DIVISION OF PEDIATRIC CLINICAL RESEARCH

Batchelor Children's Research Institute
5th Floor
INTRODUCTION & PHILOSOPHY

Tracie Miller, MD, MS
Division Director
Mission

The Division of Pediatric Clinical Research is dedicated to:

- The development and conduct of the highest quality interdisciplinary pediatric clinical research
- Promoting the University of Miami and its pediatric faculty as national leaders in child health research
Goals (1)

- To promote cutting-edge research that will result in improved child health
- To encourage interdisciplinary research across:
  - Divisions, departments, and schools within the University of Miami
  - Link the department to other institutions and organizations regionally, nationally, and internationally
Goals (2)

- To create a collaborative and supportive academic research environment and infrastructure for new and seasoned investigators
- To secure extramural funding from institutions ranging from the NIH to private foundations and industry
Infrastructure

- We have over 30 faculty and staff who are positioned to facilitate patient-oriented research
- We centralize resources and expertise to maximize organizational efficiency resulting in high quality services
Current Personnel Include:

- Director
- Division Manager
- Grants Administration Specialists
- Near Full-Time Research-Oriented Physicians
- Faculty Biostatisticians
- Faculty Epidemiologists
- Database Analysts
- Research & Clinical Dieticians
- Research Exercise Physiologists & Instructors
- Licensed Physical Therapist
- Pediatric Echo Technician
- Speech Pathologist
- Experienced Research Study Coordinators
Clinical Research Administration Supports the Division to:

- Consult with Investigators who need assistance
- Research Opportunities to match with Investigator Interests
- Develop new Community/Academic/Clinical Programs
- Liaison with Pediatrics Administration
- Assist with Interdepartmental Grant Submissions
- Oversee General Building and Office Operations
- Provide Faculty and Staff Support
- Schedule visiting professors for presentations
What Exactly is Epidemiology?

- Study of the **frequency**, **distribution**, and **determinants** of disease/health-related states in populations
  - Classifying/categorizing disease
  - Defining a population at risk
  - Measuring disease frequency
  - Determining causes of diseases/health outcomes
  - Determining disease prognoses
  - Determining effectiveness of disease treatments
What Does an Epidemiologist Do?

- **Clinical Research**
  - What are the frequencies, causes, effective treatments, and outcomes of diseases in clinical populations

- **Public Health**
  - Disease prevention and health promotion

- **Mechanisms & Susceptibility for Diseases**
  - Molecular and genetic epidemiology

- **Behavioral & Social Components of Health**
  - What are the behavioral and social determinants of health

- **Biostatistics**
  - What factors are significantly associated with health states
What an Epidemiologist Consult Can Do for You?

- Determine research plan feasibility
- Develop research aims and hypotheses
- Research design
- Data collection and management
- Power analysis
- Grant writing assistance
- Protocol development and study conduct
- Human subjects and bioethical implications
- Manuscript development and submission
BIOSTATISTICS

David A. Ludwig, PhD
Senior Biostatistician

Gaby Mitnik, MS, MPhil
Master’s Biostatistician

Kristopher L. Arheart, EdD
Senior Biostatistician

Robert O’Brien, MS
Master’s Biostatistician
Overall Design Strategy

- Formulation of Research Goals/Aims/Objectives
- Operational definition of these goals and objectives
- Quantification and measurement of the operational definitions
- Design aspects of data collection and experimental manipulation or survey methodology
- QA/QC strategies during the study
- Liaison with database management specialists
- Statistical programming “tracked” to the goals and objectives
- Interpretation and presentation of statistical outcomes
General Areas of Expertise

- Design and Analysis of Experiments and Observational Studies (Clinical Trials, Power Analysis)
- Statistical Programming (SAS, StatExact)
- Statistical Modeling (GLM, Neural Nets)
- Graphics (2-D, Motion)
- Computer Intensive Methods (Bootstrap, Monte Carlo Simulation)
- Psychometrics (Scale Evaluation & Construction)
- Multivariate Methods (Data Reduction, Mining)
- Epidemiological Risk Assessment (Contingency Tables, Logistic Models)
- Sampling (SRS, Complex)
Areas of Application

- Grants and Contracts
- Manuscripts
- Oral Presentations
- Posters
- Program Evaluation

Statistics are Fun!
DATA MANAGEMENT & DATABASE DEVELOPMENT

Maria Y. Marin, MIT
Senior Database Analyst

Sunil Mathew
Database Analyst II
Database Design & Development

- Consult with P.I.s, biostatisticians, and epidemiologists on study objectives and narratives
- Deliver an effective DBMS solution
- Create an initial backend to the database based on study requirements
- Develop the user interface to simulate case report forms
- Program internal controls (scripts, ranges, constraints, and calculations) to protect data integrity
- Develop detailed and summary reports
Host the database on the server to allow for multiple users to access the database simultaneously

Set up appropriate user accounts and privileges

Perform daily and weekly backups

Continuously update and/or modify the database based on changes to the study
Database Support

- Assist in design, modifications, and scripting of databases
- Beta test databases for data accuracy and user friendliness
- Install and update database applications on client workstations
- Configure client systems to access the server hosting the databases
- Database software training
RESEARCH GRANTS & FUNDING

Jonathan Zebrowski
Research Associate
Research Grant Opportunities

- Obtain P.I.’s research interest through the Faculty Interest Survey distributed via email to Pediatrics faculty.
- Input P.I.’s interest in the Foundation Tracking Database for future grant opportunities.
- Research and match grant opportunities to the appropriate P.I.’s interest for alerts received from private or government funding announcements such as: NIH, RWJF, Index of Diseases, etc. based on the PI’s Faculty Interest Survey response.
- Notify faculty members of foundation name, award amount, application deadlines and brief description of the announcement.
<table>
<thead>
<tr>
<th>UM C#:</th>
<th>Telephone #:</th>
<th>Other Interests:</th>
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<tr>
<td>Name:</td>
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- Adolescent Medicine
- Allergy
- Ambulatory/Community Medicine
- Analgesia
- Anesthesiology
- Apnea
- Asthma
- Audiology
- Autism
- Brain Injury
- Breastfeeding
- Burns
- Cancer Survivorship
- Cardiac Rehab
- Cardiology
- Cardiomyopathy
- Case Management
- Cerebral Ischemia
- Child Abuse
- Child Passenger Safety
- Child Protection
- Chronic Disease
- Congestive Heart Failure
- CRRT
- Critical Care
- Cystic Fibrosis
- Cyto genetics
- Cytokines
- Deafness/Hearing
- Dermatology
- Developmental Disabilities
- Diabetes
- Dialysis
- Dietary Intake
- Early Childhood
- Emergency Management
- Endocrinology
- Environmental Health
- Epilepsy
- Esophageal
- Ethical Issues/Bioethics
- Exercise Physiology
- Family Functioning
- Foster Care
- Galactosemia
- Gastroenterology
- Genetics
- Genetics [cardiovascular]
- Genetics [cancer]
- Genetics [community based medical]
- GERD
- Glycobiology
- HIV/AIDS
- Health Care Access
- Health Literacy
- Health Promotion
- Health Services Research
- Heart
- Hematology
- Hemophilia
- Hepatology
- Home Visiting
- Hypertension
- Infectious Disease
- Inflammatory Bowel Disease
- Injury
- Injury Prevention
- Immunology
- Immunoregulation
- Learning Disabilities
- Maternal Depression
- Maternal Lifestyle
- Medical Errors
- Microbiology
- Minority Health
- Muscular Dystrophy
- Neonatology
- Nephrology
- Neurodegenerative Disorders
- Neurology
- Neuropsychology
- Neurosurgery
- Newborn Screening
- Nutrition
- Obesity
- Oncology
- Ophthalmology
- Orthopaedics
- Palliative Care
- Pancreatobiliary Disease
- Parenting
- Patient Safety
- Perinatal Care
- Physical Activity
- PKU
- Poisonings
- Prematurity
- Prevention
- Preventive Cardiology
- Proteinuria
- Pulmonary Medicine
- Psychology
- Quality of Care
- Renal
- Renal Tubular Dysfunction
- Respiratory
- Sedation
- Sepsis
- Sickle Cell
- Social Work
- Special Education
- Spirituality
- Speech/Language
- Stroke in Children
- Substance Abuse
- Suicide
- Surgery
- TNF-α
- Transplant
- Transplant Surgery
- Trauma
- Urology
- Violence
- Viral Oncology
- Vitamin Dependency
- Youth Violence
- Other (use space at top of page)
Research Grant Opportunities

- Research interests can be added and/or updated at any point in time.
- Email Contact: jzebrowski@med.miami.edu
# PROJECT COORDINATION

<table>
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<tr>
<th>Name</th>
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</thead>
<tbody>
<tr>
<td>Gabriel Somarriba, DPT</td>
<td>Assistant Professor/Physical Therapist</td>
</tr>
<tr>
<td>Christina Cordero, BS</td>
<td>Research Associate I</td>
</tr>
<tr>
<td>Danielle Dauphin, BS</td>
<td>Research Associate II</td>
</tr>
<tr>
<td>Vivian Franco, MPH</td>
<td>Senior Research Associate I</td>
</tr>
<tr>
<td>Jacqueline Henkel, BS</td>
<td>Research Associate I</td>
</tr>
<tr>
<td>Joy Kurtz, BS</td>
<td>Research Associate II</td>
</tr>
<tr>
<td>Graham Appelbe, BS</td>
<td>Research Associate I</td>
</tr>
<tr>
<td>Betania Negre, MD</td>
<td>Research Associate I</td>
</tr>
<tr>
<td>Miriam Mestre, MA</td>
<td>Senior Research Associate II</td>
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<tr>
<td>Jonathan Zebrowski, BA</td>
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<tr>
<td>David Landy, MPH</td>
<td>Student, MD/PhD Program</td>
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<tr>
<td>Deanndria Seavers, MPH</td>
<td>Research Associate III</td>
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Who We Are

- Coordinate and administer research related activities. Assist in project planning, study protocol development and regulatory requirements. Recruit and coordinate study visit and procedures. Serve as principle administrative liaison for research studies. Consult on external projects with special arrangements.

- **Clinical Roles**
  - Implement procedures to collect data with appropriate documentation
  - Ensure compliance with the protocol
  - Monitor participant progress to ensure safety and completion of study procedures

- **Regulatory Roles**
  - Assess, complete and submit protocol related documents to IRB
  - Perform intermittent audits to data and study procedures to assure compliance
  - Develop Policies and Procedures for all aspects of study and provide training to new personnel

- **Grants Coordinated through DPCR**
How We Can

- At DPCR we have 12 coordinators
- Vast experience in all aspects of a research project
- A coordinator may be used for 10% of their time to 100%, depending on your needs
- May be involved from protocol development to manuscript submission
- Roles range from data entry to phlebotomy to preparation for poster presentation
- Growing responsibilities from other departments i.e. Jackson, CRIS office (patient enrollment)
What We Ask of

- **Review all documents**
  - Forms, questionnaires, data sheets (assure all data is being captured)

- **Documents we need**
  - CITI (up to date), CV, Medical license
  - Submit COI
    - These limit protocols, amendments, continuing reports from going to board
  - Meet to discuss progress/responsibilities
CLINICAL PROGRAMS

Tracie Miller, MD, MS
Division Director

Deanndria Seavers, MPH
Research Associate III

Gabriel Somarriba, DPT
Assistant Professor/Physical Therapist
Facilities

- 2 Patient Examination Rooms
- Nurses Station
- Body Composition Laboratory
- Cardiac Evaluation Laboratory
- Exercise Rehabilitation
Clinical Facilities

- Industry-sponsored protocols
- Other clinical protocols
- Commercially available exercise rehabilitation program (CRUNCHTIME™)
Clinical Facilities

- Commercially available bone mineral density and body composition laboratory
- Pediatric Nutrition Program
- Pediatric Physical Therapy Clinic
- Program for Pediatric Integrative Medicine
Pediatric Physical Therapy Clinic

- New UMMG outpatient pediatric/adolescent PT clinic
- The only outpatient Pediatric PT clinic in UM.
- Located BCRI 5th floor
What is Pediatric PT?

- **Purpose:** To improve a child's gross motor function and focus on improving a child's strength, balance, and coordination with gross motor movements.

- **Goal:** Therapy works towards a child developing age appropriate motor skills or a functional motor skill level to interact with his or her everyday environment.
Who Should Receive PT?

- Children not meeting age appropriate Milestones
- Hypertonicity/Hypotonicity
- Pediatric Gait kinematic analysis
- Balance/Proprioceptive feedback training
- Biomechanical analysis for athletes
- Common sprains, strains and post surgery rehab
Clinic Goals

- Provide better continuity of care within same institution
- Provide better follow up and communication between providers
- Set up as a evidence based clinic
- Validated clinical assessments which will allow for consistent collection of data
Program for Pediatric Integrative Medicine

- We strive to:
  - Enhance treatment for chronic medical conditions
  - Determine the effectiveness of integrative therapies and identify beneficial complementary treatments through evidence-based research
  - Disseminate research findings and educate families and health-care providers on the effectiveness of pediatric integrative medical therapies

- Any child with:
  - Chronic medical conditions
  - Weight management concerns
  - Academic and emotional stress
  - A commitment to a healthy lifestyle
Program for Pediatric Integrative Medicine

- Therapies and Services:
  - Exercise Based Therapies
  - Nutrition Services
  - Biofeedback/Neurofeedback
  - Massage Therapy
  - Body Composition/Osteoporosis Testing
    - Peapod & Bodpod
    - Bioelectrical Impedance
    - DXA
  - Preventative Cardiology
    - Ultrasound for evaluating cardiovascular disease risk
    - Echocardiology for heart function assessment
    - Resting energy expenditure testing
ADMINISTRATION

Christie Vila, PhD
Division Manager

Ivonne Rivera
Administrative Assistant
Accessing Consulting Services

DPCR faculty and staff will assist you with proposals or research in progress on a case by case basis.

Please Contact: Christie K. Vila, PhD

cvila@med.miami.edu

Email Dr. Vila to request consulting form (also available on the DPCR website)

- Complete Investigator Request Form and attach a 250 word description/abstract of project
- Faculty meets every other Wednesday to discuss assignments based on skills and time availability
- Projects are assigned
- Ivonne Rivera will contact you to coordinate initial meeting with consultant
**Investigator Request for Assistance**

**Instructions:** Please complete our Request for Assistance questionnaire to help us better assist you with your project. Submit this form via e-mail, fax, or interoffice mail (see above). A DPCR staff member will contact you within the next two weeks to schedule a meeting.

1. **Requestor**
   - Name: [Last Name] [First Name]
   - CID:

2. **Title:**
   - [ ] Prof
   - [ ] Assoc. Prof
   - [ ] Asst. Prof
   - [ ] Instructor
   - [ ] Fellow
   - [ ] Resident
   - [ ] Nurse
   - [ ] Other
   - If you are a fellow, who is your attending/mentor?

3. **Institution**

4. **Department:**
   - [ ] [Department Name]
   - Division: [Division Name]

5. **Phone/Ext #**

6. **IRB Approval Number:**

7. **Project Title (same as title on IRB protocol or grant application):**

8. **What do you require assistance with? (check all that apply)**
   - **a. Grant Proposal / Protocol Development**
     - [ ] Grant Proposal Development
     - [ ] Study Protocol Development
     - [ ] Study Design or Concept Development
     - [ ] Statistical Analysis Plan
     - [ ] Power and Sample Size Determination
     - [ ] Data Monitoring Plan (DSMP)/ Interim Analysis Plan
     - [ ] Grant Assembly
     - [ ] IRB Application
   - **b. Study Implementation**
     - [ ] Case Report Form Development
     - [ ] Survey/Questionnaire Design
     - [ ] Database Design
     - [ ] Database Development
     - [ ] Database Administration
     - [ ] Assistance with existing database
     - [ ] Data Entry
     - [ ] Consent Form Development
   - **c. Data Analysis/Interpretation**
     - [ ] Statistical Analyses
     - [ ] Results Interpretation
     - [ ] Abstract/Poster Development
     - [ ] Presentation
     - [ ] Manuscript
   - **d. Other (Specify below):**

9. **What is the deadline for completion of work for this request?**
   - [MM/DD/YYYY]:

10. **Description of Request**

11. **What type of assistance are you requesting [see program description for explanation]? (check one)**
   - [ ] Collaboration (more extensive support, requires funding)
   - [ ] Consultation (limited support/advice, no funding)

12. **Funding Status**
   - **a. Is your project currently funded?**
     - [ ] Yes
     - [ ] No
   - **b. Are you presently applying for funding?**
     - [ ] Yes
     - [ ] No
   - **c. If Yes, what type of application is it?**
     - [ ] New Submission
     - [ ] Resubmission

13. **Funding Sources**
   - **NIH**
     - **a. Name of Institute / Center:**
     - **b. Type of funding mechanism (check one):**
       - [ ] R01
       - [ ] R03
       - [ ] R21
       - [ ] K01
       - [ ] K08
       - [ ] K23
       - [ ] K24
     - **c. Is this a response to an announcement?**
       - [ ] Yes
       - [ ] No
       - i. If Yes, what is the type?
         - [ ] RFA
         - [ ] RFP
         - [ ] PA
     - [ ] Other Federal Agency:
     - [ ] Foundation / Association: 1)
     - [ ] 2)
     - [ ] Industry Sponsor:
     - [ ] Internal Award:
     - [ ] Department/Division/Program Funds:
     - [ ] Philanthropic funds
     - [ ] Other (specify):
Examples of Consulting Services

Successful Partnerships in Grant Submissions with:

- Investigators from most UM departments
- NIH/CDC/DoD/FDA/USDA funded projects
- Agency for Healthcare Research and Quality (AHRQ)
- Community Based Consulting

Services Provided:

- Epidemiological consulting
- Biostatistics support on proposals and ongoing research
- Project coordination and IRB support
- Database management, administration, and support
- Data security
- Manuscript preparation
CLINICAL RESEARCH FORUMS

Jacqueline Henkel
Research Associate
About Clinical Research Forums

- Take place every Wed, 12 – 1 PM, Sept – May
- Examples of Forum Topics (2010 – 2011)
  - Oncology Fellows Presentation
  - IRB Protocol for Pediatric Research
  - Assessment and Management of Cancer-related Neurocognitive Dysfunction
  - Physical Fitness in Children with Chronic Illness
  - The Miami Prenatal Cocaine Study
  - The Incompatibility of Clinical Research and the Common Malady of P Value Neurosis
  - Prevention of Parenteral Nutrition-Associated Cholestasis with Cyclic Parenteral Nutrition in Newborns
About Clinical Research Forums

- Examples of Speakers (2010 – 2011)
  - Julio C. Barredo, MD: Director, Pediatric Hematology-Oncology
  - Pascal Jean-Pierre, PhD, Assistant Professor of Pediatrics
  - David Landy, Student, MD/PhD Program
  - Carolyn Abitbol, MD, Professor of Pediatrics, Nephrology
  - Nestor De La Cruz Munoz, MD, Associate Professor of Surgery
  - Theresa del Del Moral, MD, Associate Professor of Pediatrics, Neonatology
About Clinical Research Forums

- Good place to share research ideas, ongoing projects, research dilemmas, etc.
- Great way for everyone to learn about research studies happening at UM and elsewhere
- Opportunity for our speakers
  - To get some feedback on their projects
  - To establish collaborations
  - To communicate with other investigators to help recruit patients for the studies
About Clinical Research Forums

- Please RSVP to attend our forums
- Contact me to be added to our distribution list

Jacqueline Henkel

[jhenkel@med.miami.edu](mailto:jhenkel@med.miami.edu)

(305) 243-2443
DIVISION WEBSITES

Sunil Mathew
Database Analyst II
The Division of Pediatric Clinical Research

The University of Miami, Miller School of Medicine's Department of Pediatrics is internationally recognized for its clinical research activities. To continue its role as a national leader in pediatric research, the department launched the Division of Pediatric Clinical Research, housed in the Batchelor Children's Research Institute in 2003. Our Division is dedicated to the development of interdisciplinary clinical, community, and population-based pediatric research.

A primary objective of the Division of Pediatric Clinical Research is to create a collaborative academic environment and infrastructure that will support and promote pediatric faculty and staff and contribute to our community. With the expertise offered by this Division, investigators are supported in conducting state-of-the-art research. The Division encourages interdisciplinary research across Divisions, Departments, and Schools within the University of Miami. We also serve as a catalyst to link the department and the University to other institutions and organizations regionally, nationally and internationally.

Click Here for an In-Depth Look at the Division

Click Here to See Our Current Research
¿Questions?

Thanks for visiting...

Visit us:
http://pediatrics.med.miami.edu
305-243-1423