# Department of Pediatrics at the University of Florida

## Site Information

### Contacts and Addresses

<table>
<thead>
<tr>
<th>Legal Name and Address:</th>
<th>Invoice Payment:</th>
</tr>
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</table>
| University of Florida Board of Trustees  
Division of Sponsored Research  
219 Grinter Hall  
P.O. Box 115500  
Gainesville, Florida 32611-5500 | University of Florida  
Contracts and Grants Accounting  
123 Grinter Hall  
Gainesville, FL 32611 |

Please make checks payable to the **University of Florida**

<table>
<thead>
<tr>
<th>Administrative and Contract questions for the Department of Pediatrics studies:</th>
<th>Study teams:</th>
</tr>
</thead>
</table>
| Randall Autrey, MBA  
1600 SW Archer RD, HD-108b  
POB 100296  
Gainesville, FL 32610  
Peds-grants@peds.ufl.edu | 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

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Source</th>
<th>Rate</th>
<th>Base</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trials</td>
<td>Federal</td>
<td>50.0%</td>
<td>Modified Total Direct Cost</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>Non Federal</td>
<td>28.0%</td>
<td>Total Direct Cost</td>
</tr>
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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)
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
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

Confidential Disclosure Agreements (CDA) Process
2 business days

Protocol Feasibility Review
5 business days

Budget Development & Compliance Paperwork Preparation *(based on the internal workflow, budget and payment terms have to be final before any other contract terms are negotiated)*
15-20 business days

Internal Approval Process (College Dean)
2-5 business days

Internal Approval Process (Research Compliance)
5 Days

Contract Negotiation
5-20 days (depends on the Sponsor)

IRB Approval *(can be in parallel with the final contract negotiation)*
10-25 Days

Study Initiation

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
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