Clinical Research Trial Site Profile

INFORMATION FOR SPONSORS

Top **10** in the nation among *U.S. News & World Report's* Best Children's Hospitals 2024–2025 Honor Roll list

#2 in the nation in NIH grants and funding for pediatrics

Certifications

AAHRPP
Association for the Accreditation of Human Research Protection Programs

CAP
College of American Pathologists

CLIA
Clinical Laboratory Improvement Act/Amendment

Magnet
American Nurses Credentialing Center

Cincinnati Children's Research Foundation

- **Clinical Trial Services:** Concept and Protocol Development to Trial Management Support
- **Pediatric Clinical Trial Test Site:** Phase I–IV
- **Adult Clinical Trial Test Site (select therapeutic areas):** Phase I–IV

Registrations

Federalwide Assurance: 00002988
IRB: 0RG0000136

Cincinnati Children's™ Research Foundation

Cincinnati Children's at a Glance

Est. 1883 Full-service, nonprofit, comprehensive pediatric health system consisting of more than 50 unique locations that comprises the Department of Pediatrics, University of Cincinnati College of Medicine

Our vision: to be the leader in improving child health

Served patients from **90 countries** and all **50 states.** Our employees represent **128 countries.**

Top 5 largest U.S. children's hospital with 762 registered beds (including 140 inpatient and residential psychiatric beds)

STATISTICAL HIGHLIGHTS (JULY 1, 2022 – JUNE 30, 2023)

Total Admissions	33,116
Total Patient Encounters	**1,652,584**

FACULTY & STAFF

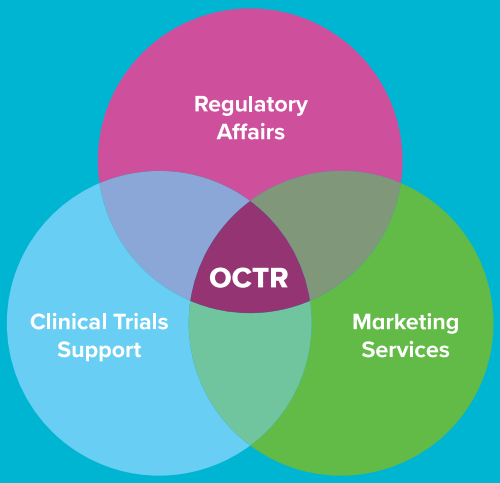
Clinical Fellows	273
Research Fellows	136
Research Associates	180
Residents	228
Faculty	1,097
Active Medical Staff	**1,914**
Total Employees	**18,589**

Office for Clinical and Translational Research (OCTR)

The OCTR functions as a "one-stop" clinical research support center—from concept development to publication. Its mission is to provide clinical investigators and sponsors with comprehensive support services, research tools, experienced research personnel, and facilities to conduct or facilitate pediatric and adult clinical research—from identification and development of research opportunities to phase I through phase IV clinical research trials. Support services provided by the OCTR include:

- Clinical Trials Support
- Translational/Early Phase Trial Support
- Regulatory Affairs
- FDA Submission Support
- Multisite Trials Support
- Marketing and Retention Support

The OCTR understands sponsors' needs and is committed to conducting clinical studies with heightened attention to time constraints and budgets. The OCTR has access to all of Cincinnati Children's therapeutic divisions, as well as collaborating with other Cincinnati Children's research centers of expertise to meet your study needs.



Site Contacts

Cincinnati Children's Research Foundation

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Investigational Pharmacy

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Investigational Drug Service
Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue, MLC 6090
Cincinnati, OH 45229
513-636-3016 | Fax: 513-636-2740

Sponsored Research Service (SRS)—for Contract and Budgets

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Additional Information

Data regarding specific patient populations, procedures and/or capabilities are available upon request.

Site visits arranged by appointment.

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Recent Research Achievements

- Experts at our CuSTOM Accelerator Lab have published breakthrough production methods that will help provide large numbers of liver, small intestine, colon, and stomach organoids for research use in labs worldwide.
- More than 500 faculty, staff and students participated in the first annual Cincinnati Children's Research Symposium on May 5, 2023, which recognized 100+ years of innovation as well as the latest research that's helping us achieve the goals of our strategic plan.
- Harnessing the capabilities of one of the world's most powerful supercomputers, experts at Cincinnati Children's and their partners are tapping into the power of artificial intelligence to help identify kids at greatest risk of developing a mental illness for early care and intervention. With successful validation, this trajectory approach will change the way we diagnose and treat mental illness.
- More than 2,400 peer-reviewed journal articles, book chapters, and other publications were published by Cincinnati Children's researchers in 2022.
- With more than 1,000 faculty researchers, Cincinnati Children's is consistently a top-3 recipient of NIH grants and funding, securing $283M in external funding plus $21.5 million in philanthropic donations for research.

Clinical Trial Services

Drug and Device Discovery Collaboration

- Cincinnati Children's supports collaborative efforts with industry.
- More than 1,100 of our investigators are pursuing studies in most of the major pediatric sub-specialties.

Protocol Development

- Our specialists are available to collaborate with pharmaceutical sponsors to develop new pediatric protocols.
- Sponsors may contact the OCTR if they would like to partner with an investigator for science/medical input and haven't identified one.
- Our services include study design optimization, leveraging our pediatric-specific insight and experience to create the most effective study design and accelerate time-to-market for pediatric drug development, which reduces overall cost.
- We have extensive experience in pediatric pharmacokinetic modeling and simulation to support pediatric study plans.
- Our pharmacometrics services offer extensive expertise in quantitative pharmacology and population pharmacokinetic/pharmacodynamic (PK/PD) modeling.
- Our sophisticated modeling and simulation software enables more effective trial design and helps meet the challenges of a limited patient population.
- We offer extensive knowledge of the FDA review process.
- Our team can coordinate the entire process, from developing the study design and writing the pediatric-specific clinical protocol to implementing the protocol and analyzing data, which provides sponsors convenience and cost efficiencies of a single location.
- Our team has connections to pediatric and adult research networks.

Biostatistics and Data Management Clinical Trial Support

- Our team can provide clinical data management support for clinical trials, as we:
  - Have data managers with more than 10 years of industry experience in supporting clinical trials.
  - Have managers certified by the Society of Clinical Data Management.
- We use the clinical data management system, Medidata Rave®.
  - Rave is an industry leader in electronic data capture and is a 21 CFR Part 11 compliant system.
  - We have certified Rave builders on staff.
- We provide statistical support for clinical trials.
  - Statisticians have more than 20 years of experience supporting pharmaceutical trials.
  - Statisticians are available to participate in study design, development, and execution of statistical analysis plans.
- Statistical programming support for clinical study reports is available.
  - Certified SAS programmers can provide tables, figures, and listings for incorporation into clinical study reports.

Regulatory Affairs and Trial Operations

- We have regulatory affairs professionals with pharmaceutical and medical device experience on staff.
  - Our team can manage IRB and FDA Submissions, regulatory files, SAE/AE reporting, FDA/NIH reports, and DSMB reports.
  - Our team can provide training, quality reviews, and audit preparation.
- Our team includes experienced regulatory, operations, and management teams that have a successful track record of operationalizing and managing multi-site trials.
- We have experienced clinical research associates on staff.
  - Our teams includes experienced monitors well versed in FDA regulations, monitoring visits, creation and execution of monitoring plans, ICH guidelines, and GCP provide training, study start-up, and SIVs.

Investigators

- Additional investigator background is available upon request once an investigator has been identified including:
  - The patient population to which the investigator has access.
  - The investigator's research study experience.
  - The number of research studies the investigator has conducted and in which specific disease(s)/condition(s).
- One PI and/or study coordinator will attend the investigator meeting.
- The PI will be available during the monitoring visit to meet with the CRA (with advance notice).

Institutional Review Board

- In most instances, we use our own local IRB, but there are instances where we will rely on an outside IRB.
- The local IRB meets weekly, every Tuesday.
- There is no submission deadline, and they are reviewed on a first-come, first-serve basis.
- Additional ancillary reviews (such as division, radiology, etc.) are required for certain projects and are embedded within the IRB application process.
- For a full board, new study submissions typically take 6 to 8 weeks from the time the submission is made.
- Additional submissions vary based on the type of submission and level of review required.
- We have experience with various inspections by regulating agencies (FDA, EMEA, and other regulatory authorities).
  - Specific audit results are available from the department or division where applicable.
- Occasionally, based on the study population, translated documents may be needed.
  - Verbal translation services during visits are available.
- We use the following off-site storage company:
  - Access Document Management
    690 Cescentville Road
    Cincinnati, OH 45246-1314
    513-671-7717

IRB Address

Cincinnati Children's Hospital Medical Center
Institutional Review Board
3333 Burnet Avenue, MLC 5020
Cincinnati, OH 45229-3039

Contracts and Budgets

- All industry-sponsored budgets are negotiated and approved through the Sponsored Research Service (SRS) in collaboration with the division.
- The final protocol, CTA, and proposed budget must be received before initiating any budget or contract negotiations.

Payment Information

Checks should be made payable to:

Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue
Research Billing, MLC 4900
Cincinnati, OH 45229-3039

Please reference the PI name and protocol number.
Tax ID # 31-0833936

Research Facilities

- We have over 1.4 million square feet of space dedicated to research including:
  - Monitor rooms.
  - Pediatric and adult-friendly exam/treatment rooms.
  - Waiting areas.
- We have onsite investigational pharmacies with locked storage.
- There are onsite laboratory facilities including:
  - A central laboratory.
  - Multiple specialty laboratories.

The Schubert Research Clinic (SRC)

The SRC provides resources that enable investigators to perform high-quality, patient-oriented research at various venues across the Academic Health Center and the community.

- The SRC is located on the main campus of Cincinnati Children's, on the first floor of the Clinical Sciences Pavilion (T-Building).
- The facility includes:
  - 28 exam rooms.
  - Preparatory lab with equipment for processing samples.
  - Packaging and shipping room for clinical research samples.
  - Metabolic kitchen for nutritional studies and teaching.
  - Body composition laboratory with DXA scanners.
  - Biochemistry laboratory.
  - Vascular research laboratory.
- The clinic accommodates visits from less than 30 minutes to over 10 hours.
- It is equipped for participants from infants to seniors.
- The clinic is fully staffed with highly trained professionals including:
  - Research nurses;
  - Registered dietitians;
  - Research assistants and
  - Study coordinators.
- The SRC has admission privileges on the main campus for inpatient stays.
- Access to the SRC is open to any clinical researcher within the Academic Health Center who has an approved IRB study.
- The SRC operates Monday through Friday and the 2nd Saturday of each month. The clinic is closed for all hospital observed holidays.

Investigational Drug Service (IDS)

The Cincinnati Children's IDS is responsible for the pharmacy activities for all clinical trials conducted at Cincinnati Children's and currently manages drug inventory and dispensing for over 300 active protocols.

- They provide services customized to each research protocol conducted at Cincinnati Children's including:
  - Randomization.
  - Inventory maintenance.
  - Drug accountability.
  - Compounding and preparation of blinded dosage forms.
  - Developing pre-printed order forms.
  - Dispensing investigational drugs according to protocol.

- The IDS is responsible for both inpatient and outpatient investigational medication dispensing for industry-sponsored, grant-funded, and investigator-initiated protocols.
- The current IDS staff includes 5 pharmacists, and one pharmacy technician.
- This area occupies over 1,800 square feet for drug storage, preparation, and office space for the staff.
- All IDS and SRC staff work within the limits of their job description and responsibilities. As such, they are not considered study staff and are not listed on the Delegation of Authority log.
- The staff can manage the destruction of a study drug, policy available upon request.
- Have temperature monitoring capabilities.
  - Room temperature is monitored via a min/max thermometer and logged daily Monday through Friday.
  - Refrigerators/freezers are monitored electronically via RMMS systems.
  - Staff are notified of any after-hours issues via page/text.
  - All equipment is on backup power.
- Monitors have access to the IDS for onsite visits but should:
  - Work with each study team (e.g., investigator, study coordinator) to schedule visits to the IDS.
  - Not contact pharmacy staff directly to schedule IDS monitoring.
- All visitors must adhere to Cincinnati Children's policies governing institutional access and badging requirements.
- The IDS uses the drug accountability system Vestigo.
  - Vestigo is an application to support investigational drug services for managing the drug therapy used as part of a research protocol.
  - The application features tools to assist with protocol management, full electronic virtual inventories with drug accountability, dispensing and labeling of prescriptions, protocol billing management, and reporting.

IDS Shipping Address

Cincinnati Children's
Investigational Drug Service
3333 Burnet Avenue, MLC 1011
Cincinnati, Ohio 45229

Electronic Medical Records (EMR)

- The EMR is validated and certified by the Office for the National Coordinator for Health Information Technology (ONC).
  - This means that documentation exists to verify that the system was installed correctly and that all functions have been tested to ensure they accurately, reliably, and consistently perform as intended.
- The EMR is primarily a clinical system and as such, FDA guidance states that EMRs will not be evaluated for Part 11 compliance. Research documentation may occur if it's determined to be of clinical relevance.
- Unique user IDs and confidential passwords are required for access and regular password changes are required.
- The EMR has an audit trail to track the entry of any changes to data, including recording the date/time/author of data creation, change, or deletion.
- Audit trail information be made available for review upon request.
- Documented training is provided for persons who use and maintain the EMR.
- Written procedures are in place for the use/operations/maintenance of the EMR system.
- External monitors may have access to the EMR, but the site research staff will choose which of the following options is best suited for the study.
  - Monitors are provided with printouts from the EMR that meet the criteria for certified copies.
  - Monitors complete an assisted review by spot-checking EMR records in the presence of site research staff.
  - Monitors can be granted access to review EMR records for specific research participants via the EpicCare Link web platform.
    - They will be asked to complete an electronic agreement and assigned a unique user ID and password.

- Monitor access is read-only, limited to research study participant records, and can occur onsite or remotely.
- The EMR system is periodically backed up and data retention periods comply with local regulations.

Equipment for Research Trials

- We have a -70°C/-20° C specimen storage freezer monitored 24/7 by an automated centralized electronic system.
- Other equipment includes (but not limited to):
  - 12-Lead ECG
  - Refrigerator
  - Treadmill
  - Pulse Oximeter
  - Ultra-sonic Nebulizer
  - Metabolic Cart for CPET
  - Body Plethysmograph (Body Box)
  - Non-Refrigerated Centrifuge
  - Refrigerated Centrifuge
  - Cycle Ergometer
  - Access to dry ice

Participant Recruitment and Retention Tactics

The Office for Clinical and Translational Research (OCTR) marketing staff works with Cincinnati Children's researchers to assess recruitment needs of research studies, construct plans, and implement actions that ensure targeted and effective recruitment and retention efforts.

Recruitment

Depending on the study's individual recruitment and retention needs (and the extent of the recruitment budget), a participant recruitment plan is customized using various appropriate strategies and tactics. Some of the recruitment tactics include:

- Printed materials including flyers, posters, brochures, postcards, etc.
- 80-plus recruitment stations (within Cincinnati Children's facilities and in the community), each displaying 10–36 branded individual clinical study flyers (specifically targeted to that location's demographics, when possible). Study information from recruitment stations has been very effective with minority population recruitment.
- Research study web pages on the Cincinnati Children's website, local and national support association websites, and targeted web advertising.
- E-newsletter—using Cincinnati Children's internal email system with more than 25,000 addresses. Study information is frequently forwarded to family and friends in the community.
- E-newsletter sent to a database of interested potential participants/households.
- Social media organic posts on Facebook (facebook.com/CincyChildrensStudies/), and Instagram (instagram.com/CincyChildrensStudies/).
- Paid advertising through a marketing agency; includes Facebook and other social media ads, TV, radio, and print ads.
- Community events such as school and community health fairs where face-to-face contact is made, and study materials distributed.
- Public relations activities through collaborations with Cincinnati Children's Marketing and Communications Department including local and national television, radio, internet, print, and other media opportunities.
- Support groups—partnering with community support groups (locally and nationally) to disseminate study information through group websites, networks, newsletters, special events/meetings, and in-person presentations.

Retention

Participant retention tactics are tailored to the individual needs of each study. Some of the retention tactics include:

- Creating branded participant reminder notes, birthday cards, magnets, stickers, appointment cards, postcards, mugs, and many more appropriate promotional items.
- Developing special promotions to encourage/remind participants of required compliance, an appointment, or other study-related activity.
- Facilitating the creation of study-specific websites to communicate/interact with the study population.
- Coordinating, writing, and publishing study newsletters—both electronic and hard-copy versions.
- Cultivating relations with internal and community support groups to pursue joint ventures to reach their constituents (and families) via their communication tools, networks, and special events.
- Planning special events and group activities for study participants.
- Identifying and branding appropriate small recognition gifts and certificates for participants to foster a sense of accomplishment and recognition for reaching study goals.

Race, Ethnicity, and Gender of Cincinnati Children's Patients

Race	
White/Caucasian	68.7%%
Black/African American	18.6%
Other	4.2%
Multi-racial	3.5%
Asian	2.8%
American Indian or Alaskan Native	0.2%
Native Hawaiian/Other Pacific Islander	0.2%
Unknown	1.8%

Ethnicity	
Non-Hispanic	90.7%
Hispanic	6.9%
Unkown	2.4%

Gender	
Female	49.6%
Male	50.4%

Investigator Experience

Some of our areas of research expertise include:

- Allergy and Immunology
- Attention Deficit Disorder/ Attention Deficit Hyperactivity Disorder
- Adolescent and Transition Medicine
- Aerodigestive Disorders
- Amyotrophic Lateral Sclerosis (ALS)
- Anesthesia
- Arthrogryposis
- Asthma
- Audiology
- Autism Spectrum Disorders
- Autoimmune Disorders
- Bariatric Surgery
- Behavioral and Mental Health
- Bioinformatics
- Bone Formation Disorders
- Brachial Plexus Injuries
- Brain Tumor
- Cancer and Blood Diseases
- Cardiovascular Disorders and Malformations
- Cerebral Palsy
- Chronic Pain
- Community Health
- Congenital Cardiac Malformations
- Congenital Diaphragmatic Hernia
- Congenital Lung Malformations
- Connective Tissue/ Skeletal Dysplasias
- Marfan Syndrome/Ehlers Danlos Syndrome
- Contraceptives
- Cystic Fibrosis
- Dermatology
- Developmental Disabilities
- Diabetes Mellitus (Type I and II)
- Down Syndrome
- Drug Metabolism, Pharmacodynamics and Pharmacokinetics
- Dyspraxia
- Eating Disorders
- Eosinophilic Disorders
- Epilepsy
- Esophageal Disorders
- Facial Plastic Reconstruction
- Fanconi Anemia
- Fragile X Syndrome
- Gastrointestinal Diseases
- Gaucher Disease
- Genetics and Genomics
- Growth Disorders
- Headache Disorders
- Head and Neck Disorders
- Head Trauma
- Hemangioma and Vascular Malformations
- Hematologic Disorders
- Hemophilia
- Hereditary Cancer
- Hirsutism
- Histiocytosis
- Home Ventilator Program
- Hypertension
- Hypoglycemia
- Imaging (all organ systems)
  - CT
  - MRI and MRA
  - Fluoroscopy
  - Ultrasound
  - PET Scanning
  - Nuclear Imaging
- Immotile Cilia Syndrome
- Immunodeficiencies
- Infectious Diseases
- Inflammatory Bowel Disease
- Intellectual Disabilities
- Juvenile Rheumatoid Arthritis
- Kidney Disorders
- Language and Speech Disorders
- Laryngeal Disorders
- Learning Disabilities
- Leukemia
- Liver Disease
- Lysosomal Disease
- Menstrual Disorders
- Metabolic Disorders
- Motility Disturbances
- Multiple Anomalies
- Muscular Dystrophy
- Myelomeningocele
- Neurological Diseases
- Neuromuscular Diseases
- Obesity
- Ophthalmic Diseases
- Otitis Media
- Pain Management
- Pervasive Developmental Disorders
- Pediatrics
- Pediatric Trauma
- Perinatal
- Pneumonia
- Polycystic Ovarian Syndrome
- Psychological and Behavioral Disorders
- Pulmonary Hemosiderosis
- Rheumatic Disorders
- Rhinitis
- Rubinstein-Taybi Syndrome
- Scoliosis
- Seizure Disorders
- Sexual Development Disorders
- Sexually Transmitted Diseases
- Short Gut Syndrome
- Sickle Cell Anemia
- Sinusitis
- Skin and Soft Tissue Disorders
- Sleep Disorders
- Spina Bifida
- Sports Injuries, Care, Prevention and Performance Training
- Stem Cell and Organoids
- Stroke
- Systemic Lupus Erythematosis Systems Biology
- Thyroid Disorders
- Tonsillitis
- Tourette Syndrome
- Transplantation
  - Blood and bone marrow
  - Heart
  - Kidney
  - Liver
  - Lung
  - Small bowel
- Trauma Medicine
- Tuberous Sclerosis
- Turner Syndrome
- Upper Airway Obstruction
- Urologic Problems
- Vaccine Development and Research
- Velopharyngeal Dysfunction
- Voiding Dysfunction