

ABSTRACT: 2015 ELAM Institutional Action Project Poster Symposium

Project Title: The Georgia Regents University Children's Research Unit (CRU) at the Children's Hospital of Georgia (CHOG)

Fellow Name and Institution: Martha S. Tingen, PhD; Medical College of Georgia (MCG), Georgia Regents University (GRU), Augusta, GA.

Mentors and Collaborators: Peter Buckley, MD, Dean, MCG; Michael Diamond, MD, Sr. Vice President of Research GRU & Associate Dean, Clinical & Translational Science, MCG; Charles Linder, MD, Chairman, Department of Pediatrics, Medical Director, CRU & Pediatrician-in-Chief, CHOG; Greg Harshfield, PhD, Director, Georgia Prevention Institute; Jim Mumford, Administrative Director Pediatric Ambulatory & Network Services, CHOG; Joel Covar, Chief Financial Officer, MCG.

Background/Challenge and Mission: The faculty in the Department of Pediatrics, although passionate about teaching and clinical care, were discouraged with the lack of infrastructure and resources to conduct research. The paucity of facilities and support were inconsistent with a primary charge of Georgia Regents University, which is to become a top-tier research institution that leads the way for novel discoveries and clinical & translational science. Also, the dearth of clinical trials units dedicated to children as well as the great opportunity of such a unit resulted in a capital improvement project called the CRU with the following mission: to conduct clinical & translational pediatric research to improve the lives of children, their health and healthcare.

Purpose/Objectives: The purpose of this IAP was to provide a venue that facilitates and supports pediatric clinical & translational research.

Methods/Approach: *Activities and Services Offered*

The CRU serves as a first contact destination for:

- Designing research studies and Assistance with IRB applications,
- Assistance with literature reviews for initiating a study idea or answering a question from morning rounds,
- Assistance with budgets.

The CRU provides:

- A venue for conducting clinical & translational studies with two fully equipped research rooms,
- A reception area with electronic check-in for study personnel and participants,
- A work room for study monitor visits,
- A phlebotomy room for blood draws and conducting pulmonary function tests (PFTs),
- A handicap-accessible restroom,
- A laboratory with refrigerated centrifuge, refrigerator, and liquid nitrogen Dewar to assure sample stability prior to shipment or final storage destination,
- A soiled utility room.

Location and Personnel:

The CRU is located on the 5th floor of the CHOG; located adjacently is the pediatric surgical and oncology unit. All traditional resources available to the patient units (code response team, etc.) are available to the CRU.

Personnel include: Medical Director (Dr. Linder), Research Director (Dr. Tingen), Research Assistant (full-time), and research study nurse (Ms. Stapp, RN; part-time). The unit is staffed daily with the research assistant who is responsible for reception, scheduling, and CRU resource coordination.

Outcomes and Evaluation Strategy: The unit was built, start-up funds obtained, an advisory council formed, and biosafety approvals achieved. The CRU's Open House occurred on January 14, 2015. The CRU has three studies running in the unit with two more on the horizon. Evaluation data is obtained from research teams using the unit. A sustainability plan is being developed.

A New Children's Research Unit at the Children's Hospital of Georgia

Martha S. Tingen, PhD; Medical College of Georgia, Georgia Regents University, Augusta, GA.

BACKGROUND / CHALLENGE

- Faculty in the Department of Pediatrics, although passionate about teaching and clinical care, were discouraged with the lack of infrastructure and resources to conduct research.
- The paucity of facilities and support were inconsistent with a primary charge of Georgia Regents University, which is to become a top-tier research institution for novel discoveries and clinical & translational science.
- There is a dearth of clinical trials units dedicated to children and there was a great opportunity for such a unit that resulted in a capital improvement project called the Children's Research Unit (CRU).
- The CRU mission: to conduct clinical and translational pediatric research to improve the lives of children, their health, and healthcare.

PURPOSE / OBJECTIVES

The purpose of this Institutional Action Project (IAP) was to provide a venue that facilitates and supports pediatric clinical & translational research.

NEWS RELEASE / OPEN HOUSE



Guests tour the CRU during the January 14th Open House. See more about the CRU at <http://www.gru.edu/research/cru/>



METHODS / APPROACH

Services and Activities of the Children's Research Unit: *Serves as a first contact destination for:*

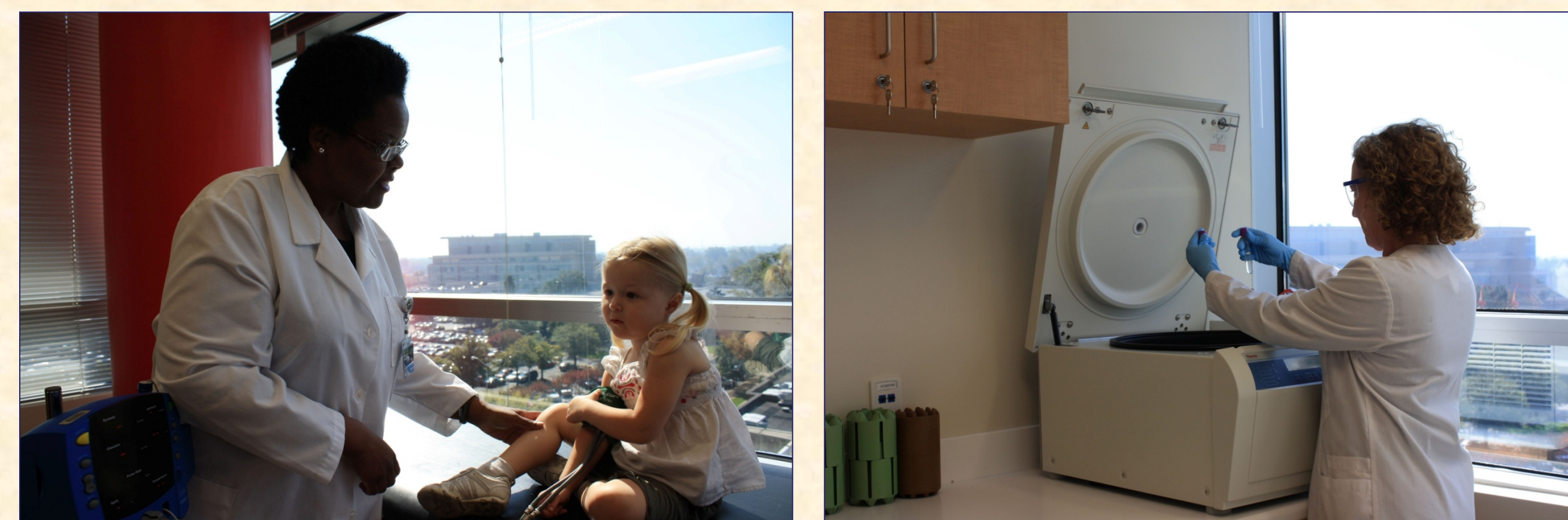
- Designing research studies and assistance with IRB applications.
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- A laboratory with refrigerated centrifuge, refrigerator, and liquid nitrogen dewar to assure sample stability prior to shipment or final storage destination.
- A soiled utility room.

OUTCOMES / EVALUATION

- The unit was constructed, start-up funds obtained, an advisory council formed, biosafety approvals achieved, and the Open House occurred in early January.
- The CRU has three studies running in the unit with two more on the near horizon.
- Evaluation data is being obtained electronically from all research teams using the unit to gather data for addressing concerns and improving services.



Above and to the left: Fully equipped clinical research rooms with computer, work station, blood pressure monitor, infusion pumps, and Trendelenburg capable research chair. Also shown is a view of the laboratory and refrigerated centrifuge.

DISCUSSION / SUMMARY / CONCLUSION

- Impact to date: Ten weeks after the Open House, three studies have used the unit and one continues to use the unit weekly for a clinical drug trial. Two additional studies are to begin using the unit in the near future.
- Evaluation data analyzed to date is all positive with no suggestions for improvement.
- Next Steps: A detailed business plan and sustainability plan are being developed in consultation with institutional leaders. Goals for the unit include daily utilization, cost recovery initially, and then to earn at minimum a 5% surplus.

Drs. Linder (Medical Director) and Tingen (Research Director) discuss ideas for moving the unit forward.



MENTORS AND COLLABORATORS

Peter Buckley, MD, Dean, MCG (*primary mentor*); Michael Diamond, MD, Sr. Vice President of Research GRU & Associate Dean, Clinical & Translational Science, MCG (*mentor*); Charles Linder, MD, Chairman, Department of Pediatrics, Medical Director, CRU & Pediatrician-in-Chief, CHOG; Greg Harshfield, PhD, Director, Georgia Prevention Institute; Jim Mumford, Administrative Director Pediatric Ambulatory & Network Services, CHOG; Joel Covar, Chief Financial Officer, MCG.

OTHER INSTITUTIONAL PARTNERSHIPS

CRU Advisory Board
Biological Safety Office
Chemical Safety Office
Clinical Trials Office
Clinical Trials Pharmacy
Division of Sponsored Program Accounting
Environmental Services
Office of Communications and Marketing
Respiratory Therapy

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