Department of Pediatrics
at the University of Florida

Site Information

Contacts and Addresses

Legal Name and Address: University of Florida Board of Trustees Division of Sponsored Research 219 Grinter Hall P.O. Box 115500 Gainesville, Florida 32611-5500	**Invoice Payment:** University of Florida Contracts and Grants Accounting 123 Grinter Hall Gainesville, FL 32611 Please make checks payable to the **University of Florida**
Administrative and Contract questions for the Department of Pediatrics studies: Randall Autrey, MBA 1600 SW Archer RD, HD-108b POB 100296 Gainesville, FL 32610 Peds-grants@peds.ufl.edu	**Study teams:** University of Florida Department of Pediatrics 1600 SW Archer RD POB 100296 Gainesville, FL 32610

Authority to Sign and Accept Applications, Proposals, Grants, Contracts, and other Research Related Agreements on behalf of the University:

- Stephanie Gray, Director of Sponsored Research and Compliance
- Brian E. Prindle, Associate Director for Sponsored Research
- Brandi Boniface, Assistant Director for Sponsored Research
- **Anthe Hoffman, Assistant Director for College of Medicine**

UF Entity Number, Employer ID (EIN), Federal ID, TIN:

59-6002052

F & A (IDC) Rates for Clinical Trials

Sponsor	Source	Rate	Base
Clinical Trials	Federal	50.0%	Modified Total Direct Cost
Clinical Trials	Non Federal	28.0%	Total Direct Cost

IRB

Western IRB (WIRB®) has been established as a UF IRB for studies utilizing FDA regulated articles that are sponsored by private companies. For Principal Investigators in the College of Medicine / the Department of Pediatrics, all industry authored and supported non-therapeutic trials MUST be submitted to WIRB®.

Non-therapeutic trials that are authored by a UF investigator and only being conducted at UF but are industry sponsored, are reviewed by the local IRB.

UF Department of Pediatrics

Quick Facts

Type of institution Academic Center and University Medical Practice

Faculty & Staff Composition

Faculty	138
Joint/Affiliate	66
Education/Research Fellows	90
After-Hours Faculty	34
Staff	419
Total	**747**

Division Listing

Cellular and Molecular Therapy
Critical Care Medicine (PICU)
Endocrinology
Family Data Center
Gastroenterology
General Pediatrics
Genetics and Metabolism
Hematology and Oncology
Hospital Medicine
Immunology, Rheumatology and Infectious Disease
Neonatology (NICU)

Nephrology
Neurology
Pulmonary

Affiliated Centers and Programs

B.J. and Eve Wilder Center of Excellence for Epilepsy Research
Center for the Arts in Healthcare Research & Education
Center for Breastfeeding & Newborns
Congenital Heart Center
Diabetes Center of Excellence
Institute on Child Health Policy
Pediatric Psychology and Family Studies
Powell Gene Therapy Center

Institutional Facilities

UF Clinical Research Center

The UF Clinical Research Center (UF CRC) is an inpatient/outpatient research unit supported by the CTSA grant from the National Institutes of Health. The unit occupies 9,400 sq. ft. on the third floor of Shands at University of Florida and is staffed by a highly trained research staff including registered nurses, medical technologists, research dietitian, bionutrition and administrative staff. A Research Patient Advocate assists participants in research protocols to access their full range of rights and responsibilities.

Facilities on the unit include 7 inpatient rooms, outpatient exam spaces, an exercise physiology room, and a special procedure room equipped for complex exams such as bronchoscopy and gene therapy. Available equipment includes pulmonary function equipment, dental chair, Bod Pod, Body Box, Metabolic cart, EKG machine and blood pressure monitors. Within the UF CRC, there is a CLIA certified Core Lab and Metabolic Kitchen. In addition, a patient lounge/activity room is available to research participants.

The UF CRC provides resources for conducting research on all age groups from neonates to geriatrics. Nursing services include clinical trial co-ordination, administration of investigational medications, specimen collection including pharmacokinetic sampling, monitoring of vital signs, administration of glucose tolerance tests, exercise testing, and 24 hour EEG monitoring. Nursing assistance is also available for studies that are conducted outside of the UF CRC through the “Scatterbed” program. “Scatterbed” RNs provide research services Monday through Friday from 0800 until 1600 for inpatients and outpatients throughout the Shands Healthcare system.

Bionutrition services include 24 hour diet recalls, food record analyses, food frequency questionnaires, anthropometric measurements and protocol specific nutrition counseling/assessment. Protocol specific controlled meals can also be developed and provided.

Core Laboratory services include sample processing with short term storage of specimens and sample analysis (urine pregnancy, glucose and lactate analysis via YSI, DNA extraction and urinalysis via

dipstick). Other analyses include hemoglobin A1C and complete blood count for research purposes. We can also help to determine which tests are most appropriate for your research/clinical purposes.
Center for Clinical Trials Research

Investigational Drug Services

The Investigational Drug Service (IDS) is an integral part of the research process at the University of Florida. University policy requires that investigators who conduct drug studies use IDS as a central pharmacy for the management and dispensing of research drugs at any UF&Shands Healthcare facility or the Veterans Affairs Medical Center in Gainesville.

The UF&Shands Main Investigational Drug Service is located on the ground floor, Rm G-533 .

Advanced Magnetic Resonance Imaging and Spectroscopy Facility

AMRIS is a state-of-the-art NMR facility for high-resolution solution NMR, solid-state NMR, microimaging, animal imaging, and human imaging. There are currently eight spectrometer systems, including a 750 MHz wide bore, an 11 T/40 cm bore horizontal animal imaging magnet, and a 3T human system.

University of Florida Pathology Laboratories

University of Florida Pathology Laboratories (UF PathLabs) is a leading provider of surgical pathology and diagnostic laboratory services for the southeastern United States. Headquartered in Gainesville, Florida, UF PathLabs has been offering pathology services, testing, pathology second opinion services and autopsy services for more than 20 years. We serve all major markets across the state of Florida, including Jacksonville, Orlando and Tampa, just to name a few.

Home to more than 30 nationally recognized pathologists who are knowledgeable in all subspecialties of pathology, UF PathLabs has the experience and expertise to diagnose your patient's condition quickly, accurately and professionally.

Contracting Process and Study Initiation

Sample Timeline

Institutional Workflow

University of Florida provides the Principal Investigator with scientific review, regulatory, IRB, fiscal, study coordinator, and data management support. UF's responsibility is not only to determine the

feasibility of conducting this trial but also to assure that the trial is developed and managed in compliance with the policies and procedures guiding clinical research at UF.

UF charges its standard overhead of 25% on total direct costs and any pass-through costs coming through UF for clinical trial research. These overhead charges do not subsidize personnel costs for clinical trial development. Therefore, we are expected to charge trial sponsors for all direct costs associated with the development, management, and conduct of the clinical trial.

All confidentiality agreements (CDAs) and clinical trial agreements (CTAs) are negotiated by UF's Research Administration and Compliance (RAC) and signed by Division of Sponsored Research. For the Department of Pediatrics, budgets are negotiated by the Grants Office team and need be final prior to the CTA review and execution by the RAC.

To determine the feasibility of conducting a clinical trial at the Department of Pediatrics at UF, please contact Yulia Strekalova, Associate Director of Research (Pediatrics Grants Office) at peds-grants@peds.ufl.edu.

Subject Injury Language – University of Florida Standards

Insurance Contingency

To be in compliance with the Medicare Secondary Payor Rule, University of Florida will not accept insurance contingency language (e.g. bill insurance first for either payment or subject injury costs and Sponsor will pay what is not covered by the insurance) in contracts or informed consents.

Patient Follows Directions

Per Common Rule 45 CFR 46.116, University of Florida cannot accept Contract or Informed Consent Language that indicates the sponsor will not pay Subject Injury if the patient has not followed directions.

Acceptable Contract Language

"In the event of a study-related injury or if a research subject experiences a serious adverse event (Event), Sponsor will pay for any required medical treatment if the injury or Event is the result of an intervention that the research subject would not have received if the individual were not enrolled in the study."

Please Note: Other similar language is acceptable as long as insurance contingency and exculpatory clauses are not included.

UF Informed Consent Language

"If you are injured as a direct result of your participation in this study, the Sponsor will pay for all reasonable and necessary medical expenses required to treat your injury, as long as the injury occurs during the course of the study and results directly from the Study Product or Study-related procedures which you would not have received as part of your routine medical care.

The Sponsor and the Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

*Please contact **<insert Principal Investigator's name and 24-hour phone number>** if you experience an injury or have questions about any discomforts that you experience while participating in this study."*

Notes