



The Carl & Edyth Lindner Center for Research and Education at Christ Hospital

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Overview

- General Information
- History
- Trials
- IRB
- Team
- Physicians/Principle Investigators
- Executive Management and Regulatory
- Screening Coordinator
- Research Coordinator
- Future
- Questions

General Information

- Lindner Research Center is located at The Christ Hospital Main Campus
- Address
 - 2123 Auburn Avenue, Suite 424
Cincinnati, OH 45219
- Contact Information
 - Main office – 513-585-1777
 - Physician Referral Line – 513-585-1737
 - Fax – 513-585-4858
 - Email – LindnerTrials@TheChristHospital.com
 - Website – www.LindnerResearch.com

General Information

- Goal
 - Strive to identify the most promising therapies and provide them to patients
 - Work hard to establish satisfying relationships with patients and physicians to ensure the best outcomes
- Participated in over 1,200 clinical research trials
 - 130 active trials
- These studies have included first-in-man as well as first-in-the-U.S.
- Full accreditation from The Association for the Accreditation of Human Research Protection Programs (AAHRPP)

General Information

- The Lindner Research Center has a reputation of providing fast project start up, with more than 50 percent of trials being the first site initiated, as well as strong patient enrollment and high quality efficient data reporting
- The Center continues to grow through the years in number of trials and the complexity of the protocols
- Produces more than 50 publications a year
- Provides educational forums for both physicians, health-care providers, and consumers

History

- 1985 – Dean Kereiakes, M.D. partnered with Charles Abbottsmith, M.D. and began participating in formal research trials at the Christ Hospital
- 1988 – Dr. Kereiakes received the opportunity to participate in a large PTCA/restenosis trial. The Christ Hospital Cardiovascular Research Center was opened to provide resources for this study
- 1996 – The center's name was changed to The Carl & Edyth Lindner Center for Clinical Cardiovascular Research, to honor the couple who contributed so much to the hospital and the Center
- 1999 – The Center became an independent
- 2000 – By this time the Center was conducting multi-specialty medical research trials
- 2009 – The Center formally re-joined The Christ Hospital and became what is known as The Carl & Edyth Lindner Center for Research and Education at The Christ Hospital

Trials

- Focus on cardiovascular trials
 - Heart Attack/ACS
 - Heart Failure/CHF
 - Heart Rhythm Disorder/EP
 - Heart Surgery/ CVS
 - Heart Valve Disease
 - Coronary Artery Disease
- Including trials that pertain to risk modification
 - Hyperlipidemia
 - Diabetes
 - Weight Loss
 - Hypertension

Trials

- Other types of trials
 - Cell/Gene therapy
 - Dementia
 - Infectious diseases
 - Nutrition
 - Peripheral vascular disease
 - Pulmonary hypertension
 - Others
 - Fibromyalgia and bleeding disorders
- New Departments
 - Orthopaedic/spine
 - Women's health

Trials

- Trials are funded by sponsors, NIH, and grants
- Phase I to phase IV trials
- Trials involve new devices, surgical procedures, medications, and treatment strategies
 - Devices – coronary stents, heart valves, implantable defibrillators, pacemaker leads, and implantable sleep apnea devices
 - Procedures – valve replacement, diagnostic testing for coronary artery disease, resistant hypertension
 - Medications – pulmonary hypertension, congestive heart failure, hyperlipidemia, and weight loss
 - Treatment strategies – medical device that reduce stroke risk in patients with atrial fibrillation

IRB

- The Christ Hospital has an internal IRB
- Process for submitting new protocols
 - Protocols and proposed consent forms are submitted 2 weeks in advance of meeting
 - The meeting is monthly and our Executive Director, Assistant Director, and at times the Principle Investigator will attend the meeting for discussions and questions
 - Typically receive approval within 2 weeks

Team

- Multidisciplinary Team
 - Physicians, Nurses, Pharmacists, Phlebotomists, Technicians, Administrative Assistants
- In office
 - 2 Physicians
 - 27 Nurses
 - 5 Phlebotomists/Technicians
 - 7 Administrative Assistants
- Team is Delineated into 3 Functions
 - Executive Management and Regulatory
 - Screening Coordinators
 - Research Coordinators

Team

- Office hours are from 7am to 5:30pm
- There is always a nurse and manager on call 24hrs/day and 7 days/week after hours
 - Perform after hour duties
 - Works in conjunction with hospital staff (MD's, RN's, lab, pharmacy) to complete tasks
 - Example – long PK studies

Physicians/Principle Investigators

- The key philosophy is that the Principle Investigators are experts in the field
- Principle Investigators are from various departments
 - Ohio Heart and Vascular Physician Group
 - Orthopaedic/Spine
 - Women's Health
 - Internal Medicine
 - Center for Aging

Executive Management and Regulatory

- Responsible for regulatory, contract, and administrative duties
- IRB submissions
- Overseen by Linda Martin – Clinical Director
 - Darlene Rock - Assistant Director
 - Facilitates new growth and new trial execution
 - Linda Anderson – Operational Manager
 - Helps to orient new staff, keeps monthly metrics regarding enrolling trials and participating physicians
 - Deborah Garza – Operational Manager
 - Manages staff and facilitates ongoing execution of trials once they are initiated
 - Wendy Howard – Operational Manager
 - Offers assistance in any trial that needs additional manpower
 - Karen Ibanez – Operational Manager
 - Manages screening and interfaces with physicians for recruitment and enrollment

Screening Coordinators

- Overseen by Karen Ibanez – Operational Manager
- Responsibilities
 - Screen patients throughout the Christ Hospital Network
 - In house admissions
 - OR
 - Catheterization laboratory
 - Physicians' offices
 - Referrals
 - Identify potential patients for all trials
 - Recruit and enroll patients
 - Secure physician approval
 - Maintain recruitment logs

Research Coordinators

- Overseen by Debbie Garza – Operational Manager
- Responsibilities
 - Plan the implementation and execution of protocol as it relates to the patient
 - Testing and imaging
 - Visits/Phone Calls
 - Medication compliance
 - Maintain documents
 - Complete electronic data collection system

Future

- Challenges
 - Patient recruitment
 - Patient retention
 - Patient Safety
- Concerns
 - Ethical dilemmas
 - Increasingly complex trials
 - Lack of sponsor oversight and/or support

Questions and Comments

