

Clinical Research Center

DIVISION PROFILE

Number of Faculty	1
Number of Support Personnel	37
Annual Total Grant Support (direct)	\$1,944,109
Patient Encounters	
Outpatient	4,374
Inpatient	63

FACULTY LISTING

James E. Heubi, MD, Professor of Pediatrics, Program Director, GCRC; Associate Chair, Clinical Research, Associate Dean, Clinical Research

OVERVIEW

During this annual report period, the General Clinical Research Center (GCRC) was in the fourth and fifth years of five years of funding supported by the National Center for Research Resources, National Institutes of Health. We have successfully competed for additional funding that will begin December 1, 2006, and extend to November 30, 2010. In the interim, the Children's Hospital and University of Cincinnati will seek funding under an Institutional Clinical and Translational Science Award from the NIH which will replace the existing GCRC program with a larger more comprehensive program to support clinical and translational research. During the past year, 87 studies were performed by investigators from 26 Divisions of the Children's Hospital and members of the Departments of Medicine, Environmental Health, Psychiatry and Schools of Allied Health and Nutritional Sciences which utilized the resources of the GCRC. The well-trained research nursing staff, research dietitian, core laboratory staff, administrative personnel, and a part-time biostatistician are available to assist investigators in the execution of research protocols. The Core Laboratory is now divided into two sections: 1. Biochemistry Core, and 2. Body Composition Core. There is a strong Bioinformatics Core which helps investigators with data management and a Behavioral Core which focuses on investigator support for psychological/behavioral studies. The GCRC provides support for educational and training programs, including the 6-module course, entitled "Introduction to Clinical Research." This curriculum is designed to be a more comprehensive introduction to clinical research with the goal of enhancing participants' knowledge of patient-oriented research, and is now available on the CCHMC ELM. Young investigators can take the course work online at convenient times and document participation by completing content questions. The GCRC sponsors a monthly Clinical Research Forum that showcases clinical research at Cincinnati Children's Hospital Medical Center and University of Cincinnati. The CRC News, a newsletter produced two times a year, has helped to update faculty on patient-oriented research at the Children's Hospital and the GCRC. The GCRC supports research for entry level faculty and fellows interested in pursuing careers in biomedical research. This program, the Clinical Research Enhancement Feasibility Fund (CR EFF), has supported six young investigators, who have been successful in obtaining additional external funding.



J. Heubi

HIGHLIGHTS

During the last grant year, there were 164 investigators (including co-investigators) with 87 active protocols utilizing resources supplied by the GCRC. Seventy-nine of the protocols were from investigators from the Department of Pediatrics, while three were from the Department of Medicine, one from the Center for Health

Related Programs, one from the College of Applied Health, one from Environmental Health, one from Nutritional Sciences, and one from the Department of Psychiatry. Predominant users in the CCRF include investigators from the Divisions of Gastroenterology, Cardiology, Endocrinology, Human Genetics, General and Community Pediatrics, Behavioral Medicine and Clinical Psychology, Neonatology, Rheumatology, Nephrology, Pulmonary Medicine, Adolescent Medicine, Allergy, and Developmental and Behavioral Pediatrics. The major focus areas of patient-oriented research include mechanisms of bone accretion and bone disease in health and associated disease conditions; body composition with maturation including obesity; cholesterol metabolism; diabetes mellitus in children and adults; inborn errors of bile acid metabolism; cholestatic liver disease; sleep disorders; diarrheal diseases; renal disease; cystic fibrosis; rheumatic diseases; and Gaucher Disease. Research subjects comprised 4,374 outpatient visits and were hospitalized for 47 inpatient days on the CRC between December 1, 2004 and November 30, 2005. Subjects were studied outside the CRC in "scatter beds" for a total of 16 days. During that same period of time, industry-sponsored subjects accounted for 27 inpatient bed days and 324 outpatient visits, while non-research patients comprised 1970 inpatient bed days and 15,047 outpatient visits. A high percentage of both inpatient and outpatient utilization are studies initiated by externally funded investigators who need CRC resources to perform their patient-oriented research projects. There were 41 peer-reviewed journal articles that resulted from research conducted on the CRC. Publications are listed individually in the reports of the divisions, and a copy of each is kept on the Center in the official CRC bibliography. The following is a summary report of CRC inpatient and outpatient utilization for each CHMC division or UC department and its study protocols:

Division	Outpatient Visits	Inpatient Days	Title of Project
Adolescent Medicine	38	0	Developmental Psychobiology of Premature Adrenarche ¹
	158	0	Smoking & Metabolic Complications in Adolescent Girls ²
	25	0	Puberty and Cancer Initiation: Environment, Diet and Obesity ³
Allergy/Immunology	49	0	Effect of Intravenous Anti-IL5 in Hypereosinophilic Syndromes
Cardiology	710	0	Epidemiology of Body Mass Index Rebound
	179	0	Visceral Adiposity and CVD Risk in Women ⁴
	43	0	Genetic Epidemiology of Energy Metabolism ⁵
	170	0	Role of Carbohydrate Modification in Weight Management Among Obese Children ⁶
	30	0	Cardiovascular Disease in Adolescents with Type 2 Diabetes ¹
	1	0	Trial of Single Ventricle vs. Modified Blalock-Taussig Shunt in Infants with Single Ventricle Defect ⁷
Center for Epidemiology and Biostatistics	59	0	The Role of Infant Feeding in Childhood Allergy ⁸
Ctr for Health-Related Programs (U.C.)	221	0	Comparison of Diets on Glycemic Control & CV Risk Factors ⁹
College of Applied Health (U.C.)	32	0	Effect of Combined Drug & Nutrition Therapy on HBA1c Levels in Type 2 Diabetes ⁹
Endocrinology	18	0	GH in Children with Short Stature Due to Growth Hormone Insensitivity (GHIS)
	237	0	SEARCH for Diabetes In Youth ¹⁰ Biochemical Characteristics of Type 2 Diabetes Mellitus in Adolescents ⁹
	14	5	Endocrinopathies After Head Injury ¹¹
	48	0	Metformin and Diet in Managing Weight Gain After Initiation of Olanzapine Therapy ¹²
	16	0	Glucocorticoid Effects on Growth and Bone

		0	Mineral Accretion in Infants with Hemangioma ¹³
	10	0	Adrenal Suppression in Infants with Hemangioma ¹³
	5	0	Thyroid Hormone in Children with Fanconi Anemia ¹⁴
	78	0	Type 1 Diabetes Genetics Consortium
Environmental Health (U.C.)	7	0	Neurobehavioral Effects of Low-Level Manganese Exposure ¹⁵
Gastroenterology	1	0	Bioavailability of Ursocarb Compared to Actigall in Liver Disease and CF
	1	0	Cholesterol Absorption and Fractional Synthetic Rate in Adults ¹⁶
	0	16	Multi-Center Group Study of Acute Liver Failure (16 scatterbed days)
	3	0	Antiresorptive Therapy for Osteopenia Associated with Chronically Immobilized Children & Adults with Neuromuscular Disease ¹⁷
	7	0	Mechanisms of Growth Hormone Resistance in Colitis
	8	0	Prospective Database of Infants with Cholestasis (BARC P003)
	23	0	Fecal Behenic Acid: A New Marker for Fat Malabsorption ¹⁸
	39	0	Pegylated Interferon +/- Ribavirin for Children with HCV
	92	0	Correlation between Small Intestinal Cholesterol Transporters and Measured Cholesterol Absorption in Humans ¹⁹
	38	0	Phase II Randomized Trial of Growth Hormone Therapy in Pediatric Crohn's Disease
	130	0	Intraluminal Effects on Cholesterol Absorption/Synthesis ²⁰
	48	0	Prevalence of Reduced Bone Mass in Children with Duchenne Muscular Dystrophy ²¹
General & Community Pediatrics	312	0	Bone Mineral Density in Childhood Study ²²
	86	0	Structural Effects of Renal Osteodystrophy During Growth ²³
Hematology/Oncology	66	0	Donation of Peripheral Blood Stem Cells for Use In Experiments Involving In Vitro Expansion and Gene Transfer Reinfusion of Autologous Bone Marrow, Cord Blood & Peripheral Blood Progenitor Cells from Patients with Fanconi Anemia
	29	0	Oxandrolone for the Treatment of Bone Marrow Aplasia in Patients with Fanconi Anemia
	3	0	Collection of Hematopoietic Cells from Patients with Fanconi Anemia for Future Autologous Reinfusion & Research ²⁴
Human Genetics	30	0	Studies of Gaucher Disease: A Prototype Lipidosis
	14	0	Trial of Alendronate Disodium in Pediatric Gaucher Disease ²⁵
	32	0	RhGAA Treatment in Patients > 6 and < 36 Months Old
	26	0	Iduronate-2-Sulfatase Replacement Therapy in Mucopolysaccharidosis II

	39	6	Intravenous Zoledronic Acid Compared to Intravenous Pamidronate in Children with Severe Osteogenesis Imperfecta
	31	0	Safety & Efficacy of Fabrazyme in Patients with Fabry Disease
	9	0	rhGAA Treatment in Patients < 6 Months
Internal Medicine (Digestive Disease)	12	0	Response of Hepatitis C Virus to Interferon in Hemophilic Patients ²⁶
Internal Medicine (Endocrinology)	28	0	Pancreatic Islet Cell Function and Glucose Tolerance Following Transplantation ²⁶
	33	0	Regulation of Nutrient-Stimulated Insulin Secretion by Glucagon-Like Peptide (GLP-1)
Nephrology	7	0	Vascular Abnormalities in CRD ¹²
	66	0	Rapamycin Therapy of Renal Angio- myolipomas in Patients with Tuberous Complex and Sporadic LAM ²⁷
	1	0	Normalization of Hematocrit in Patients with CRF ²⁸
	2	0	ABPM & End Organ Damage in Children with Renal Transplantation ¹²
	9	0	Chronic Kidney Disease in Children
	9	0	RAD001 Therapy of Angiomyolipomata in Patients with Tuberous Sclerosis Complex and Sporadic Lymphangioliomyomatosis ²⁹
Neurology	105	0	Childhood Absence Epilepsy RX, PK, PD Pharmacogenetics
	12	0	Language Processing Studies with Functional Resonance Imaging in Persons with Down Syndrome ³⁰
Nutritional Sciences (U.C.)	75	0	Effects of High Protein, Low Carbohydrate Diet on Acid-Base Balance: Pilot Study to Examine the Potential Differences in Older Compared to Younger Adults ³¹
Pathology (Mass Spectrometry)	36	0	Soy Isoflavone Metabolite Equol - Its Formation and Fate ³²
Psychiatry (U.C.)	0	26	Hypothalamic-Pituitary-Adrenal Dysregulation and Phenomenology of Major Depression
Psychology	21	0	Nutrition/Behavior in Children with Chronic Illness ³³
	7	0	Dietary Calcium/Behavioral Intervention in Children with JRA ³⁴
	41	0	Behavior Treatment & Nutrition in Pediatric Chronic Disease ³²
	4	0	Neuropsychological Functioning & Psycho- social Adjustment in Adolescents with Spina Bifida and NLD ³⁵
	56	0	Children's Health and Natural Growth Evaluation Study (CHANGES) ³⁶
	32	4	Neurobehavioral Effects of OSA among Obese Teens and Preteens ³⁷
	100	0	Assessment of Quality of Life and Self- Concept in Children & Adolescents Pursuing Weight Management Intervention ¹²
	31	0	Extreme Obesity in Adolescents: Psycho- logical Adjustment, QOL & Relationship to Food ³⁸
	12	0	Sleep & Neurobehavioral Features of Health in

			Preteens & Teens ³⁹
	27	0	Social Development Following Pre-School Brain Injury ¹¹
Pulmonary Biology	68	0	Anticytokine Autoantibodies & Growth Factors in Rare Lung Diseases ⁴⁰
Pulmonary Medicine	219	5	Mechanisms Mediating Cardiovascular Disease in Children with OSA ¹⁰
	9	0	Vascular Function in Children with OSA ¹⁰
	23	0	Assessment of Pharyngeal Collapsibility in Obese Children with OSA by Volume Segmentation of Cine MR Data ⁴¹
	2	0	Vascular Function in Morbidly Obese Children with OSA Undergoing Bariatric Surgery ³⁸
Rehabilitation	79	0	Child and Family Sequelae of Pre-School Brain Injury ⁴²
Rheumatology	9	0	Long-Term Outcomes & Gonadal Function in Childhood Onset Systemic Lupus Erythematosus ²³
	5	0	Triptorelin for Ovary Protection in Childhood Onset Lupus ⁴³
	3	0	Atherosclerosis Prevention in Pediatric Lupus Erythematosus
Surgery	0	1	Endocrine Evaluation of Hypothalamic Obesity
	1	0	Intravenous Methylprednisolone vs. Oral Prednisolone in Transplant Rejection ³²
	9	0	Collection and Banking of Biological Specimens from Patients with Obesity ⁴⁴
	6	0	Adolescent Gastric Bypass and Diabetic Precursors ⁴⁵
Totals	4374 (16*)	63	*Scatter Bed Days (Subjects studied in beds off of CRC Unit)

Collaboration of Various CCHMC Divisions and University of Cincinnati Departments

¹with the Divisions of Epidemiology and Endocrinology

²with the Divisions of Epidemiology and General Pediatrics

³with the Center for Epidemiology & Biostatistics and the Department of Environmental Health, UC

⁴with the Division of Epidemiology & Biostatistics

⁵with the Division of Adolescent Medicine

⁶with the Center for Health Related Programs and Department of Internal Medicine (Endocrinology)

⁷with the Divisions of Psychology, Cardiothoracic Surgery, and Human Genetics

⁸with the Divisions of Allergy & Immunology, Immunobiology, Pulmonary Biology and Dept. of Int Med (Immunology), UC

⁹with the Department of Internal Medicine (Endocrinology)

¹⁰with the Divisions of Biostatistics and Cardiology

¹¹with the Division of Physical Therapy and Rehabilitation

¹²with the Division of Cardiology and Psychology

¹³with the Divisions of Surgery and Dermatology

¹⁴with the Divisions of Epidemiology & Biostatistics and Hematology/Oncology

¹⁵with the Divisions of Radiology and General & Community Pediatrics

¹⁶with the Division of Pathology (Clinical Mass Spectrometry)

¹⁷with the Divisions of Biostatistics and Radiology

¹⁸with the Division of Pulmonary Medicine, CCHMC Resident, and the Dept. of Pathology & Lab Med, UC

¹⁹with the Department of Pathology & Laboratory Medicine

²⁰with the Divisions of Biostatistics and Mass Spectrometry and the Dept. of Pathology & Laboratory Medicine, UC

²¹with the Division of Neurology and Medical Student, UC

²²with the Divisions of Adolescent Medicine, Gastroenterology and Radiology
²³with the Division of Nephrology
²⁴with the Hoxworth Blood Center
²⁵with the Division of Community and General Pediatrics
²⁶with the Department of Surgery, UC
²⁷with the Division of Neurology and Department of Internal Medicine (Pulmonary)
²⁸with the Division of Psychology
²⁹with the Divisions of Biostatistics, Radiology and Neurology and the Dept. of Internal Medicine (Pulmonary),
 UC
³⁰with the Divisions of Psychology and Developmental Disorders
³¹with the Department of Internal Medicine (Nephrology & Hypertension)
³²with the Division of Gastroenterology
³³with the Divisions of Endocrinology, Pulmonary Biology and Pulmonary Medicine
³⁴with the Division of Rheumatology
³⁵with the Division of Developmental Disabilities
³⁶with the Division of Adolescent Medicine and Department of Psychiatry, UC
³⁷with the Divisions of Pulmonary Medicine and Cardiology
³⁸with the Divisions of Cardiology and Surgery
³⁹with the Divisions of Pulmonary Medicine and Cardiology
⁴⁰with the Department of Internal Medicine (Pulmonary)
⁴¹with the Divisions of Cardiology and Radiology
⁴²with the Divisions of Radiology, Biostatistics and Psychology
⁴³with the Division of Endocrinology
⁴⁴with the Division of Cardiology and the Department of Pathology & Laboratory Medicine, UC
⁴⁵with the Divisions of Cardiology, Endocrinology, Epidemiology and the Dept. of Internal Medicine
 (Endocrinology)

GRANTS, CONTRACTS AND INDUSTRY AGREEMENTS

Grant and Contract Awards	Annual Direct/Project Period Direct
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Boat, T – PI

Heubi, J – Program Director

General Clinical Research Center

National Institutes of Health

M01 RR 008084

12/30/93 – 11/30/06

\$1,938,968/\$9,601,897

Heubi, J

BARC Central Lab

National Institutes of Health (University of Michigan subcontract)

U01 DK 062451

09/01/05 – 05/31/10

\$5,141/\$25,705

Current Year Direct

\$1,944,109

Industry Contracts

Current Year Direct Receipts

\$0

TOTAL

\$1,944,109

PUBLICATIONS

All publications resulting from projects utilizing the Clinical Research Center are listed in the divisional sections of this annual report. A complete listing of these publications is available in the CRC bibliography, along with a copy of each journal article and book chapter.