institutes of Health, industry sponsors, foundations, organizations, and research networks.

Training

All CTO clinical research coordinators and monitors undergo an extensive clinical research orientation program. Training at the CTO includes:

- Human research subject protection
- GCP guidelines
- FDA and ICH guidelines
- Ethics and the role of the IRB
- Informed consent process
- Confirmation of subject eligibility
- Protocol adherence
- Enrollment goals
- Research registration and billing compliance
- Adverse event reporting
- Preceptor and shadowing opportunities
- Mandatory continuing education

In order to maintain a high level of quality for our staff and their research studies, the CTO encourages all eligible coordinators to sit for the Clinical Research Coordinator Certification examination, administered by the Association of Clinical Research Professionals (ACRP). ACRP is a nationally recognized organization that promotes effective clinical research.