DIVISION OF PEDIATRIC CLINICAL RESEARCH

Batchelor Children's Research Institute
INTRODUCTION & PHILOSOPHY

Tracie L. Miller, MD, MS
Division Director
Professor
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
- To develop the next generation of pediatric clinical researchers
Infrastructure

- We have 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
- Near Full-Time Research-Oriented Physician
- Faculty Biostatistician
- Faculty Epidemiologist
- Database Analyst
- Research Exercise Physiologist & Instructor
- Licensed Physical Therapist
- Certified Pediatric Yoga Instructor
- Experienced Research Study Coordinator
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
Division of Pediatric Clinical Research

Clinical Programs

Research Support

Consulting Services Support for Investigators

Educational Programs

Weekly Luncheon Seminar Series

Planning & Scheduling of Visiting Professors

Program for Pediatric Integrative Medicine

Research Opportunities Tracking Database

Pediatric Nutrition Program

Exercise Rehab CRUNCHTIME® UMMG

Pediatric Preventative Cardiovascular Laboratory

Pediatric Bone Densitometry Center

Pediatric Clinical Research Center

Pediatric Physical Therapy Program

Administrative Support for Staff and Faculty

Pediatric Clinical Research Center
EPIDEMIOLOGY

Sarah E. Messiah, PhD, MPH
Epidemiologist
Research Associate Professor
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
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

“Sorry the dementia statistics are not ready, they keep losing count.”
DATA MANAGEMENT & DATABASE DEVELOPMENT

Sunil Mathew, BS
Database Analyst
Database Design & Development

- Deliver an effective database management 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
Database Administration & Support

- 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
- Beta testing, training, and support
PROJECT COORDINATION

Gabriel Somarriba, DPT
Physical Therapist
Assistant Professor of Clinical Research
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 Help

- 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 You

- As PI’s play an active role
- Review all documents
  - Forms, questionnaires, data sheets (assure all data is being captured)
- Have consistent meetings to discuss progress/ responsibilities
- This will ensure your studies are completed correctly and efficiently
CLINICAL PROGRAMS

Tracie L. Miller, MD, MS
Division Director
Professor

Gabriel Somarriba, DPT
Physical Therapist
Assistant Professor of Clinical Research
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
- Pediatric Clinical Research Center
- Program for Pediatric Integrative Medicine (PPIM)
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 (PPIM)

- 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
  - Pediatric yoga classes
  - 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
PPIM Kid’s Yoga Program

- Goals:
  - Increase self-confidence
  - Exercise the body
  - Promote self-discipline
  - Help physical coordination and balance
  - Promote physical and emotional self-awareness
  - Promote relaxation through mediation and breathing
  - Encourage spiritual awareness (the little light within)
  - Have fun!
PPIM Kid’s Yoga Program

- Child yoga instructor certified through Radiant Child Yoga Program® (RCYP)

- Partnered with the Debbie School
  - Teaching preschoolers ages 3-5 years old
  - Community classes are offered in BCRI 2nd floor
ADMINISTRATION

Christie K. Vila, PhD
Senior Division Administrator
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
- Katie Repici 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
   Last Name: ___________________ First: ___________________ CID#: ___________________

2 Title:  
   □ Prof  □ Assoc. Prof.  □ Asst. Prof.  □ Instructor  □ Fellow  □ Resident  □ Nurse  □ Other

2a If you are a fellow, who is your attending/mentor?

3 Institution: ___________________

4 Department: ___________________ Division: ___________________

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:
         □ Type of Institute / Center (check one): □ R01 □ R03 □ R21 □ K01 □ K08 □ K23 □ K24
      b. Is this a response to an announcement?  □ Yes  □ No
      c. If Yes, what is the type?  □ RFA  □ RFP  □ PA
   □ Other Federal Agency:
   □ Foundation / Association: □  □
   □ Industry Sponsor: □  □
   □ Internal Award: □  □
   □ Department/Division/Program Funds: □  □

1/27/2011
Examples of Consulting Services

Successful Partnerships in Grant Submissions with:

- Investigators from most UM departments (ex. Surgery, Medicine, OB/Gyn, and Other Clinical Areas)
- 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

Miriotte Augustin
Administrative Assistant
About Clinical Research Forums

- Take place every other Wed, 12 – 1 PM, Sept – May

Examples of Past Forum Topics

- Zinc Finger Nuclease Technology for Treatment of HIV-1 and New Directions for Research in Primary Immune Disease
- IRB Protocol for Pediatric Research
- Data Management for Clinical Research
- Physical Fitness in Children with HIV
- An Overview of IRB protocol, as applicable to Pediatric and other Clinical Research
- The Incompatibility of Clinical Research and the Common Malady of P Value Neurosis
- Childhood Obesity Prevention Using Schools as “Hubs” of Community-wide Obesity Prevention Efforts
About Clinical Research Forums

Examples of Past Speakers

- Patricia Cantwell, MD: Director of the Pediatric Critical Care
- Alan Delamater, PhD: Director of Clinical Psychology
- Charles D. Mitchell, MD: Co-Director of Clinical Core, Developmental Center for AIDS Research
- David Landy, MPH: MD/PhD Program
- Elizabeth J. Willen, PhD: Assistant Professor of Clinical Pediatrics, Psychology
- Mustafa Tekin, MD: Associate Professor, Clinical and Translational Genetics
- Gabriel Somarriba, DPT: Assistant Professor of Pediatrics, Pediatric Clinical Research
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
  Miriotte Augustin
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  (305) 243-1722
Questions

Visit Us
http://pediatrics.med.miami.edu

Contact Us
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