



Children's Foundation Research Institute





Children's Foundation Research Institute

- Established 1995 as Crippled Children's Foundation Research Center
- Partnership of CFOM, LBCH and UTHSC
- Basic and clinical research support and infrastructure
- Expansion and renaming as CFRI
- Housed in Children's Foundation Research Tower
 - New staff and faculty offices
 - 30,000 sq ft of basic research space and shared equipment on 3rd and 4th floors
 - Planned laboratory space expansion to 5th floor
 - Pediatric Clinical Research Unit on 7th floor



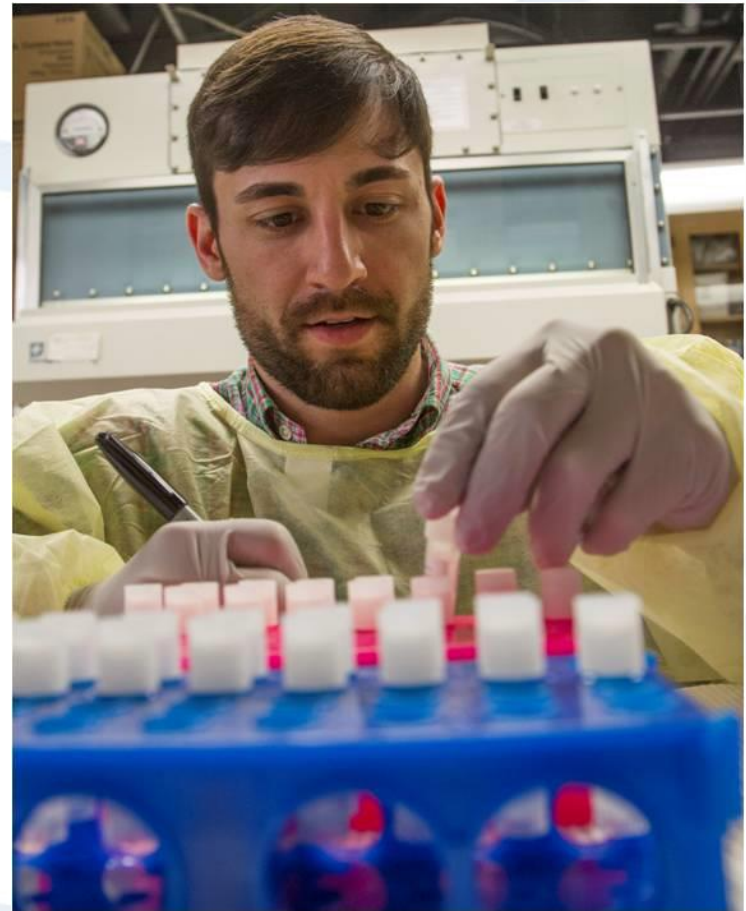
CFRI

Mission

To provide infrastructure, expertise, support and coordination to facilitate basic, clinical and translational research to improve the health of children.

What Does the CFRI Do?

- Functions as the “glue” that holds the research enterprise together and moves it forward in a coordinated and efficient manner.
- Provides researchers with expertise, services, equipment and resources to conduct research.





CFRI Support Infrastructure

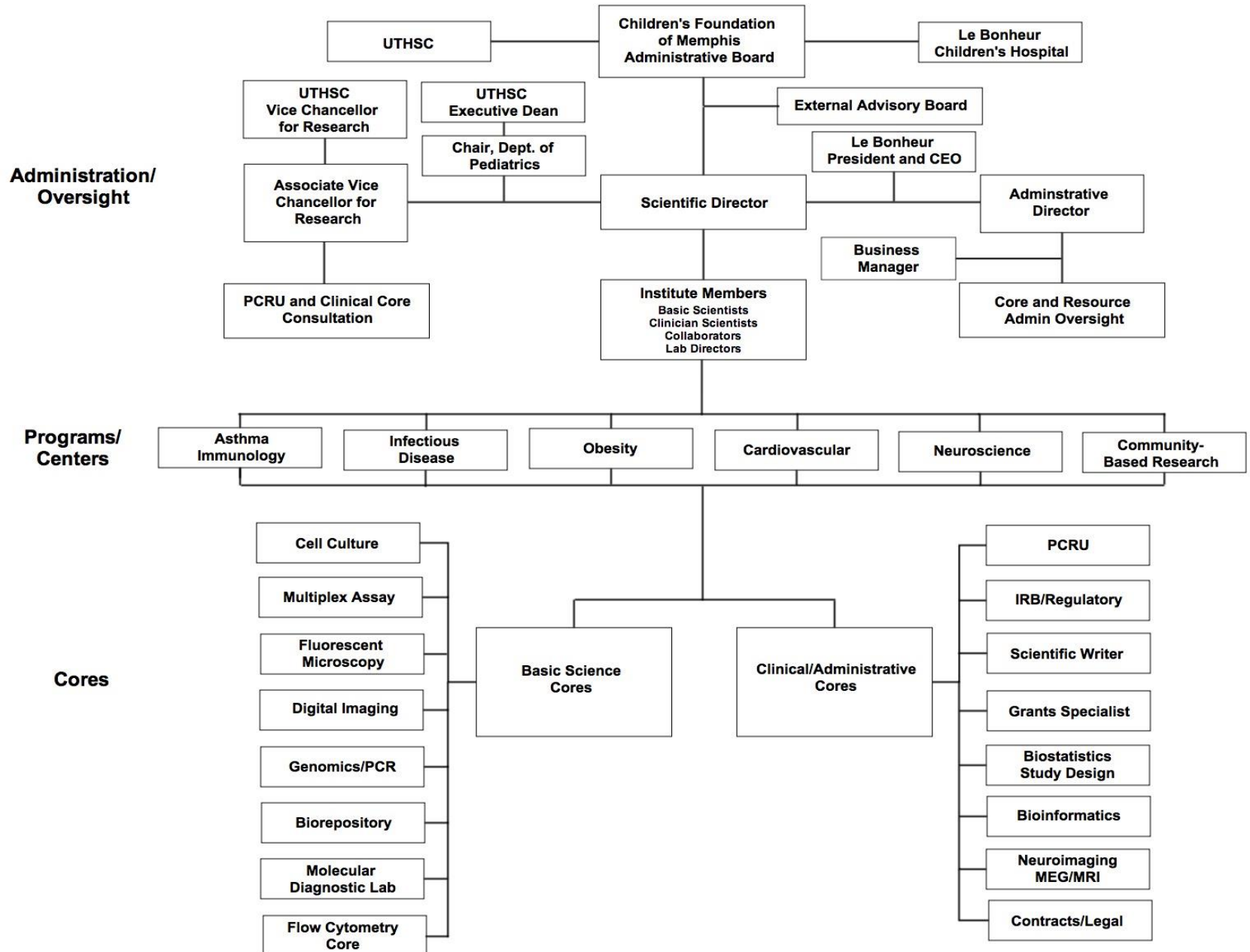
- Bioinformatics
- Biostatistics
- Scientific Editor
- Contract and Grant coordination
- Clinical Trials coordination—Pediatric Clinical Research Unit
- IRB (Institutional Review Board) and regulatory support
- Research study billing
- Research study feasibility
- Research lab resource management



Five-Year Goals

- Recruitment of pediatric physician scientists
- Increase in federal and non-federal research funding
- At least double the number of active clinical studies
- Emphasis on participation in pediatric consortia and collaborative grants
- Develop training grants
- Increase the number of young physician scientists
- Establishment of research endowment

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Grants

- Le Bonheur grants
 - Junior faculty
 - Peer review
 - Require faculty mentor and protected time
 - \$25-50k per year up to 3 years
 - Do not cover PI salary
 - Deadline April 30
 - Funding starts July 1



Clinical and Translational Science Institute Grant

- iRISE (Institute for Research, Innovation, Synergy and Health Equity)
 - Program Director: Jonathan McCullers, MD
 - Operations Manager: Dennis Black, MD
- Emphasis on health equity and diseases affecting our local population (obesity, diabetes, asthma, cancer, developmental disabilities, others)
- Translational Research: Community outreach, education, expertise/infrastructure, Career Development/Pilot Grants, collaboration with national CTSA consortium
- Expansion of CFRI research infrastructure concept across UTHSC campus and affiliates
- \$20 million over 5 years plus UTHSC matching



The Institute for Research, Innovation, Synergy and Health Equity (iRISE)

- Biomedical Informatics
- Community Engagement/Collaboration
- Translational Workforce Development
- Research Methods
 - Biostatistics/Study Design Support
 - Regulatory Knowledge and Support
- Clinical/Translational Research Infrastructure Support
- Collaborative Multicenter Study Support
- Biorepository and Integrative Genomics (BIG)
- Institutional Career Development Grants (KL2)
- Pilot Translational and Clinical Studies Grants
- Website link on UTHSC facepage



Grant Writing and Submission

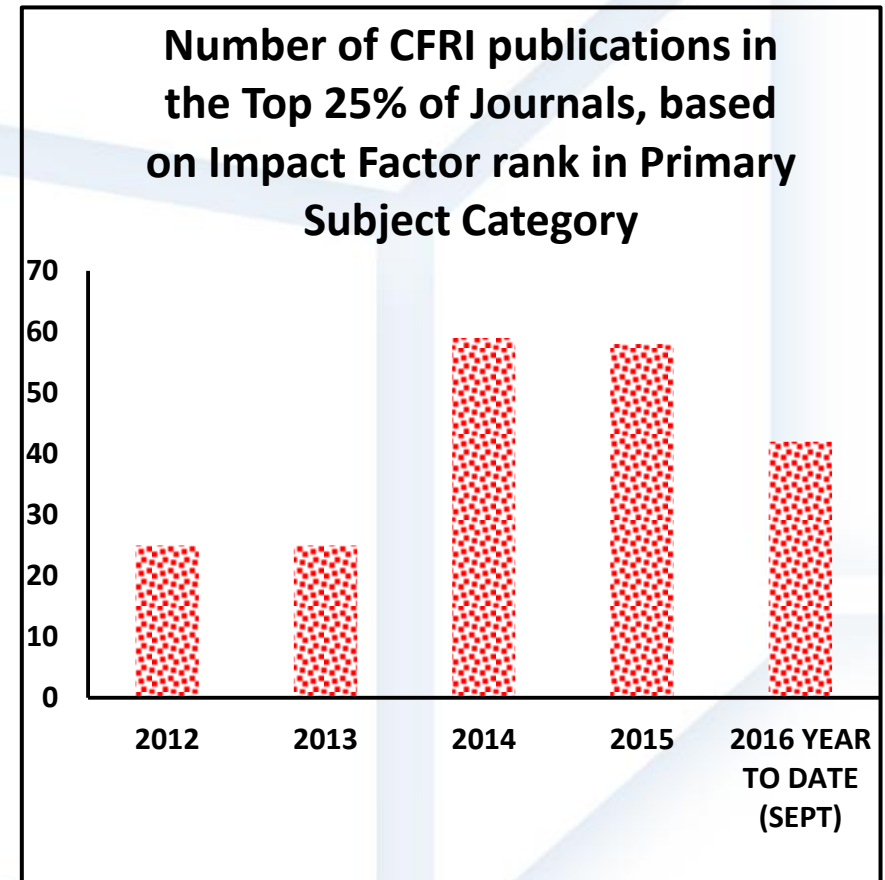
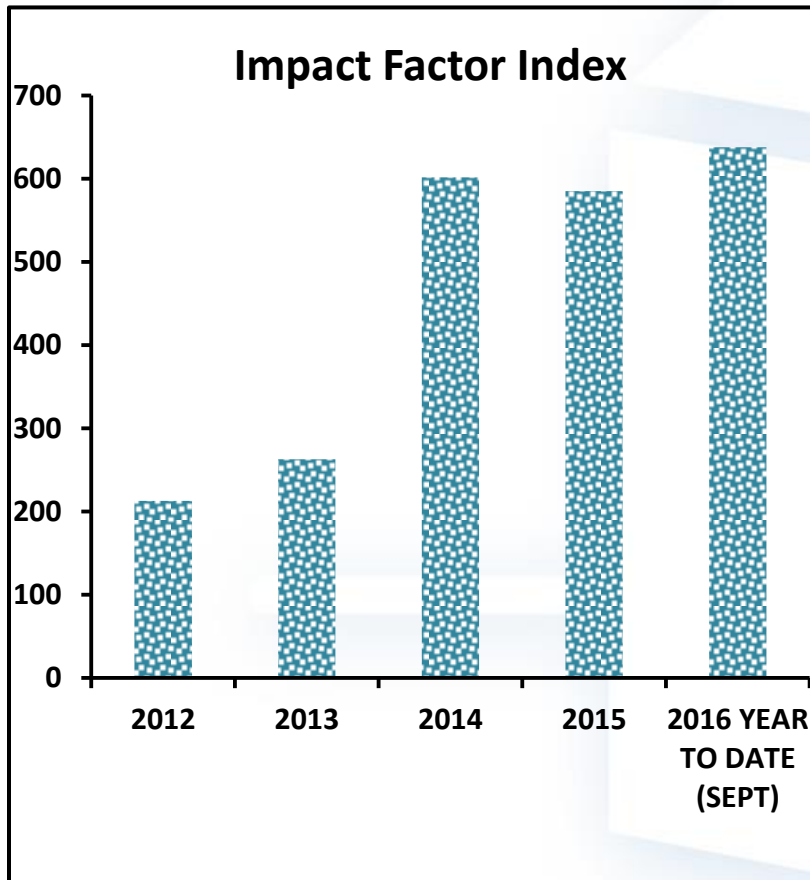
- Mentor
- K Club
- UTHSC Office of Research Administration
- Grants consultant - Israel Goldberg
- CFRI Grant Director - Venessa Spearman, MPA
- Formal internal peer-review process for all grant applications



Scientific Writing and Editing

- Assistance with manuscript preparation, submission and revision
- Scientific Editor
Amanda Preston, PhD
- Total # of Publications from CFRI Researchers
 - 2012--118
 - 2013—131
 - 2014—162
 - 2015—182
 - 2016---184

CFRI Publication Impact Factor





Basic Research

- Basic laboratory space and equipment
- Access to CFRI shared equipment and cores
- UTHSC Molecular Resource Center technology and resources
(http://www.uthsc.edu/research/research_resources/)
- Access to SJCRH facilities
- Space/access negotiated with Drs. McCullers and Black



Biostatistics Core

- Tamekia Jones, PhD, Director
- Study planning, study design and statistical analysis
- Sample size and power calculations
- Additional assistance from UTHSC Department of Preventive Medicine, U of M School of Public Health and SJCRH



Bioinformatics Core

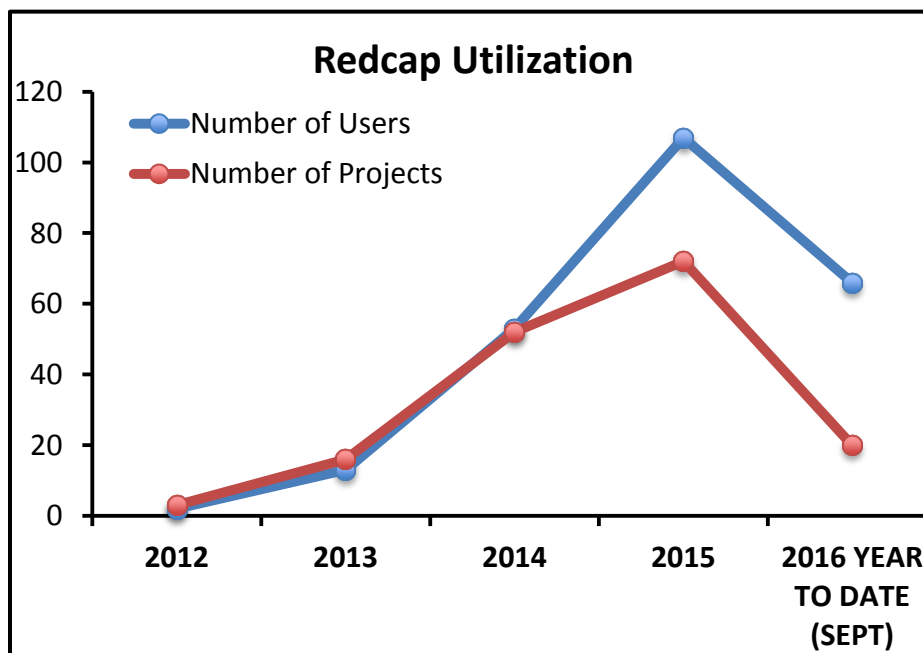
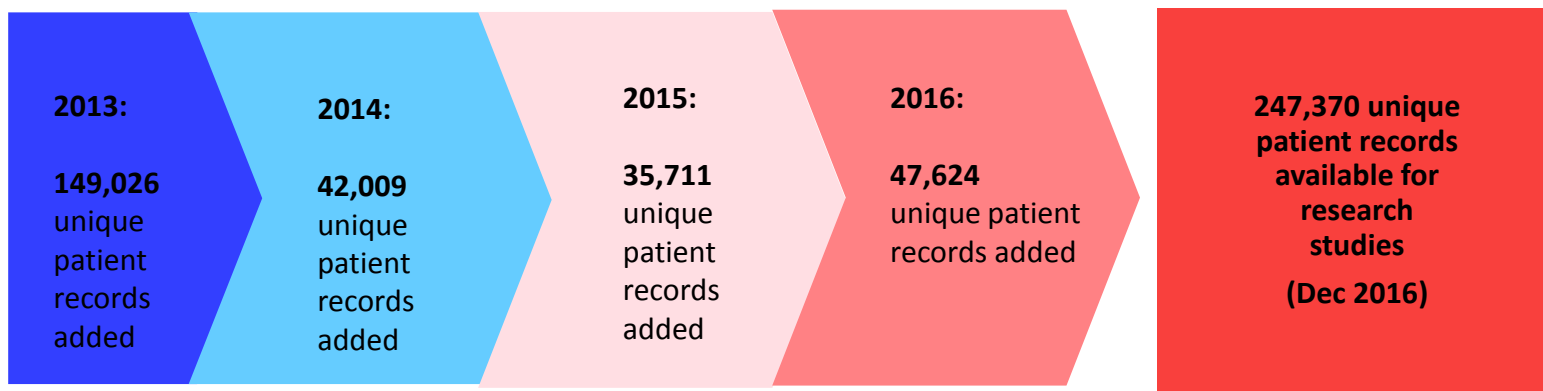
- Eunice Huang, MD, Chief Research Bioinformatics Officer
- Teeradache Viangteeravat, PhD (Dr. Tee)-Director
- Other BMIC personnel
Rahul Mudunuri, Seun Ajayi, Ruchi
- Assistance from UTHSC BMI, U of M and SJCRH
- Access form for bioinformatics/biostatistics on CFRI website: <http://www.lebonheur.org/research-and-education/research/investigator-resources/>



Bioinformatics Core

- Database design and data collection/processing
 - REDCap-Small/medium studies
 - Slim-Prim-Customizable for large-scale studies
 - Data access from Cerner
 - De-identified Pediatric Research Database (PRD) for Cerner Data Access and cohort analysis and hypothesis testing
 - Data storage
 - Support from UTHSC CBMI

Pediatric Research Database: Development and Updates





Human Research

- Pediatric Clinical Research Unit
 - 7th floor Research Tower
 - Research coordinators, nurses and assistants
 - IRB and regulatory support
 - Molly Rolen
 - Financial and Operations oversight
 - Executive Director—Sheon Lynch
 - PCRU Director—Amy Doville
 - Director of Grants and Contracts—Venessa Spearman
 - Finance Director—Chris Smith
 - Business Manager—Thomas Hobson



Human Research

- Industry-sponsored clinical trials
 - Managed by LB Foundation and CFRI
 - Low recruitment
 - Consume manpower and resources
 - Study revenue around 0.7 M per year
- Initial review
 - Alignment with program goals and career development
 - Feasibility
 - Budget



Human Research

- Federally sponsored human research
 - NIH, FDA, CDC, etc.
 - Managed by UTHSC
 - Well-designed
 - Regulatory oversight (DSMB)
 - Study revenue about 2.0 M per year
 - Career enhancement



Industry Sponsored Clinical Trials Process

- Pre-clinical testing-both in vitro and in vivo (animals)
- Investigational New Drug (IND) submission to FDA
- Phase I study- to assess safety
- Phase II study—to test for effectiveness
- Phase III study—large scale testing
- Licensing and approval
- Post marketing



Investigator-Initiated Research

- Pilot studies to generate data for grant submission
- Unfunded or underfunded—no charge for LB services for those meeting requirement
- Often have highest rate of violations with internal IRB review/audit
- Often with study design flaws



Investigator-Initiated Research

- Review by the PCRU Advisory Committee
 - To improve the quality of these projects and more efficient use of PCRU resources
 - Applies to PI initiated studies that would qualify for an IRB full Board review
 - PI must present his/her study at monthly PCRU Advisory meetings
 - Scientific merit and feasibility

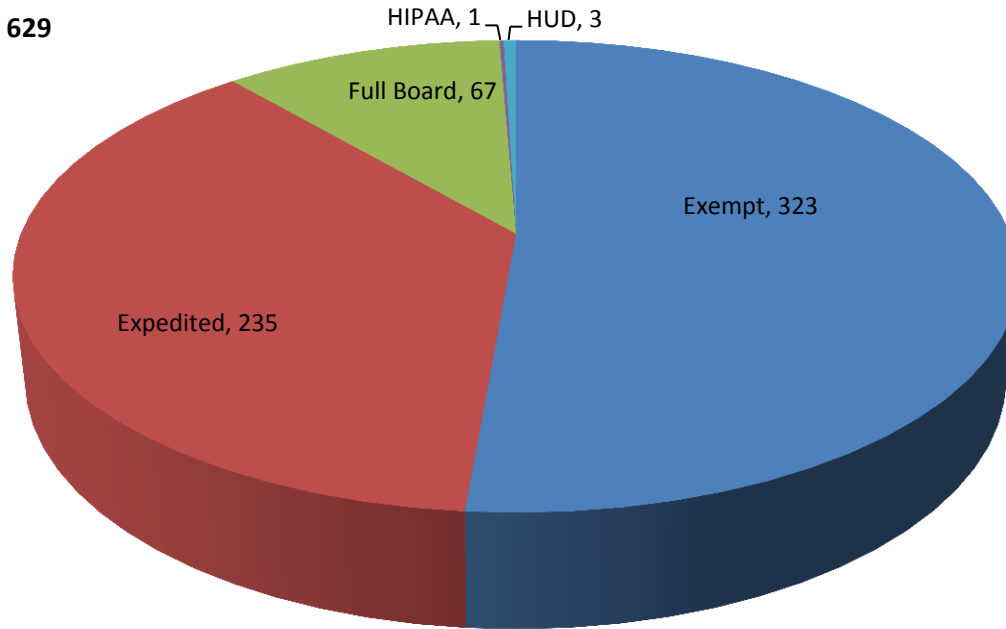


Investigator-Initiated Research

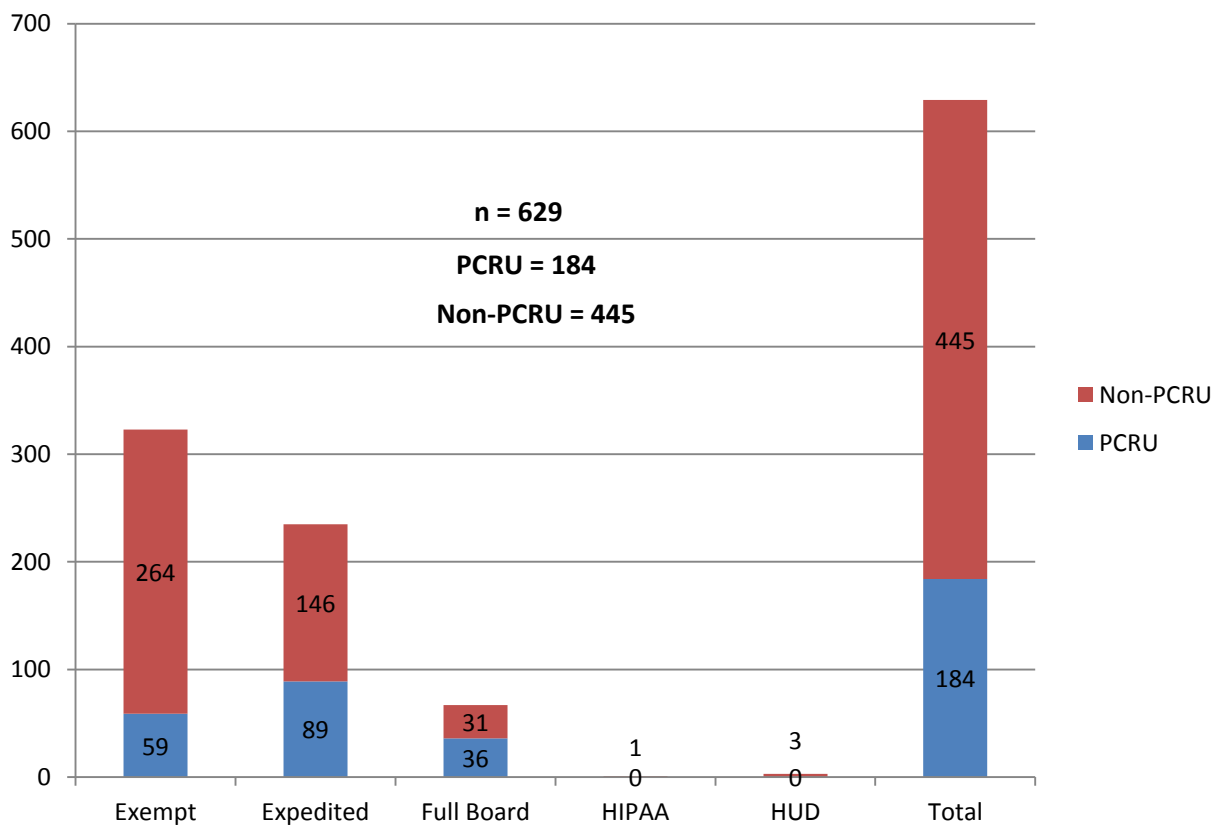
- Important for program/career advancement
- Synergy with other ongoing clinical/translational research
- Likelihood of generating extramural funding
- PI is responsible for study registration on ClinicalTrials.gov website
- PI Initiated Study Binder available for regulatory and administrative documentation available from the CFRI office

Le Bonheur Total Active Studies by Type 2016

n = 629



■ Exempt ■ Expedited ■ Full Board ■ HIPAA ■ HUD
HUD: Humanitarian Use Device
HIPAA: Screening Purposes





2016 CFRI Metrics

- IRB Related Metrics
 - Full Board Studies 57 work days
 - Expedited Studies 16 work days
 - Exempt Studies 4 work days
- Industry Sponsored Clinical Trials
 - CDA Receipt to Execution 9 work days
 - CTA Receipt to Execution 48 work days



Research and Education

Research

Participate in Our Research

Published Research

Research Facilities

Meet Our Team

Education

Research at Le Bonheur

Le Bonheur Children's is committed to the **prevention, treatment and elimination of pediatric disease.**

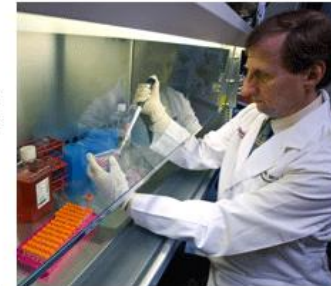
At the Children's Foundation Research Institute, our researchers are looking for new discoveries and treatments to promote the health of children. Le Bonheur continues to develop an infrastructure to support research and to enhance collaboration among our physician scientists.



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Researchers at Le Bonheur are working on projects aimed at improving the health of children. Some of those studies include:

- A multi-centered study on **flu-associated pneumonia**, sponsored by the Centers for Disease Control and Prevention. Investigators at Le Bonheur, St. Jude Children's Research Hospital and The University of Tennessee Health Science Center are working to find microbiologic causes of pneumonia, a potentially deadly childhood disease.
- A national project to test seizure drugs in children in **absence epilepsy**, a common version of the disease also known as "staring spells." The study is sponsored by the National Institutes of Health.
- A program aimed at tackling **pediatric asthma**, Le Bonheur's most common diagnosis. The project is working to reduce asthma-related deaths, hospitalizations Emergency Department visits, asthma exacerbations and episodes. The project is funded by the U.S. Department of Health and Human Services.
- A look into the usefulness of a bile acid in treating children with **primary sclerosing cholangitis (PSC)**, a disease that affects bile ducts of the liver. Le Bonheur is home to the STOPSC registry, a multi-center database and DNA repository for patients with PSC. The bile study is funded by the Food and Drug Administration.



About the CFRI

The Children's Foundation Research Institute is a **partnership** of The University of Tennessee Health Science Center, Le Bonheur Children's Hospital and the Children's Foundation of Memphis. The Children's Foundation was created by community members who wanted to promote the health and well being of children in Memphis. Since 1993, it has provided significant resources to the Children's Foundation Research Institute.



Thank You!

Questions?

Children's Foundation Research Institute

4th Floor, CFRI Research Center

901-287-5355

<http://www.lebonheur.org/research-and-education/>