

UT Southwestern

Medical Center™

CTSA Program

Office of Research
Administration
Children's Health

Children's HealthSM Make life better for children

W. W. Caruth, Jr. Center for Pediatric Translational Clinical Research

Children's Research Administration was established in 2002 to provide support for the clinical and translational research conducted at Children's Health.

With emphasis on maintaining high ethical standards and compliance with local, institutional, and federal regulations, Children's Health Research Administration's overarching role is to ensure that research at Children's Health is supportive of our patients, their families, and researchers across affiliated and non-partner organizations.



1,373
Active Research Studies
48% are Interventional
18% are Cancer-Related



502
Active Principal Investigators
[254 Active Non-Physician Credentialed
Study Team Members]



14,310
Active Research Patients
Data as of 1/1/2023

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Our mission is comprised of 9 primary areas and service roles:

1. Administrative Oversight – Our organizational core is responsible for the overarching management of the department and for providing support to the other primary areas. This includes the management and deployment of research support staff, fiscal management, contracts management, policy creation and management, internal funding, and all aspects of research operations. For more questions, please email: Research@childrens.com
2. Research Support Staff – We employ, train, and deploy Clinical Research Coordinators, Clinical Research Associates and Clinical Research Nurses across all clinical areas within Children's. They are trained in a wide array of research sub-specialties as well as in regulatory start-up and study close out; and are available to support clinical research across the institution on a short or long-term basis. For more questions, please email: Research@childrens.com
3. Patient Advocacy - Research Administration can offer the service of having a third-party person acting as a Patient/Family Advocate during informed consent and other phases of the project as needed. The Patient/Family Advocate acts with impartiality to ensure that the patient/family is treated fairly and that they understand the risks and benefits of study participation. For more questions, please email: Research@childrens.com
4. Clinical Research Education –To ensure compliance with institutional research policies, we offer initial and ongoing research education (e.g. Research 101 Faculty, Research 101 – Tier 1, Research 101 – Tier 2) to all personnel who conduct research at Children's Health. We also create research education tools, individualized training plans, and upon request, department-level training for medical students and fellows. For more questions, please email: Research.Education@childrens.com

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5. Research Finance – Finance Team is comprised of professionals trained in finance, accounting, and business management. A part of their responsibilities includes maintenance of the research fee schedule, management of service order agreements (SOA), invoicing/billing for all research services performed on clinical trials, tracking research and grant expenditures, managing research revenue, and performing revenue allocations. For more questions, please email: Research.Finance@childrens.com
6. Quality Specialists (QS) Team – Our QS team provides internal oversight to all research protocols initiated at Children's Health by verifying credentialing, conducting performance site reviews, initiating and executing pricing agreements, and assisting with Children's Health site approval. They also assist research teams in the proper conduct of studies by performing quality reviews on research trials. For more questions: please e-mail: Research_Department@childrens.com
7. Funding - Children's Health has internal funding mechanisms to support innovative research ideas. Through our Mission and Service Package Grants, we also provide funding support for biostatistical needs, data pulls, and clinical research staff for meritorious PI-initiated projects. For more questions, please email: Research@childrens.com
8. Statistical design & analysis - Biostatisticians in Research Administration are available to provide statistical support and training to all members of the research community at Children's Health in the areas of study design, study implementation, analysis, and interpretation of the research data. For more questions, please email: Research@childrens.com / Rong.Huang@Childrens.com
9. Grant Writing - Children's Health offers assistance with writing grants and research proposals. Our Grant Writer works with investigators to plan, prepare, write, complete, and submit grants and research proposal. This resource is limited and is available on a first come, first serve basis. For more questions, please email: Research@childrens.com / Daniel.Mcmillan@childrens.com

Performance Site Review & Approval – Areas of Responsibility

- ✓ Verification of IRB Approval
- ✓ Verification of IRB Reliance agreement (for studies under external IRB oversight)
- ✓ Approval from Children's Ancillary Service Departments (IDS pharmacy, Laboratory/Pathology, IT, Radiology, Advanced Analytics)
- ✓ Credentialing of Research Staff (Initial and Annual re-credentialing) or Attestation Statement
- ✓ Documentation of CMC required research training
- ✓ Pass thru review and approval of Advanced Analytics data requests
- ✓ Documentation of PI-approved clinical trial coverage analysis or authorized waiver
- ✓ Review and Verification of Patient Facing Documents (e.g., IC/Authorization) against study protocol
- ✓ Verification of MTA, DUA, LOI (as applicable)
- ✓ Executed contracts/legal agreements (FUA required for industry funded projects)
- ✓ Executed Service Order Agreement (SOA)/Scope of Work (SOW)

Contact information



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General Inquiries | research@childrens.com



Internal |

[https://dallaschildrens.sharepoint.com/Research%20Administration/
Pages/default.aspx](https://dallaschildrens.sharepoint.com/Research%20Administration/Pages/default.aspx)

External | <https://www.childrens.com/>



Department Leadership

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