Clinical Study Site Profile Questions and Answers for Sponsors

Cincinnati Children's Research Foundation

- Pediatric Clinical Studies Test Site:
 Phase I-IV
- Adult Clinical Studies Test Site (select vaccine and cancer): Phase I-IV



change the outcome®



Site Background Information

Cincinnati Children's Hospital Medical Center/Cincinnati Children's Research Foundation is a not-for-profit hospital and research center pioneering breakthrough treatments, providing outstanding family-centered patient care and training health care professionals for the future. Cincinnati Children's is accredited to conduct clinical research by The Association for the Accreditation of Human Research Protection Programs (AAHRPP) and has been conducting pediatric research since 1931. It is the second highest recipient of NIH research grant funding among comprehensive pediatric centers. Annually, it has more than 1,500 investigator-initiated, industry- and federally-sponsored IRB active protocols including pediatric Phase I-IV, and select adult (vaccine and cancer) Phase I-IV clinical studies.

Cincinnati Children's is a full-service, pediatric academic medical center with 523 registered inpatient beds (including 36 registered residential psychiatry beds) serving Southwestern Ohio, Southeastern Indiana and Northern Kentucky. It has more than 1,003,000 patient encounters, annually.

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

Research Investigators and Staff Contacts

Medical Director Clinical Trials Office

- Board certified in Pediatrics, Adolescent Medicine, Internal Medicine and Clinical Pharmacology

Michael Spigarelli, MD, PhD michael.spigarelli@cchmc.org 513-636-3232

Initial New Study Contact

Mark Schuller mark.schuller@cchmc.org 513-636-0314

Potential Principal Investigator

Facilitated based upon study need and investigator interest within institution

Potential Study Coordinator

Facilitated based upon study need

Investigational Pharmacy

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Regulatory Affairs

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Contracts and Budgets

Pamela Jordan pamela.jordan@cchmc.org 513-636-3203 Steve Hope stephen.hope@cchmc.org 513-803-0772

Investigator Specialties

How many potential investigators?

Cincinnati Children's has 450 investigators in most of the major pediatric sub-specialty areas.

Is additional investigator background available on request?

Yes, more information may be obtained 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)

How many study coordinators?

More than 300 institution-wide GCP trained coordinators

Is Cincinnati Children's part of a site management organization (SMO)?

No

Are all staff English-speaking (including the PI and at least one study coordinator)?
Yes

Will one PI and/or study coordinator be able to attend the investigator meeting? Yes

Will the PI be available during the monitoring visit to meet with the CRA (with advance notice)? Yes

How many studies do coordinators work on at a time?

The number of studies each coordinator works on depends on the requirements and complexity of the studies.

Can coordinators conduct home visits? Yes

Are there qualified staff to draw blood and prepare multiple samples for shipping?

Yes

Institutional Review Board

Is the use of a central Institutional Review Board/ Ethics Committee (IRB/EC) permitted? No. We use our local IRB.

How often does the local IRB meet? Weekly, every Tuesday

What is the submission time prior to a meeting? Submit when ready, electronic submission system, ASAP

What is the turn around time for written approval documentation?

Four to six weeks for a full IRB review for a typical study

Has the FDA, EMEA, or other regulatory authority audited Cincinnati Children's?
Yes

When?

Specific audit results available from department or division where applicable

When was the last FDA inspection of the IRB and what was the outcome?

September 2006, no 483 was issued

What is the IRB complete name and address?

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

Is there a need to have informed consent forms translated into other languages?

Occasionally, based on study population, translation services available through Cincinnati Children's approved vendors.

Facilities

Are there overnight-stay beds available for research studies?

Yes, the Clinical Translational Research Center (CTRC) at Cincinnati Children's Hospital Medical Center supports research in childhood and adult diseases. It is one of 52 CTRCs and 24 Clinical and Translational Science Award Consortium member institutions throughout the United States funded by the National Institutes of Health to conduct clinical research. The 12-bed inpatient/12-room outpatient 11,000 sq. ft. unit, including four beds for sleep research, is located on Cincinnati Children's main campus. The CTRC is staffed by a patient services director, a full complement of nurses, clinical department technicians, a research dietitian, core laboratory technicians, an administrative manager, research coordinators, and a unit service coordinator.

Also, beds throughout the hospital (523 beds total) may be accessed for research purposes depending upon the disease/study area and availability.

Are there onsite investigational pharmacies with locked storage?

Yes

Are there onsite laboratory facilities?

Yes

- Central Laboratory
- Laboratory of Applied Pharmacokinetics and Therapeutic Drug Management
- Mass Spectrometry Laboratory
- Multiple specialty laboratories

Is there designated research space?

Cincinnati Children's has approximately 1,000,000 sq. ft. of research facilities. This includes monitor rooms, pediatric- and adult-friendly exam/treatment rooms and waiting areas.

Computer Equipment and Internet Capabilities

Is there an IT/Technical contact available 24/7? Yes

Is there a site preference to work with paper source documents or electronic source documents? Electronic data capture (EDC)

Is there prior site experience with use of an EDC system?

Yes, various sponsor-specific systems have been frequently used.

When changes are made to the system, is there repeat testing and documentation of this testing? Yes

Is there documentation that system users have been trained?

Yes

Does the system employ unique IDs and passwords for each user?

Yes

Is there a historical electronic log that captures all users' actions?

Yes

Are the computer's electronic records available for inspection and/or review?

Yes

Are there written procedures for protection of the electronic records?

Yes

Are electronic signatures used in our system? Yes

If so, do system users who electronically sign records understand that they are essentially replacing their handwritten signature with the legally binding equivalent?

Yes

Are sponsors or its designees allowed direct access to the electronic systems that contain source data?

No, we prefer to provide a printout of required documents signed by the PI to ensure authenticity.

Are there multiple access ports for internet use? Yes, Cable, DSL, wireless

What Windows Operating System (OS) and Service Pack (SP) is used?

Windows XP

What is the computer's processor speed?

Speed: All>300 MHz/GHz (minimum = 128MB)

What is the computer's memory (RAM)?

Memory: exceeds requirements MB

(minimum = 128MB)

What is the monitor's display resolution?

Resolution: exceeds requirements (minimum = 1024 X 768 with a Super Video Graphics Adapter(SVGA)

What is the Internet Explorer (IE) version?

IE Version: 7-8 on all machines (minimum version = 5.5)

Are there CD-ROM drives?

Yes

Is a computer available for EDC data entry at all times throughout the whole term of the study?

Yes

How do the computers connect to the internet?

Broadband (LAN, Cable, ADSL, DSL and wireless)

Are there monthly usage limitations for access to the Internet?

No

Are there internet security software installed on the computer?

Yes (Virus software, Spyware blocker, etc.)

Can the CRA connect to the internet while on-site? Yes

Can a dedicated fax line be established for a study? Yes

Equipment

Is a -70°C/-20° C specimen storage freezer available? If so, are the freezers alarmed and monitored?

Yes / Monitored 24/7 by an automated centralized electronic system

What other equipment is available?

Other available 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

Sample of Study Procedures

(Cincinnati Children's is a comprehensive medical center and performs most procedures)

6-minute walk test

12-Hour PK blood draws

Antigen challenge

Arterial blood gases

Bronchoscopy w/biopsy

Bronchoscopy w/bronchiolar brushings

Bronchoscopy w/lavage

Cardiopulmonary exercise test (CPET)

Chest radiograph

CT scan

DEXA

DLco(TLco)

Exercise challenge

Exhaled nitric oxide (NO)

Histamine challenge

Holter ECG monitoring

Maximum expiratory pressure (MEP)

Maximum inspiratory pressure (MIP)

Maximum voluntary ventilation (MVV)

Methacholine challenge

Overnight facilities for 24-hour PK

Shuttle walk

Skin testina

Spirometry

Sputum induction

Staffing for serial spirometry

Static lung volumes

... and many more

Recruitment Tactics

Depending on the recruitment needs of the study, a participant recruitment plan is customized using various tactics including (but not limited to the following):

- Cincinnati Children's hospital, outpatient and satellite clinics and community-based practice referrals
- Advertising internet, radio, television, newspaper (daily and community) as well as special interest magazines such as "Cincinnati Family," "Cincinnati Parent," Super Shopper, REACH Magazine and others
- Cincinnati Children's publications including print and electronic newsletters, magazines and other publications
- Database recruitment children and adults
- Email using Cincinnati Children's internal email system to 12,000 employees
- Grand Rounds presentations and other speaking opportunities within Cincinnati Children's and in the community
- Internet and intranet using the Cincinnati Children's web site, CenterWatch (largest clinical trials web site), targeted web advertising and social media
- Printed materials including flyers, post card size flyers and direct-mail pieces
- Public relations activities through Cincinnati Children's Marketing and Communications Department
- Community events such as baby, family and senior expos, and community health fairs where face to face contact may be made and study materials distributed
- 40-plus recruitment stations, each displaying
 5 25 individual clinical studies (specifically targeted to that location's demographics, when possible)

Participant Population

Cincinnati Children's recruits pediatric and adult participants from the Greater Cincinnati area including eight counties in Southwestern Ohio, Southeastern Indiana and Northern Kentucky.

- 19.9 percent African-American
- 0.1 percent American Indian/Alaska Native
- 1.0 percent Asian/Pacific
- 62.1 percent Caucasian
- 1.86 percent Hispanic
- 10.6 percent other

Statistical Highlights (fiscal 2009)

Patient Care

| Admissions (includes short stay) | 31,217 |
|---|-----------|
| Emergency Department Visits | 114,985 |
| Home Care/Hospice Visits | 13,795 |
| Outpatient Visits (includes neighborhood locations) | |
| Primary Care | 60,243 |
| Specialty | 735,926 |
| Test Referral Center | 29,635 |
| Surgical Procedures | |
| Inpatient | 5,667 |
| Outpatient (includes neighborhood locations) | 24,669 |
| Patient Encounters | 1,003,079 |

Statistical Highlights (fiscal 2009)

Faculty and Staff

Faculty

| Pediatrics | 504 |
|----------------------|--------|
| Surgery | 71 |
| Radiology | 46 |
| Anesthesia | 41 |
| Subspecialty Fellows | 178 |
| Active Medical Staff | 1,442 |
| Total Employees | 11,666 |

Payment Information:

Study specific checks should be made payable - Cincinnati Children's Hospital Medical Center Attn: "Business Director"

MLC XXXX

(the business director and MLC are based on the division conducting the specific study)

3333 Burnet Avenue Cincinnati, OH 45229-3039 Tax ID # 31-0833936

Therapeutic Areas

Allergies

Adolescent and Adolescent Gynecology

Aerodigestive Disorders

ALS

Arthrogryposis

Asthma

Attention Deficit Hyperactivity Disorder

Autism

Blood and Marrow Transplantation

Bone Formation Disorders
Brachial Plexus Injuries

Brain Tumor Bronchitis

Cardiac Transplantation

Cardiovascular Disorders and Malformations

Cerebral Palsy

Congenital Cardiac Malformations Congenital Diaphragmatic Hernia Congenital Lung Malformations

Connective Tissue/Skeletal Dysplasias – Marfan Syndrome/Ehlers Danlos Syndrome

Contraceptives
Cystic Fibrosis
Dermatology
Diabetes Mellitus

Down Syndrome

Dual Diagnosis of Developmental Disability/Mental Health Disorder

Dyspraxia

Eating Disorders

Eosinophilic Disorders

Epilepsy

Esophageal Disorders

Facial Plastic Reconstruction

Fanconi Anemia

Food Allergies

Gastrointestinal Diseases

Gaucher Disease

Goiter

Growth Disorders
Headache Disorders

Head and Neck Disorders

Head Trauma

Hemangioma and Vascular Malformation

Hematologic Disorders

Hemophilia

Hereditary Cancer

Hirsutism
Histiocytosis
Hypertension
Hypoglycemia

Immotile Cilia Syndrome Immunodeficiencies Infectious Diseases

Inflammatory Bowel Disease Intestine Transplantation

Juvenile Rheumatoid Arthritis

Kidney Disorders

Kidney Transplantation
Laryngeal Disorders
Learning Disabilities

Leukemia Liver Disease

Liver Transplantation

Lupus

Lysosomal Disease Mental Retardation Menstrual Disorders Metabolic Disorders Motility Disturbances

Multiple Anomalies

Muscular Dystrophy

Myelomeningocele

Neurological Diseases

Neuromuscular Diseases

Obesity

Obsessive Compulsive Disorder

Ophthalmic Diseases

Otitis Media

Pain Management

Pervasive Developmental Disorders

Pediatrics

Pediatric Trauma

Pneumonia

Polycystic Ovarian Syndrome

Psychiatric Disorders

Psychological and Behavioral Disorders

Pulmonary Hemosiderosis

Rhinitis

Rubinstein-Taybi Syndrome

Seizure Disorders

Sexual Development Disorders

Short Gut Syndrome

Sickle Cell Anemia

Sinusitis

Skin and Soft Tissue Disorders

Sleep Disorders

Small Bowel Transplantation

Speech Disorders

Spina Bifida

Sports Injuries, Care, Prevention and Performance Training

Stroke

Thyroid Disorders

Tonsillitis

Tourette Syndrome

Transplantation

- Blood and bone marrow
- Heart
- Kidney
- Liver
- Lung
- Small bowel

Trauma Medicine

Tuberous Sclerosis

Turner Syndrome

Urologic Problems

Vaccine Development and Research

Velopharyngeal Dysfunction

Voiding Dysfunction

Adult Therapeutic Areas

Adult Genetic Disorders – Hemochromatosis, Hypercholesterolemia and Polycystic Kidney Disease

Centers of Expertise

Cincinnati Children's has more than 90 centers of major clinical studies expertise, which are also affiliated with other treatment and research centers nationally and internationally.

Acute Pain Service

Adult Genetics Clinic

Aerodigestive and Sleep Center

Attention Deficit Hyperactivity Disorder

Blood Disease Center

Brachial Plexus Center

Cancer and Blood Disease Institute

Cardiac Intensive Care Unit

Catheterization and Interventional Cardiology

Center for Heritable Immunodeficiencies

Center for Infants and Children with Special Needs

Central Venous Catheter Program

Cerebral Palsy Clinic

Child Abuse Team / Mayerson Center

Chronic Ventilation Program

Clinic for Systemic Lupus Erythematosus

Clinical Neuropharmacology Laboratory

Cochlear Implant Program

Comprehensive Neuromuscular Center

Comprehensive Weight Management Center

Congenital Diaphragmatic Hernia Team

Connective Tissue / Skeletal Dysplasias Clinic

Craniofacial Center Cystic Fibrosis Clinic

Cystic Fibrosis Center

Developmental Assessment for Infants / Toddlers

Diabetes Center

Dialysis Unit

Electrophysiology

End-Stage Renal Disease Care Program

Enteral Access Clinic

Eosinophilic Disorders

Epidermolysis Bullosa (EB) Center

Epilepsy Program

Feeding Team

Fetal Care Center of Cincinnati

Food Allergy Clinic

Gaucher Disease Treatment Center

Genetics Outreach Clinics

Growth Disorders

Hand and Upper Extremity Center

Headache Center

Hearing and Deafness Research Center

Heart Institute

Heart Transplant

Hemangioma and Vascular Malformation Center

Hereditary Cancer Program

High-Risk Infant Follow-up Clinic

Hip Deformity Service

Human Genetics Metabolic Diseases Clinic

Hypertension Clinic

Immunodeficiencies and Histiocytosis Program

Inflammatory Bowel Disease Center

Inpatient Rehabilitation

International Adoption Center

Interventional Radiology

JRA Affected Sib-Pairs Registry

Juvenile Arthritis Special Treatment Center

Kelly O'Leary Center for Autism

Spectrum Disorders

Kidney Clinic/Institute/Transplant Program

Lactation Education Resource Center

Liver Care Center

Lysosomal Disease Center

Marfan / Ehlers Danlos Syndrome Clinic

Molecular and Genetic Cardiology

Molecular Genetics Laboratory Services

Movement Disorder Clinic

Myelomeningocele Clinic

Neurobehavioral Clinic

Neurometabolic Program

Neuromuscular Program

Neuropsychological Evaluation

New Onset Seizure Clinic

Nutrition and Intestinal Care Center (NICC)

Outpatient Centers

Pain Management Clinic

Perinatal Institute

Plastic Surgery Clinic

Preventative Cardiology

Process Improvement and Outcomes Research

Psychiatric Intake Response Center

Regional Center for Newborn Intensive Care (RCNIC)

Rubinstein-Taybi Syndrome Program

Schubert-Martin Inflammatory Bowel Disease Center

Sickle Cell and Hemoglobin Disorders Center

Skin Sciences Institute

Sleep Disorders Center

Smoking Cessation

Sports Medicine Biodynamics Center

StarShine Hospice

Teen Health Center

Tourette Syndrome Clinic

Translational Research Trials Office

Trauma Services

Tuberous Sclerosis Program

Turner Syndrome Clinic

Vaccine Trial and Evaluation Unit

Velopharyngeal Dysfunction Clinic

Voiding Dysfunction Center

Youth Shyness Program

Sponsor Feedback Questionnaire

To serve you better, we appreciate your input regarding our profile information. Please send feedback to the questions below or general comments to mark.schuller@cchmc.org

- 1. Was this information helpful to you in considering Cincinnati Children's as a site partner to conduct your study?
- 2. To which other questions would you like us to provide information about Cincinnati Children's?
- **3.** Is Cincinnati Children's site information entered into your site identification database?

We look forward to working with you on future studies.

Thank you.

Contact:

Cincinnati Children's Hospital Medical Center Research Foundation Office for Clinical and Translational Research 3333 Burnet Avenue, MLC 7004 Cincinnati, OH 45229 513-636-3232 (office) 513-636-0168 (fax) mark.schuller@cchmc.org

Site visits arranged by appointment. Please contact Mark Schuller, Marketing and Recruiting Manager (above)

Additional Information:

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



www.cincinnatichildrens.org